Development and Evaluation of a Health-Related Lifestyle Self-Management Intervention for Patients with Acute Coronary Syndrome

Ritin Santiago Fernandez

A thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy

College of Health and Science

2007
Dedication

This thesis is dedicated to my

dad Santiago D’Silva

and

mum Brigid D’Silva

without you none of this would have been possible

In remembrance of Rudolph Malcolm Fernandez who was received by the Lord during the writing of this thesis
Acknowledgments

This thesis is the product of many years of work, procrastination, and an enormous amount of assistance, and is the end of a long journey in obtaining my degree in Doctor of Philosophy. I would like to thank many people for a huge variety of reasons that made this journey easier. First, a very special thanks to my family who journeyed with me throughout this research, particularly my husband Ulric who stood by me. His belief that one should always follow what they love allowed me the freedom to pursue my PhD. To Garth, my son, who provided technical advice and proofread the HeLM booklet with the eye of an eleven-year-old knowledgeable technical scientific writer, and to Erika, my four-year-old daughter, who came with me every morning and patiently sat and coloured in during data collection. To my brother Sydney and sister Melita, thank you for your support, encouragement and confidence in my pursuit.

This work would not have been possible without the encouragement of my principal supervisor Professor Rhonda Griffiths. Professor Griffiths gave me the confidence and support to begin my PhD program, and encouraged me to set high standards and to look for solutions to problems rather than focus on the problem. I learned to believe in my future, my work and myself. I cannot overstate the importance of her involvement in my career. Thank you, Professor, for your friendship and intellectual advice.

My overwhelming thanks go to the other members of my supervisory panel: Professor Patricia Davidson, Dr Yenna Salamonson and my advisor Associate Professor Craig Juergens, who have in every way been available as a resource, be it emotionally, socially, scholarly, or administratively. I cannot imagine having better advisors and mentors for my PhD.

I would like to say a big ‘thank you’ to all the patients who participated in the study and completed the lengthy questionnaires. Thanks also to all the CR coordinators who agreed to be interviewed by me for this thesis. Thanks to all the staff at the Australian Institute of Health and Welfare who contributed to the development of the
national data dictionary. Thanks also to Dr Sharon Andrew, Ms Bronwyn Everett, Ms Jean Montgomery and Bruce Stafford, who worked tirelessly to enable thorough data collection. Thanks to all my national and international colleagues who provided resources guidance and advice on different aspects during the development of this thesis, including:

Dr Benjamin Smith  Dr Kerrie Goldston  Dr Renee Bittoun  
Professor Andrew Tonkin  Professor Neil Oldridge  Mr Chris Medlin  
Dr Barbara Riegel  Dr Elaine Miller  Mr Robert Brooks  
Ms Rosemary Chester  Mr Jose Caballo  Mr Mark Buhagiar  
Professor Michael Jelinek  Professor Robert West  Dr Steve Bunker  
Ms April Fonti  Ms Darron Webber  Ms Robyn Speerin  
Ms Tracy Greenberg  Dr Margarite Vale  Dr Kelly Evenson  
Ms Carolyn Astley  Dr Roshinee Oupra  Dr Susan Plummer  
Ms Roslyn Weaver  Mr Steve Salamonson  

I would also like to gratefully acknowledge the support of the staff of the library, Clinical Information Services and the Coronary Care Units at Liverpool Hospital, as well as the academic staff of the School of Nursing, University of Western Sydney, who provided me with support and collegiality throughout the process. This thesis would not appear in its present form without the kind assistance and support of the following organisations: Merck Sharpe & Dohme, Iscover, Samsung and Unilever Australia for providing resources for patients, and the Health Research Foundation Sydney South West for the financial support to the value of $45,000 to conduct this project, which supported the appointment of two research assistants.

Ritin Fernandez
Statement of Authentication

I Ritin Santiago Fernandez declare that this thesis, submitted in fulfilment of the requirements for the award of Doctor of Philosophy at the University of Western Sydney, is my own work unless otherwise referenced or acknowledged, and contains as its main content work which has not previously been submitted in whole or in part, to any other tertiary educational institution.

.........................................................
(Ritin Fernandez)
Table of Contents

ACKNOWLEDGMENTS ......................................................................................... I
STATEMENT OF AUTHENTICATION .................................................................. III
TABLE OF CONTENTS ....................................................................................... IV
LIST OF TABLES .................................................................................................. XIII
LIST OF FIGURES ............................................................................................... XV
LIST OF APPENDICES ....................................................................................... XVII
LIST OF ABBREVIATIONS ................................................................................... XVIII
GLOSSARY ........................................................................................................... XXI
ABSTRACT ........................................................................................................... XXIII
ANTHOLOGY OF PUBLICATIONS ....................................................................... XXV

CHAPTER 1 THE BURDEN OF CARDIOVASCULAR DISEASE:
IMPLICATIONS FOR SECONDARY PREVENTION .............................................. 1

1.1 INTRODUCTION .......................................................................................... 2

1.2 CARDIOVASCULAR DISEASE ..................................................................... 2

1.3 CORONARY HEART DISEASE ..................................................................... 2

1.4 ACUTE CORONARY SYNDROME ................................................................ 5

1.4.1 MANAGEMENT OF ACUTE CORONARY SYNDROMES ....................... 6

1.4.2 MANAGEMENT FOLLOWING ACUTE CORONARY SYNDROMES .......... 8

1.5 CORONARY RISK FACTORS ....................................................................... 9

1.5.1 SMOKING CESSATION ......................................................................... 11

1.5.2 PHYSICAL ACTIVITY ......................................................................... 12

1.5.3 DIETARY MODIFICATION ................................................................... 13

1.5.4 OBESITY ............................................................................................ 13

1.5.5 HYPERLIPIDAEMIA ......................................................................... 15

1.5.6 BLOOD PRESSURE LEVEL .................................................................. 17

1.5.7 DYSGLYCAEMIA ................................................................................. 18

1.6 PROBLEM STATEMENT ............................................................................... 19

1.7 STUDY AIMS ............................................................................................ 19

1.7.1 STUDY 1 BRIEF INTERVENTIONS STUDY ...................................... 20

1.7.2 STUDY 2 ICEBRG STUDY ................................................................. 20

1.7.3 STUDY 3 FACT STUDY ...................................................................... 20

1.7.4 STUDY 4 HELM STUDY .................................................................... 20
1.8 STRUCTURE OF THE THESIS ................................................................. 22
1.9 SIGNIFICANCE .................................................................................. 22
1.10 CONCLUSION ................................................................................... 23

CHAPTER 2 APPROACHES TO SECONDARY PREVENTION AND BEHAVIOUR CHANGE .................................................... 24
2.1 INTRODUCTION .................................................................................. 25
2.2 AUSTRALIA’S RESPONSE TO SECONDARY PREVENTION ........ 25
2.3 PHARMACOTHERAPY ....................................................................... 26
  2.3.1 CHALLENGES IN ADHERENCE TO MEDICATIONS ....................... 26
2.4 BEHAVIOUR CHANGE ..................................................................... 27
  2.4.1 IMPROVING SELF-MANAGEMENT AND HEALTH BEHAVIOUR .......... 28
  2.4.2 THEORETICAL UNDERPINNINGS TO ADDRESS BEHAVIOUR CHANGE ........ 28
2.5 APPROACHES TO PATIENT EMPOWERMENT IN CHRONIC DISEASE .................................................................................. 33
  2.5.1 CHRONIC DISEASE SELF-MANAGEMENT ........................................ 34
  2.5.2 PROGRAM MODELS ...................................................................... 36
2.6 EVIDENCE OF SELF-MANAGEMENT PROGRAMS IN PEOPLE WITH CHD .................................................................................. 39
  2.6.1 BIBLIOTherapy ............................................................................. 40
2.7 EVIDENCE FOR DISEASE MANAGEMENT APPROACHES ........ 40
2.8 CARDIAC REHABILITATION ............................................................... 43
  2.8.1 BENEFITS OF PARTICIPATION IN CR ............................................ 43
  2.8.2 LIMITATIONS OF THE STUDIES .................................................. 48
  2.8.3 BARRIERS TO PARTICIPATION IN CR ............................................ 49
  2.8.4 ALTERNATE APPROACHES TO CARDIAC REHABILITATION .......... 51
2.9 CONCLUSION ................................................................................... 53

CHAPTER 3 OVERALL RESEARCH METHODS AND CONCEPTUAL FRAMEWORK ........................................................................... 54
3.1 INTRODUCTION .................................................................................. 55
3.2 OVERALL RESEARCH DESIGN ......................................................... 55
3.3 CONCEPTUAL FRAMEWORK ............................................................. 58
  3.3.1 EVIDENCE-BASED PRACTICE ..................................................... 58
  3.3.2 CHRONIC DISEASE SELF-MANAGEMENT ..................................... 59
  3.3.3 TRANSTHEORETICAL MODEL ..................................................... 59
3.4 SUMMARY ....................................................................................... 60
CHAPTER 4 EFFECT OF BRIEF STRUCTURED INTERVENTIONS ON RISK FACTOR MODIFICATION FOR PATIENTS WITH CORONARY HEART DISEASE – A SYSTEMATIC REVIEW ................................................................. 61

4.1 INTRODUCTION .................................................................................. 62

4.2 WHAT IS A BRIEF INTERVENTION? .................................................. 62

4.3 METHODS FOR DELIVERY OF BRIEF INTERVENTIONS .............. 62

4.4 ELEMENTS OF BRIEF INTERVENTIONS ...................................... 63

4.4.1 DESCRIPTION OF FRAMES ....................................................... 63

4.5 BRIEF INTERVENTIONS AND MOTIVATIONAL INTERVIEWING .............................................................................................................. 65

4.6 SYSTEMATIC REVIEWS AS A RESEARCH METHOD .................. 65

4.7 RESEARCH QUESTION AND OBJECTIVES .................................... 65

4.8 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW .. 66

4.9 SEARCHING THE LITERATURE ...................................................... 67

4.10 METHODS OF THE REVIEW ............................................................. 68

4.10.1 ASSESSING THE METHODOLOGICAL QUALITY OF THE TRIALS .......................................................................................... 68

4.10.2 EXTRACTING DATA FROM THE TRIALS ...................................... 69

4.10.3 SYNTHESISING THE DATA ............................................................ 69

4.11 DESCRIPTION OF STUDIES INCLUDED IN THE REVIEW ....... 70

4.11.1 SAMPLE SIZES ........................................................................... 70

4.11.2 TRIAL DESIGN .......................................................................... 70

4.11.3 PARTICIPANTS ............................................................................ 71

4.11.4 REASONS FOR HOSPITAL ADMISSION ..................................... 71

4.11.5 INTERVENTIONS ......................................................................... 71

4.12 METHODOLOGICAL QUALITY OF THE INCLUDED TRIALS .. 71

4.12.1 RANDOMISATION ...................................................................... 72

4.12.2 INTENTION-TO-TREAT ANALYSIS ............................................ 72

4.12.3 FOLLOW-UP .............................................................................. 72

4.12.4 BASELINE COMPARABILITY OF GROUPS .................................. 72

4.12.5 BLINDED OUTCOME ASSESSMENT .......................................... 72

4.12.6 METHODS TO ASSESS OUTCOMES ........................................ 72

4.13 RESULTS ......................................................................................... 73

4.13.1 BRIEF STRUCTURED INTERVENTION VS USUAL CARE FOR DIETARY MODIFICATION ................................................................. 73
4.13.2 BRIEF STRUCTURED INTERVENTION VS EXTENSIVE INTERVENTION FOR DIETARY MODIFICATION ................................................................. 75
4.13.3 BRIEF STRUCTURED INTERVENTION VS USUAL CARE FOR SMOKING CESSATION ................................................................................. 76
4.13.4 BRIEF STRUCTURED INTERVENTION VS. EXTENSIVE INTERVENTION FOR SMOKING CESSATION ................................................................. 80
4.13.5 BRIEF STRUCTURED INTERVENTION VS. USUAL CARE FOR MULTIPLE RISK FACTOR MODIFICATION .......................................................... 81
4.13.6 Costs ........................................................................................................ 88

4.14 DISCUSSION ................................................................................................. 88
4.14.1 BRIEF STRUCTURED INTERVENTION VS USUAL CARE FOR DIETARY MODIFICATION ............................................................................. 89
4.14.2 BRIEF STRUCTURED INTERVENTION VS EXTENSIVE INTERVENTION FOR DIETARY MODIFICATION ................................................................. 89
4.14.3 BRIEF STRUCTURED INTERVENTION VS USUAL CARE FOR SMOKING CESSATION ................................................................................. 90
4.14.4 BRIEF STRUCTURED INTERVENTION VS EXTENSIVE INTERVENTION FOR SMOKING CESSATION ................................................................. 90
4.14.5 BRIEF STRUCTURED INTERVENTION VS USUAL CARE FOR MULTIPLE RISK FACTOR MODIFICATION .......................................................... 90

4.15 LIMITATIONS OF THE TRIALS ................................................................. 91
4.16 IMPLICATIONS FOR PRACTICE .................................................................. 91
4.17 IMPLICATIONS FOR RESEARCH ................................................................. 92
4.18 CONCLUSION ............................................................................................... 93
4.19 IMPLICATIONS FOR THE DEVELOPMENT OF THE HELM INTERVENTION ................................................................. 93

CHAPTER 5 IMPLEMENTATION OF THE CARDIAC EVIDENCE-BASED REDUCING RISK IN HEART DISEASE GUIDELINES (ICEBRG) ................. 94
5.1 INTRODUCTION ............................................................................................. 95
5.2 CARDIAC REHABILITATION WITHIN THE AUSTRALIAN CONTEXT .............................................................................................................. 95
5.3 AIM OF THE STUDY ...................................................................................... 96
5.4 MIXED-METHODS AS A RESEARCH DESIGN .............................................. 96
5.5 SAMPLING STRATEGY .................................................................................. 97
5.5.1 METHOD USED FOR CALCULATING ARIA+ SCORE ................................. 98
5.5.2 JUSTIFICATION FOR THE SAMPLE SIZE ............................................. 99
5.5.3 SELECTION OF CR PROGRAMS .............................................................. 99
5.5.4 Recruitment of CR Coordinators .................................................. 99

5.6 Ethical Considerations ................................................................. 100
  5.6.1 Informed Consent ...................................................................... 100
  5.6.2 Maintaining Privacy and Confidentiality .................................... 100

5.7 Methods of Data Collection .......................................................... 101
  5.7.1 Interviews as a Data Collection Method ...................................... 101
  5.7.2 Surveys as a Data Collection Method .......................................... 102
  5.7.3 Design of the Interview Schedule .............................................. 102
  5.7.4 Design of the Self-Administered Questionnaire ......................... 104
  5.7.5 Pilot Testing the Interview Schedule and the Self-Administered
       Questionnaire ............................................................................ 104
  5.7.6 Conducting the Qualitative Interview ....................................... 105
  5.7.7 Establishing the Trustworthiness of Information .......................... 106

5.8 Managing the Interview Data ......................................................... 108
  5.8.1 Note Taking and Audio Taping the Interviews ............................. 108
  5.8.2 Transcribing Interviews ........................................................... 109
  5.8.3 Within-Case Analysis ............................................................... 109
  5.8.4 Cross Analysis .......................................................................... 109

5.9 Managing the Data Obtained from the Postal Survey ..................... 110

5.10 Findings ....................................................................................... 110
  5.10.1 Classification of CR Programs and Participation Rates .............. 110
  5.10.2 Profile of CR Coordinators ...................................................... 111
  5.10.3 Description of the Programs .................................................... 113
  5.10.4 Staffing in the CR Programs ..................................................... 113
  5.10.5 Waiting Lists for CR Participation ............................................ 114
  5.10.6 Referral to CR ........................................................................... 114
  5.10.7 Participation in CR According to Diagnosis .............................. 115
  5.10.8 Reasons for Nonparticipation in CR Programs ............................ 115
  5.10.9 Knowledge of the RRIHD Guidelines ....................................... 116
  5.10.10 Stage of Change Assessment .................................................. 116
  5.10.11 Performance Indicators for CR ................................................. 117
  5.10.12 Barriers, Strategies and Facilitators to Implementation of the
         Guidelines .................................................................................... 117
5.10.13 Barriers to implementation of the guidelines ............................................. 118
5.10.15 Strategies employed to overcome barriers to implementation of the guidelines .................................................................................................................. 133
5.10.16 Facilitators to delivering evidence-based CR services ........................ 137

5.11 DISCUSSION............................................................................................................ 141
5.11.1 Compliance with guidelines ........................................................................ 141
5.11.2 Issues relating to guideline implementation ................................................. 142
5.11.3 Advantages of the methods used ................................................................. 144
5.11.4 Limitations of the study ............................................................................. 144

5.12 RECOMMENDATIONS FOR RESEARCH......................................................... 145

5.13 CONCLUSION ....................................................................................................... 145

5.14 IMPLICATIONS FOR THE DEVELOPMENT OF THE HELM INTERVENTION ................................................. 146

CHAPTER 6 FOLLOW-UP (12-24) OF PATIENTS AFTER CORONARY
TREATMENT (FACT) STUDY .......................................................................................... 147
6.1 INTRODUCTION ..................................................................................................... 148
6.2 RATIONALE FOR THE STUDY .......................................................................... 149
6.3 AIMS OF THE STUDY .......................................................................................... 150
6.4 RESEARCH QUESTIONS ..................................................................................... 150
6.5 RESEARCH DESIGN ............................................................................................. 151
6.5.1 Surveys as a research method ...................................................................... 151
6.6 METHOD ............................................................................................................... 151
6.6.1 Consultation with key stakeholders .............................................................. 151
6.6.2 Selection of participants for the study ......................................................... 151
6.6.3 Recruitment of patients ................................................................................ 152
6.6.4 Data collection ............................................................................................... 154
6.7 DATA ANALYSIS ................................................................................................ 160
6.7.1 Assessment of cardiac risk factors ............................................................... 160
6.7.2 Health related quality of life ......................................................................... 160
6.7.3 Medication adherence .................................................................................. 161
6.7.4 Knowledge of CHD and risk factors ......................................................... 161
6.7.5 Participation in cardiac rehabilitation ......................................................... 161
6.8 ETHICAL CONSIDERATIONS .......................................................................... 161
6.9 RESULTS ............................................................................................................. 162
6.9.1 CHARACTERISTICS OF PARTICIPANTS ................................................................. 164
6.9.2 DETAILS OF THE PCI PROCEDURE ................................................................. 165
6.9.3 PRESENCE OF CARDIOVASCULAR RISK FACTORS ......................................... 165
6.9.4 HEALTH-RELATED QUALITY OF LIFE ............................................................ 170
6.9.5 MEDICATION ADHERENCE .............................................................................. 174
6.9.6 KNOWLEDGE OF CHD AND MODIFIABLE RISK FACTORS ............................ 176

6.10 DEVELOPMENT OF THE CARDIAC REHABILITATION ENROLMENT OBSTACLE (CREO) SCALE ................................................................. 182
6.10.1 ITEM GENERATION AND CONTENT VALIDATION FOR THE CREO SCALE .... 182
6.10.2 INSTRUMENT TESTING ................................................................................... 183
6.10.3 THE FINAL CREO SCALE .............................................................................. 184
6.10.4 FACTOR ANALYSIS OF CREO SCALE ............................................................ 184

6.11 DISCUSSION ....................................................................................................... 187
6.11.1 CARDIOVASCULAR RISK FACTORS STATUS .................................................. 187
6.11.2 FUNCTIONAL STATUS AND HEALTH-RELATED QUALITY OF LIFE ............ 190
6.11.3 MEDICATION ADHERENCE .......................................................................... 190
6.11.4 KNOWLEDGE OF CHD AND RISK FACTORS ................................................. 191
6.11.5 IMPORTANT ELEMENTS OF A CR PROGRAM ............................................... 191
6.11.6 PARTICIPATION IN CR PROGRAMS ................................................................. 192
6.11.7 DEVELOPMENT OF THE CREO SCALE .......................................................... 193
6.11.8 LIMITATIONS OF THE STUDY ...................................................................... 194

6.12 CONCLUSIONS .................................................................................................... 195

6.13 IMPLICATIONS FOR THE DEVELOPMENT OF THE HELM INTERVENTION ................................................................. 195

CHAPTER 7 FEASIBILITY OF THE HEALTH-RELATED LIFESTYLE SELF-MANAGEMENT (HELM) INTERVENTION ................................................................. 196
7.1 INTRODUCTION .................................................................................................... 197
7.2 THE HELM INTERVENTION .................................................................................. 198
7.2.1 GOAL-SETTING ............................................................................................... 198
7.2.2 THE HELM BOOKLET ..................................................................................... 199
7.2.3 FEEDBACK OF PERSONAL RISK ..................................................................... 203
7.2.4 TEAM BUILDING AND COMMUNICATION WITH GPs ................................... 204
7.2.5 THREE SUPPORTIVE TELEPHONE CALLS .................................................... 204
7.2.6 FRIDGE MAGNET ........................................................................................... 205
7.2.7 Health Diary for Self-Monitoring

7.3 Feasibility of the HELM Intervention

7.4 Aim of the Study

7.5 Design of the Study

7.6 Research Methods

7.6.1 Recruitment of Participants

7.6.2 Data Collection and Management

7.6.3 Clinical Outcomes

7.6.4 Quality of Life

7.6.5 Psychosocial Risk Factors

7.6.6 Medication Adherence

7.6.7 Readiness of Change for the Following Risk Factors: Smoking, Physical Activity and Fat Intake

7.6.8 Medical Records Audit

7.6.9 Incidence of Major Acute Coronary Event (MACE)

7.7 Recruitment Process

7.8 Randomisation

7.9 Implementation of the HELM Intervention

7.10 Outcome Assessment and Follow-up Data Collection

7.11 Management of the Data

7.12 Ethical Considerations

7.13 Results

7.13.1 Incidence of Major Coronary Events (MACE)

7.13.2 Feasibility of Participant Recruitment

7.13.3 Treatment Program Attrition, Adherence and Completion Rates

7.13.4 Suitability of Data Collection Methods and Questionnaire Completion

7.13.5 Acceptability of the HELM Intervention

7.13.6 Effect of the HELM Intervention on Participation in CR Programs

7.13.7 Effect of the HELM Intervention on Behavioural Risk Factor Status

7.14 Discussion

7.14.1 Feasibility of Recruiting Patients with ACS
7.14.2 Adherence to Treatment Program Completion and Attrition Rate .................................................................................. 231
7.14.3 Data Collection Methods and Questionnaire Completion .......... 232
7.14.4 Acceptance of the Intervention ................................................................. 232
7.14.6 Effect of the HeLM Intervention on Risk Factor Modification and Stages of Change .......................................................... 233
7.14.7 Strengths of the HeLM Study and the HeLM Intervention ................. 233

7.15 Implications for the Conduct of a Larger Trial ........................................ 234

7.16 Conclusions ........................................................................................................ 235

CHAPTER 8 DISCUSSION AND CONCLUSION .................................................. 236

8.1 Introduction .......................................................................................................... 237

8.2 Key Findings ......................................................................................................... 238

8.2.1 What is the Effectiveness of Brief Structured Interventions on Risk Factor Modification for Patients with CHD? ......................... 238

8.2.2 What are the Barriers and Facilitators Identified by the CR Coordinators to Implementing the Reducing Risk in Heart Disease Guidelines? ........................................................................ 238

8.2.3 What are the Cardiac Risk Factors, HRQoL Status, Long-Term Medication Adherence Rate, and Knowledge Level of CHD and Its Risk Factors in Patients 12-24 Months Following PCI? ................ 239

8.2.4 What are the Obstacles Identified by Patients for Nonparticipation in CR Programs and What are Their Preferences? ..................... 240

8.2.5 Development of the CREO Scale ..................................................................... 241

8.2.6 Characteristics of the HeLM Intervention ..................................................... 241

8.2.7 Feasibility of the HeLM ..................................................................................... 242

8.3 Implications for Practice ...................................................................................... 243

8.4 Limitations of the Project ..................................................................................... 244

8.5 Conclusion ............................................................................................................ 245

References ................................................................................................................. 246
List of Tables

TABLE 2.1 CONSTRUCTS OF COMMONLY USED SELF-MANAGEMENT THEORIES ...............29
TABLE 2.2 EVIDENCE FROM SYSTEMATIC REVIEW OF CDSM INTERVENTIONS ..........42
TABLE 2.3 ALL-CAUSE MORTALITY AND MI IN TRIALS EVALUATING SECONDARY PREVENTION PROGRAMS ................................................... .............................45
TABLE 2.4 SUMMARY OF THE BENEFITS OF LIFESTYLE MODIFICATION ...............48
TABLE 3.1 RESEARCH DESIGNS USED FOR EACH OF THE STUDIES THAT CONSTITUTED THE MULTI-METHODS................................................... ........................................57
TABLE 4.1 OVERVIEW OF THE SEARCHING TECHNIQUES .................................................68
TABLE 4.2 MEAN CHANGE IN DIETARY INTAKE FROM BASELINE TO FOLLOW-UP .........76
TABLE 5.1 ARIA+ CATEGORIES .................................................................... 98
TABLE 5.2 DISTRIBUTION OF CR PROGRAMS ACCORDING TO ARIA+ CATEGORY AND PARTICIPATION RATES ................................................... .............................................. 111
TABLE 5.3 PROFILE OF THE CR COORDINATORS ................................................... 112
TABLE 5.4 HEALTH PROFESSIONAL WHO REFER PATIENTS TO CR ..................115
TABLE 5.5 REASONS FOR NONPARTICIPATION IN CR PROGRAMS ..........................116
TABLE 6.1 DEPRESSION ANXIETY AND STRESS SEVERITY RATING INDEX 467 .......157
TABLE 6.2 DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS .........................164
TABLE 6.3 NUMBER OF PATIENTS WITH RISK FACTORS .........................................165
TABLE 6.4 COMPARISON BETWEEN SMOKING STATUS BEFORE AND AFTER PCI .......166
TABLE 6.5 NUMBER OF PARTICIPANTS WITH HIGH BLOOD PRESSURE AT FOLLOW-UP .... 167
TABLE 6.6 NUMBER OF PARTICIPANTS WITH HIGH CHOLESTEROL AT 12-24 MONTH FOLLOW-UP ................................................... .............................................. 168
TABLE 6.7 PARTICIPATION IN PHYSICAL ACTIVITY .................................................. 168
TABLE 6.8 BMI CLASSIFICATION ............................................................................ 169
TABLE 6.9 PSYCHOSOCIAL STATUS ......................................................................... 169
TABLE 6.10 MEDICATIONS TAKEN BY PARTICIPANTS ................................................. 175
TABLE 6.11 MEDICATION ADHERENCE RATES OF PARTICIPANTS ..........................176
TABLE 6.12 OVERALL NUMBER OF PARTICIPANTS WITH CORRECT RESPONSES TO THE KNOWLEDGE OF CHD QUESTIONS ................................................... ............ 177
TABLE 6.13 CORRECT RESPONSES TO QUESTIONS RELATING TO KNOWLEDGE OF CHD ... 178
TABLE 6.14 CORRECT IDENTIFICATION OF MODIFIABLE RISK FACTORS IN PARTICIPANTS WITH THAT SPECIFIC RISK FACTOR ................................................... 180
TABLE 6.15 CRPF-R SCORES COMPARISONS: DEMOGRAPHIC CHARACTERISTICS ....... 181
TABLE 6.16 FACTOR LOADINGS FOR PRINCIPAL COMPONENT ANALYSIS WITH OBLIQUE ROTATION (N=104) ................................................................. 186
TABLE 6.17 MEAN AND STANDARD DEVIATION TOTAL AND FACTOR SCORES ......... 187
TABLE 7.1 FINDINGS FROM CHAPTERS 4, 5 AND 6 .................................................... 197
TABLE 7.2 REASONS FOR PATIENTS EXCLUDED FROM THE STUDY .......................... 217
TABLE 7.3  REASONS FOR NONPARTICIPATION IN THE STUDY .................................218
TABLE 7.4  DEMOGRAPHIC DATA OF THE PARTICIPANTS........................................219
TABLE 7.5  COMPARISON BETWEEN DROPOUTS AND PARTICIPANTS COMPLETING THE
STUDY ..................................................................................................................221
TABLE 7.6  SATISFACTION WITH THE HeLM INTERVENTION...................................224
TABLE 7.7  RISK FACTOR STATUS AT 6-WEEK FOLLOW-UP...........................................227
TABLE 7.8  SMOKING - PARTICIPANTS STAGE OF CHANGE AT 6-WEEK FOLLOW-UP ........228
TABLE 7.9  PHYSICAL ACTIVITY - PARTICIPANTS STAGE OF CHANGE AT 6-WEEK FOLLOW-
UP .........................................................................................................................228
TABLE 7.10  FAT INTAKE - PARTICIPANTS STAGE OF CHANGE AT 6-WEEK FOLLOW-UP.....228
List of Figures

Figure 1.1 Death rate for coronary heart disease 1940-2004 ......................... 4
Figure 1.2 Incidence of revascularisation procedures .................................. 7
Figure 1.3 Revascularisation techniques according to categories of ACS .......... 7
Figure 1.4 Percutaneous coronary intervention procedure ............................. 8
Figure 1.5 Flow diagram of the study .......................................................... 21
Figure 2.1 The transtheoretical model of change .......................................... 31
Figure 3.1 Conceptual model for the HeLM intervention ................................. 60
Figure 4.1 Mean change in fat intake at 12 week follow-up .......................... 73
Figure 4.2 Mean change in lipid profile at 12 week follow-up ....................... 74
Figure 4.3 Mean change in weight at 12 week follow-up .............................. 74
Figure 4.4 Number of patients who did not achieve their target LDL-C at the 6 month follow-up .................................................. 75
Figure 4.5 Number of patients who continued to smoke at three week follow-up .................................................................................. 77
Figure 4.6 Number of patients who continued to smoke at six week follow-up .................................................................................. 77
Figure 4.7 Number of patients who continued to smoke at three month follow-up .................................................................................. 78
Figure 4.8 Number of patients who continued to smoke at six month follow-up .................................................................................. 78
Figure 4.9 Number of patients who continued to smoke at the 12 month follow-up ............................................................................... 79
Figure 4.10 Number of patients who continued to smoke at 24 month follow-up .................................................................................. 79
Figure 4.11 Number of patients who continued to smoke at 30 month follow-up .................................................................................. 80
Figure 4.12 Number of patients who continued to smoke at three month follow-up .................................................................................. 80
Figure 4.13 Number of patients who continued to smoke at 12 month follow-up .................................................................................. 81
Figure 4.14 Number of patients who had an elevated blood pressure at the 6 month follow-up .......................................................... 81
Figure 4.15 Lipid profile at six month follow-up ............................................ 82
Figure 4.16 Number of patients who had raised triglycerides and LDL-C between the two groups at the six month follow-up ..................... 83
Figure 4.17 Changes to diet, medications and exercise at six month follow-up .................................................................................. 84
List of Appendices

APPENDIX 1 REDUCING RISK IN HEART DISEASE GUIDELINES ..................... 285
APPENDIX 2 VERIFICATION OF STUDY ELIGIBILITY ............................... 293
APPENDIX 3 SEARCH STRATEGIES .................................................. 294
APPENDIX 4 JBI CRITICAL APPRAISAL CHECKLIST FOR EXPERIMENTAL
STUDIES .................................................................................. 306
APPENDIX 5 QUALITY ASSESSMENT OF INCLUDED TRIALS .................... 307
APPENDIX 6 DATA ABSTRACTION SHEET ....................................... 309
APPENDIX 7 STUDIES EXCLUDED FROM THE REVIEW ......................... 312
APPENDIX 8 SUMMARY TABLES ................................................... 316
APPENDIX 9 PATIENT INFORMATION SHEET .................................. 332
APPENDIX 10 ETHICS APPROVAL FROM SSWAHS ............................. 333
APPENDIX 11 PATIENT CONSENT FORM ...................................... 334
APPENDIX 12 QUALITATIVE TELEPHONE INTERVIEW GUIDE .................. 335
APPENDIX 13 SURVEY OF CR PROGRAMS ACROSS NSW ................. 346
APPENDIX 14 SELF ADMINISTERED ANGIOPLASTY QUESTIONNAIRE .... 351
APPENDIX 15 ETHICS APPROVAL FROM SSWAHS (WESTERN ZONE) FOR
THE PCI STUDY ......................................................................... 370
APPENDIX 16 ETHICS APPROVAL FROM UNIVERSITY OF WESTERN
SYDNEY FOR THE PCI STUDY .................................................. 371
APPENDIX 17 THE CREO SCALE ................................................... 372
APPENDIX 18 RECRUITMENT SCRIPT ............................................. 373
APPENDIX 19 PARTICIPANT INFORMATION SHEET ............................. 374
APPENDIX 20 PARTICIPANT CONSENT FORM (HELM STUDY) ............... 376
APPENDIX 21 SELF ADMINISTERED QUESTIONNAIRE ...................... 378
APPENDIX 22 MEDICAL RECORDS AUDIT FORM ................................ 393
APPENDIX 23 ADDITIONAL QUESTIONS FOR 6 WEEK FOLLOW UP (HELM
STUDY) .................................................................................. 399
APPENDIX 24 TAKE THE HELM BOOKLET ...................................... 403
APPENDIX 25 PERSONALISED RISK FACTOR CARD ............................ 429
APPENDIX 26 PATIENT FEEDBACK FORM ...................................... 430
APPENDIX 27 LETTER TO THE PARTICIPANTS .................................. 432
APPENDIX 28 INTERVIEWER GUIDE FOR MOTIVATION SUPPORT ......... 433
APPENDIX 29 HEALTH DIARY ..................................................... 439
APPENDIX 30 ETHICS APPROVAL FOR THE HELM STUDY (SSWAHS
WESTERN ZONE) .................................................................... 440
APPENDIX 31 ETHICS APPROVAL FOR THE HELM STUDY (UWS) ......... 441
### List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAS</td>
<td>Active Australia Survey</td>
</tr>
<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
</tr>
<tr>
<td>ACE</td>
<td>Angiotensin-converting enzyme</td>
</tr>
<tr>
<td>ACS</td>
<td>Acute coronary syndrome</td>
</tr>
<tr>
<td>ADL</td>
<td>Activities of daily living</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>AMI</td>
<td>Acute myocardial infarction</td>
</tr>
<tr>
<td>ARIA+</td>
<td>Accessibility/Remoteness Index of Australia</td>
</tr>
<tr>
<td>ASR</td>
<td>Age standardised rate</td>
</tr>
<tr>
<td>BAI</td>
<td>Beck Anxiety Inventory</td>
</tr>
<tr>
<td>BDI</td>
<td>Beck Depression Inventory</td>
</tr>
<tr>
<td>BGL</td>
<td>Blood glucose level</td>
</tr>
<tr>
<td>BI</td>
<td>Brief intervention</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>BP</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>CABG</td>
<td>Coronary artery bypass grafting</td>
</tr>
<tr>
<td>CANR</td>
<td>Centre for Applied Nursing Research</td>
</tr>
<tr>
<td>CCU</td>
<td>Coronary Care Unit</td>
</tr>
<tr>
<td>CCU-S</td>
<td>Coronary Care Unit - Subacute</td>
</tr>
<tr>
<td>CDSM</td>
<td>Chronic disease self-management</td>
</tr>
<tr>
<td>Cert.</td>
<td>Certificate</td>
</tr>
<tr>
<td>CHD</td>
<td>Coronary heart disease</td>
</tr>
<tr>
<td>CHW</td>
<td>Community health workers</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CIS</td>
<td>Clinical information service</td>
</tr>
<tr>
<td>cm</td>
<td>centimetre</td>
</tr>
<tr>
<td>CO</td>
<td>Carbon monoxide</td>
</tr>
</tbody>
</table>
COACH  Coaching patients On Achieving Cardiovascular Health
COAG  Council of Australian Governments
CR  Cardiac rehabilitation
CREO  Cardiac rehabilitation enrolment obstacles
CRPF-R  Revised cardiac rehabilitation preference form
CSANZ  Cardiac Society of Australia and New Zealand
CVD  Cardiovascular disease
DALY  Disability-adjusted life year
DASS  Depression and Anxiety Stress Scale
EBP  Evidence-based practice
EN  Enrolled nurse
EP  Exercise physiologist
FACT  Follow-up After Coronary Treatment
FRAMES  Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy
GP  General practitioner
HA  Highly accessible
HDL-C  High-density lipoprotein cholesterol
HeLM  Health-related Lifestyle self-Management
HF  Heart failure
HRQoL  Health-Related Quality of Life
ICEBRG  Implementation of the Cardiac Evidence-Based Reducing risk in heart disease Guidelines
JBI  Joanna Briggs Institute
LDL-C  Low-density lipoprotein cholesterol
MA  Moderately accessible
MACE  Major acute coronary event
MI  Myocardial infarction
MMAS  Morisky Medication Adherence Scale
MMSE  Mini Mental State Examination
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHFA</td>
<td>National Heart Foundation of Australia</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NSTEACS</td>
<td>Non-ST-segment-Elevation ACS</td>
</tr>
<tr>
<td>NSW</td>
<td>New South Wales</td>
</tr>
<tr>
<td>NUM</td>
<td>Nursing unit manager</td>
</tr>
<tr>
<td>OT</td>
<td>Occupational therapist</td>
</tr>
<tr>
<td>PCI</td>
<td>Percutaneous coronary intervention</td>
</tr>
<tr>
<td>PT</td>
<td>Physiotherapist</td>
</tr>
<tr>
<td>PVD</td>
<td>Peripheral vascular disease</td>
</tr>
<tr>
<td>RA</td>
<td>Research assistant</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>RN</td>
<td>Registered Nurse</td>
</tr>
<tr>
<td>RR</td>
<td>Relative risk</td>
</tr>
<tr>
<td>RRIHD</td>
<td>Reducing Risk In Heart Disease</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SMART</td>
<td>Specific, Measurable, Achievable, Realistic, Time</td>
</tr>
<tr>
<td>SP</td>
<td>Speech pathologist</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>SSWAHS</td>
<td>Sydney South West Area Health Service</td>
</tr>
<tr>
<td>STEACS</td>
<td>ST-segment-Elevation ACS</td>
</tr>
<tr>
<td>TC</td>
<td>Total cholesterol</td>
</tr>
<tr>
<td>TICS</td>
<td>Telephone interview for cognitive status</td>
</tr>
<tr>
<td>TTM</td>
<td>Transtheoretical model</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WMD</td>
<td>Weighted mean difference</td>
</tr>
<tr>
<td>WTHR</td>
<td>Waist-to-hip ratio</td>
</tr>
</tbody>
</table>
## Glossary

### Definition of terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Myocardial infarction (AMI)</td>
<td>The presence of at least two of the following criteria: (a) appropriate clinical presentation, (b) typical ECG changes, and (c) raised cardiac enzymes (Troponin T-0.01 ug/L; Troponin I-0.3 ug/L)</td>
</tr>
<tr>
<td>Adequate physical activity</td>
<td>Exercising for at least 30 minutes on most days (150 minutes per week minimum)</td>
</tr>
<tr>
<td>Adherence</td>
<td>Concordance between a patient’s behaviour and medical or health advice.</td>
</tr>
<tr>
<td>Angina</td>
<td>Is a medical term used to describe a discomfort or chest pain felt by a patient. Angina can be the result of a spasm, narrowing or blockage of a coronary vessel depriving the heart muscle of blood and oxygen.</td>
</tr>
<tr>
<td>Coronary Artery Bypass Grafts (CABGS)</td>
<td>This is a surgical procedure where a vein or an artery is grafted surgically to bypasses the blocked vessel or vessels to improve blood supply from the aorta to the heart muscle.</td>
</tr>
<tr>
<td>Coronary Heart Disease (CHD)</td>
<td>Is a disease of the heart caused by the narrowing of coronary blood vessels which can lead to angina or myocardial infarction or death.</td>
</tr>
<tr>
<td>Cardiovascular Disease (CVD)</td>
<td>This term encompasses coronary heart disease (CHD) other vascular diseases, stroke and heart failure.</td>
</tr>
<tr>
<td>Cardiac Markers</td>
<td>These blood tests are used to confirm damage to the myocardium (heart muscle). The tests include, creatine kinase (CK): a fraction of the CK is known as CK-MB which is raised within 6 hours of damage and peaks 18 hours before returning to normal. Troponin is a sensitive marker which is specific to cardiac muscle proteins and can detect cardiac muscle damage early.</td>
</tr>
<tr>
<td>Disability Adjusted Life Year (DALY)</td>
<td>The Disability Adjusted Life Year or DALY is a health gap measure that extends the concept of potential years of life lost due to premature death (PYLL) to include equivalent years of ‘healthy’ life lost by virtue of being in states of poor health or disability</td>
</tr>
<tr>
<td>Global Registry of Acute Coronary Events (GRACE))</td>
<td>This is a prediction tool used to identify all cause mortality of patients following discharge at six months post cardiac event</td>
</tr>
<tr>
<td>Health Behaviour</td>
<td>Undertaking methods to prevent or reduce the incidence of developing diseases</td>
</tr>
</tbody>
</table>
## Definition of terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td>This is a medical term used to identify a heart attack. This is an acute episode when the heart muscle is deprived of oxygenated blood caused by one or more blocked coronary vessels.</td>
</tr>
<tr>
<td><strong>Non-ST elevation Myocardial Infarction (NSTEMI)</strong></td>
<td>No changes are noted on the electrocardiogram but the cardiac markers are elevated indicating the patient has had an infarct.</td>
</tr>
<tr>
<td><strong>Percutaneous Coronary Intervention (PCI)</strong></td>
<td>This is a broad term used to describe methods to open coronary blood vessels by either the use of a balloon or a stent.</td>
</tr>
<tr>
<td><strong>Percutaneous Transluminal Coronary Angioplasty (PTCA)</strong></td>
<td>This is an effective method used to dilate the coronary vessel. A balloon tip catheter is passed through the vessel to where it becomes narrowed. The balloon is inflated and plaque is pushed against the vessel wall to allow sufficient blood flow through the coronary vessel.</td>
</tr>
<tr>
<td><strong>Reperfusion therapy</strong></td>
<td>This is a drug treatment used to dissolve blood clots to open the blocked coronary vessel/s. This treatment can be given during and following a myocardial infarction to improve circulation to the myocardium.</td>
</tr>
<tr>
<td><strong>Risk Factors</strong></td>
<td>This refers to the factors which contribute to the development of cardiac disease. These factors can either be modifiable, obesity, physical inactivity, cigarette smoking, high fat diet, high cholesterol and hypertension. Non-Modifiable risk factors include age, gender and family history.</td>
</tr>
<tr>
<td><strong>Secondary prevention</strong></td>
<td>Identifying and treating people with established heart disease and those at very high risk of developing cardiovascular disease.</td>
</tr>
<tr>
<td><strong>Stent</strong></td>
<td>This is a prosthetic metal device which is implanted into the coronary vessel at the site of the narrowing to maintain integrity of the lumen and to improve blood flow.</td>
</tr>
<tr>
<td><strong>Stenosis</strong></td>
<td>Narrowing or blockage of a coronary vessel.</td>
</tr>
<tr>
<td><strong>Thrombolysis in Myocardial Infarction (TIMI)</strong></td>
<td>This risk score was created to identify independent predictors for mortality in patients following a myocardial infarction. The tool was developed and has been validated for both Non-STEMI and STEMI.</td>
</tr>
</tbody>
</table>
Abstract

Acute coronary syndrome (ACS), the acute manifestation of coronary heart disease (CHD), is the leading cardiovascular cause of mortality and morbidity globally, and represents one of the most common causes of acute medical admissions to Australian hospitals. Following medical and/or surgical management of ACS, lifestyle modification to reduce the underlying risk factors that contribute to the progression of the disease remains vital. Cardiac rehabilitation (CR) has been widely accepted as an intervention that can reduce mortality and modify risk factors for subsequent coronary events and cardiovascular disease. While the benefits of cardiac rehabilitation programs have been demonstrated, participation and adherence to these programs remain low for various reasons, particularly among patients whose treatment includes revascularisation with percutaneous coronary intervention. This method of revascularisation has become increasingly common due its immediate success, rapid procedural technique, short hospital stay and early return to work for patients of working age.

The aim of this study was to develop and test the feasibility of an evidence-based health-related lifestyle management program for risk factor modification in patients with ACS undergoing percutaneous coronary intervention. Four distinct yet interrelated studies were undertaken as part of the Development and evaluation of a Health-related Lifestyle self-Management (HeLM) intervention for patients with ACS Project. Three of these studies informed the development of the HeLM intervention, which was based on the principles of chronic disease self-management and evidence-based practice that included best evidence from the literature, clinical expertise and patient preferences.

The first study was a systematic review of the literature to identify the best available evidence of the effect of brief interventions for lifestyle modification in patients with CHD. Findings from the 17 trials included in the systematic review, although inconclusive suggest that brief structured interventions can have beneficial effects on risk factor modification and consequently on progression of CHD.

The second study was a qualitative interview of CR coordinators to identify from their clinical expertise the influence of the Reducing Risk in Heart Disease guidelines on practice: the Implementation of the Cardiac Evidence-Based
Reducing Risk in Heart Disease Guidelines (ICEBRG) study. Findings from this study indicated limited implementation of the guidelines due to various barriers relating to health services, CR programs, professional practice and the patient and their families. Despite these barriers, it was evident that CR coordinators were striving to overcome these odds and provide evidence-based care.

The third study undertaken to identify patient preferences for CR was the Follow-up After percutaneous Coronary Treatment (FACT) Study. The findings indicated that although the majority of the participants had two or more risk factors, they lacked knowledge of the link between risk factors and CHD, and less than a third had attended CR. The main reasons for nonattendance included timing, distance to travel, length of program, work commitments and lack of motivation to attend the programs. Their suggestions for improvement included telephone follow-up and flexibility of the CR programs. This study also informed the development of a tool that can be used by clinicians to flag patients who are unlikely to attend traditional CR. Identification of these people will allow alternate strategies to reduce risk factors to be tailored to their needs. The findings from these three studies were used to develop the HeLM intervention.

The final study was undertaken to assess the feasibility of the HeLM intervention that was based on evidence compared to standard treatment for promoting lifestyle modification. This study was undertaken in 51 participants who were followed up two weeks following the completion of the intervention. The findings demonstrated that patients found the information beneficial and were pleased to receive it in their homes. The telephone support was also extremely well received. The study enabled the program and the process for implementation to be refined and indicated that a large multicentre trial would be feasible.

The HeLM may be a strategy that could reach patients who have thus far eluded traditional CR programs and support them to make the necessary lifestyle changes. It may also be an adjunct to traditional CR and have a synergistic effect in facilitating health-promoting behaviours in CHD patients. Studies of interventions for risk factor modification in participants with CHD require longer term follow-up to assess the effect of the intervention in the sustainability of behaviour modification. Further research is necessary to evaluate the long-term effects as well as the cost-effectiveness of the intervention.
Anthology of publications

CONFERENCE PRESENTATIONS


REFEREED JOURNAL MANUSCRIPTS


**NEWSPAPER ARTICLES**


Chapter 1

The burden of cardiovascular disease: implications for secondary prevention
1.1 Introduction
This thesis will report a series of studies undertaken to describe the risk factor burden and the developing of a brief, tailored self-management intervention to improve the outcomes of people following the diagnosis of an acute coronary syndrome (ACS). This chapter provides a background to these studies by describing the burden of cardiovascular disease, specifically coronary heart disease (CHD), and the acute and chronic management of acute coronary syndromes. Risk factors impacting on the genesis and progression of CHD will be discussed, as well as the implications for secondary prevention. In addition, the study aims will be described and an outline of the thesis plan presented.

1.2 Cardiovascular disease
Cardiovascular disease (CVD), also known as circulatory disease, encompasses coronary heart disease (CHD) other vascular diseases, stroke and heart failure. The major contributors to CVD include CHD, cerebrovascular disease, heart failure (HF), and peripheral vascular disease (PVD). Cardiovascular disease remains the largest health problem globally. This is also the case in Australia, where CVD is the leading cause of morbidity and mortality, affecting one in every six Australians and accounting for 18% of the burden of disease. Cardiovascular disease contributes to significant illness, disability, poor quality of life and premature death, and is the most costly condition in Australia in terms of health expenditure. In 2004, CVD accounted for 47,512 deaths (35.9% of all deaths) and affected 3.5 million Australians. In 2000-01, the official fiscal cost of CVD was $5.5 billion, dominated by CHD ($1.76 bn). In 2004, the human expense of CVD totalled 600,000 years of healthy Australian life.

1.3 Coronary heart disease
Coronary heart disease, also known as ischaemic heart disease (IHD), is the major contributor of CVD and remains the leading cardiovascular cause of mortality and morbidity globally. Every day, around 80 Australians die from CHD, underscoring the importance of primary and secondary prevention. Coronary heart disease has been identified as the leading underlying or associated cause of death among both
men and women, second only to cancer.\textsuperscript{1} The term CHD, which includes both ACS and stable angina, affects 334,500 Australians (1.7\% of the population).\textsuperscript{6} Of these, 214,400 (64\%) Australians suffer angina and 152,200 people (45\%) have experienced an ACS event,\textsuperscript{1} creating a substantial economic burden on both individuals and the community due to resulting physical and psychosocial disability.\textsuperscript{9} This burden of disease also creates significant costs for health care systems.\textsuperscript{4} In 2006, CHD was the highest single cause of death, claiming over 26,000 lives in Australia and representing 19.2\% of all deaths.\textsuperscript{1} Mortality rates from CHD peaked in the late sixties in men and in the early sixties in women, however technological advances and improvements in secondary prevention strategies, both pharmacological and non-pharmacological, have seen the mortality rate decline by over 60\%, as shown in Figure 1.1.\textsuperscript{1} In the last decade alone (1995 to 2004), the age-standardised CHD death rate has declined by about 39\%. These declines could be attributed to a reduction in acute myocardial infarctions (AMI) and improved survival\textsuperscript{1} as well as reductions in population risk factors from primary and secondary prevention.\textsuperscript{10} However it should be noted that the prevalence of overweight and obesity and diabetes has increased in the past decade.\textsuperscript{11} In addition, according to the World Health Organization’s (WHO) Multinational MONI\textsuperscript{t}oring of trends and determinants in CA\textsuperscript{r}diovascular disease (MONICA) Project, advances and improvements in acute coronary care as well as easy access to coronary revascularisation and thrombolysis in the acute phase have accounted for nearly two-thirds of the decline in CHD death rates.\textsuperscript{12-14} Inpatient mortality rates have also halved from 22\% in 1980 to 12\% in 2006.\textsuperscript{1}
In spite of improving mortality, morbidity due to CHD remains high and is one of the major causes of disability. In 2003, 49,800 events related to CHD were estimated to have occurred in Australia among those aged 40–90 years, with 57% of these events considered non-fatal.\(^1\) Approximately half of these people (49%) require assistance or have difficulties with self-care, mobility or communication, diminished quality of life, compromised functional abilities, and loss of productivity.\(^{15}\)

To a large extent, CHD is preventable, and over the last few decades there has been a substantial decline in death rates, mainly due to advances in treatment\(^1\) as well as secondary prevention strategies. The main underlying cause of CHD is atherothrombosis,\(^{16}\) a condition that forms abnormal deposits of fat, cholesterol and other substances in the inner lining of the arteries (plaque). The condition can become acute if the plaque ruptures and occludes the coronary arteries causing ischaemia.\(^{17}\)
1.4 Acute coronary syndrome

Acute coronary syndrome is an umbrella term for a broad range of clinical presentations, including ST-segment-elevation ACS (STEACS) and non-ST-segment-elevation ACS (NSTEACS).\(^{18,20}\) Despite the range of conditions that comprises ACS, the underlying pathophysiology of this syndrome includes coronary inflammation, rupture of epicardial plaque, coronary thrombosis and distal embolisation leading to myocardial ischaemia.\(^{20,21}\) Acute coronary syndrome represents one of the most common causes of acute medical admissions to Australian hospitals.\(^{20}\) It is estimated that the incidence has increased by 25\%, mainly due to the redefinition of AMI, which is a manifestation of CHD, to ACS.\(^{22}\) In addition, greater sensitivity of diagnostic markers, such as troponin,\(^{23}\) and increased screening have increased the morbidity rates.\(^{24}\)

Hospital discharge data from the United States of America (USA) indicates 1,680,000 unique discharges for ACS during 2001.\(^{25}\) In Australia, the Acute Coronary Syndrome Prospective Audit (ACACIA) was undertaken between November 2005 and May 2006 in 39 hospitals across all states and territories. The findings from this audit demonstrated that 3,402 patients were diagnosed with some form of ACS in the given period.\(^{19}\) Australia does not have a national heart disease register,\(^{26}\) however data obtained from the Western Australia Health Data Linkage System demonstrates that rates for coronary revascularisation procedures rose steeply from 1980 to 1993 following which they abruptly stabilised or started to decline.\(^{27}\) It is clear however that ACS accounts for more than 25,000 deaths each year in Australia, and an enormous burden of acute in-hospital clinical care and morbidity.\(^{18}\)

The morbidity and subsequent disability associated with ACS alone have extensive medical and socioeconomic implications. Acute coronary syndrome is a major contributor to the overall economic burden of CVD in Australia.\(^{18}\) Even after initial management, ACS continues to impose a significant financial burden on the health care system. Although the majority of the costs are associated with the initial ACS event, recurrence of events contributes significantly to health care utilisation.\(^{28}\) In a study involving 9,876 ACS patients, the mean 10-year discounted ACS inpatient medical costs were $AUD 45,253; $23,510 in the acute phase and $AUD 21,819 in
the post-acute phase. These findings indicate that the economic burden of CHD continues long after a patient's ACS event has resolved.\textsuperscript{28}

In Australia, the direct cost of CHD is the largest of any single cardiovascular condition, comprising $1.76 billion, or 28.6\%, of all costs associated with CVD.\textsuperscript{4} An estimated 39,000 coronary revascularisation procedures are performed each year.\textsuperscript{2} The cost of the procedure, together with the direct health costs associated with hospital stays, medications, medical personnel and health care facility charges, resulted in an estimated cost in 2004 of AUD$1.6 billion for CHD.\textsuperscript{4} In addition, indirect financial costs incurred due to lower employment, premature mortality, carer and other costs were estimated to be AUD$14.2 billion.\textsuperscript{4} Although the death rates from CHD will continue to decline, these costs have been projected to rise by up to 50\% by 2011 as the population ages.\textsuperscript{4}

In an attempt to mitigate the high mortality and associated treatment cost, extensive research has been undertaken and guidelines developed for the management of the ACS phase of CHD.\textsuperscript{20} The National Heart Foundation of Australia (NHFA) and the Cardiac Society of Australia and New Zealand (CSANZ) have developed data elements for monitoring clinical management of patients with ACS and incorporated these into the National Health Data Dictionary, the national standard for health data definitions in Australia.\textsuperscript{18} It is anticipated that use of these data elements will improve the quality of care provided to these patients.

1.4.1 Management of acute coronary syndromes

The treatment of ACS is dependent on clinical presentation and risk assessment. The goal of treatment includes either stabilisation of the plaque and prevention and reduction of myocardial ischaemia, or revascularisation of the culprit vessel to maintain sufficient myocardial perfusion, using either pharmacological means such as thrombolytic therapy or technical strategies such as coronary artery revascularisation procedures.\textsuperscript{20} The choice of treatment modality is primarily based on access and expertise. For example, if PCI is unable to be performed within a pre-specified window, thrombolytic therapy is favoured. The introduction and development of PCI has provided an alternative option to surgical revascularisation and medical management.\textsuperscript{29,30} Since 1997, PCI has replaced CABG as the most common revascularisation treatment for ACS in Australia.\textsuperscript{17} In contrast to the
previous decade, in 2001–02 there was a twofold increase in the number of PCI procedures (n=23,949), with stents inserted in over 90% and a 15% decline in CABG procedures (n=16,252). Since 1997–98, PCI has replaced CABG as the most common revascularisation treatment for ACS in Australia, as shown in Figure 1.2.

Figure 1.2 Incidence of revascularisation procedures


Data obtained from the ACACIA study demonstrated that the majority of the patients with ACS were treated with PCI compared to CABG. A pictorial depiction of the revascularisation technique used according to the categories of ACS is presented in Figure 1.3. The method of PCI is discussed below.

Figure 1.3 Revascularisation techniques according to categories of ACS
Percutaneous coronary interventions
A PCI involves inserting a catheter, carrying a balloon, through a peripheral artery into the coronary arteries, as shown in Figure 1.4. When the occlusion is encountered, the balloon in the catheter is inflated, which compresses the plaque against the arterial wall, re-establishing blood flow.\textsuperscript{30} Rather than promising to eliminate an atherosclerotic plaque, angioplasty proposes to render the plaque less prone to rupture by making it non-stenotic and thus unable to cause angina or ischaemia.\textsuperscript{31} In addition to the compression of plaque, another development is the deployment of intracoronary stents at the site of an atheromatous lesion.\textsuperscript{32} These stents hold down dissection flaps and provide mechanical support. They also reduce elastic recoil and vascular remodelling associated with restenosis and provide a wider and smoother coronary lumen than balloon angioplasty alone.\textsuperscript{33}

![Figure 1.4 Percutaneous coronary intervention procedure](http://www.medicinenet.com/coronary_angioplasty/article.htm)

**1.4.2 Management following acute coronary syndromes**
The primary aim of post-acute management of an ACS event is preventing recurrent cardiac events through risk factor modification and cardioprotective pharmacotherapy. Therefore, ongoing treatment with appropriate medications, including antiplatelet agent(s), β-blocker, angiotensin-converting enzyme (ACE) inhibitor, and statin, and other therapies as appropriate is imperative.\textsuperscript{20,34} Guidelines recommend that patients should be given advice on lifestyle changes that will reduce the risk of further ACS, including smoking cessation, regular physical activity, good
nutrition, moderate alcohol intake, and weight management, as appropriate.\textsuperscript{20,34} However, it should be noted that although alcohol restriction and weight management are important lifestyle behaviours to manage, evidence from RCTs to demonstrate that these changes lead to reduce cardiovascular event is limited. In addition, patients should be actively referred to comprehensive cardiac rehabilitation (CR) and secondary prevention programs.\textsuperscript{20,34}

Cardiac rehabilitation as defined by the WHO is "the sum of activities required to ensure patients the best possible physical, mental and social conditions so that they may resume and maintain as normal a place as possible in the community."\textsuperscript{35} The strong evidence base for CR means that this model of a secondary prevention intervention is recommended to people following acute coronary events and coronary revascularisation.\textsuperscript{34}

Despite the physical, psychological and social benefits obtained from CR, participation rates range from 10-30\%.\textsuperscript{36-42} This is due to the fact that CR services are traditionally delivered within a health facility environment, and are often seen by patients as exercise-focussed and protocol directed. In addition, participation in CR have additional associated costs relating to travel for the patients. This has compelled researchers to look at a range of alternate mechanisms.\textsuperscript{43,44} Adhering to prescribed medications and lifestyle modifications to reduce the risk factors associated with CHD is challenging because of the inherent complexities related to social, economic, self-management, medications and patient factors.\textsuperscript{45} In order to develop effective secondary prevention programs, it is important to appreciate the range of risk factors associated with CHD progression. These risk factors are discussed below.

\subsection{1.5 Coronary risk factors}
Risk factors are traits or health-related lifestyle behaviours that commonly precede chronic disorders associated with lifestyle factors, such as diabetes, CHD and lung disease, and increase the likelihood of the development of a disease or health disorder. Risk factors for CHD, which is the underlying cause of ACS, have been classified into behavioural and biomedical factors. The INTERHEART study, a large case-control study undertaken in 52 countries in approximately 30,000 patients with AMI (now classed as ACS), demonstrated that 90\% of MI cases could be attributed to nine risk factors.\textsuperscript{46} These include tobacco smoking,\textsuperscript{46} lack of daily exercise,\textsuperscript{46} an
abnormal ratio of blood lipids, \(^{46,47}\) high blood pressure, \(^{46,48}\) diabetes, \(^{46,49}\) abdominal obesity, \(^{46}\) stress, \(^{46}\) insufficient consumption of fruits and vegetables, \(^{46}\) and increased alcohol intake. These risk factors can be modified by improved lifestyle practices such as stopping smoking, increasing physical activity and decreasing saturated fats. The modifiable risk factors identified in the INTERHEART study play a major role in the development and progression of CHD, although other non-modifiable factors, such as socioeconomic status, genetic, environmental and societal factors, also contribute to the development of the disease.\(^1\)

Most of these risk factors are interrelated; for example, lack of physical activity and increased body weight. There is also substantial evidence of a relationship between the lack of physical activity and hypertension and diabetes.\(^50\) While each of the risk factors can individually contribute to CHD, the presence of multiple risk factors can accelerate the development of atherosclerosis and increase the risk of the disease.\(^51\)

For example, a person with mildly raised blood pressure (hypertension) and no other risk factors will be at a lower risk of a cardiovascular event than someone with mild hypertension and one or two other risk factors.\(^52\) In addition, people who have had a history of ACS or any other cardiovascular event have a greater than 20% risk, which is considered as high risk of further ACS episodes in 5 years.\(^53\)

Despite the technical and pharmacologic innovations for the management of ACS, the presence of the underlying risk factors contributing to the genesis and progression of CHD remains a significant problem. The failure to address the underlying biomedical and behavioural risk factors – namely hypercholesterolaemia (cholesterol level >4mmol/L), \(^{46,47}\) hypertension (blood pressure level >140/90), \(^{46,48}\) diabetes, \(^{46,54}\) smoking, physical inactivity and obesity\(^{46,55}\) – is associated with progression of coronary atherosclerosis, \(^{46,56}\) restenosis of the revascularised artery\(^{57,58}\) and diminished quality of life.\(^{46,59-61}\) While each of the risk factors can individually contribute to CHD, the presence of multiple risk factors can accelerate the development of atherosclerosis and increase the risk of the disease.\(^62\)

The Australian government, in collaboration with the NHFA and the CSANZ, has taken major steps towards secondary prevention of CHD. The publication titled “Reducing Risk in Heart Disease 2007. A summary guide for preventing
cardiovascular events in people with coronary heart disease” is an example of this initiative.34

Along with local, state and federal government initiatives, health-related behaviour modification and adherence to prescribed pharmacotherapy by individuals is also vital for reducing the risk of heart disease. Adjustment and lifestyle changes following an ACS event can sometimes be a long and arduous journey for the few that achieve risk factor control. Whilst some individuals are successful in adopting health-promoting behaviours following an ACS event, many fail to change their health-damaging behaviours. Risk perception alone is a poor predictor of behaviour change.63 Knowledge about the disease provides the means to increase health promotion behaviours and thus reduce the impact of risk factors.64

A comprehensive healthy lifestyle change along with cardioprotective pharmacotherapy has now become one of the main aspects for the long-term management of ACS patients.61,65,66 CR is an intervention that can reduce subsequent costs, mortality and modify risk factors for subsequent ACS events.67 While the benefits of CR programs have been demonstrated, participation in and adherence to these programs remain low,68-72 particularly among patients who have undergone revascularisation by PCI. In order to overcome poor participation rates, various models for delivery of CR programs have been trialled.43,44,73-78 However participation rates among certain groups of patients, particularly those who have had PCI, remain low.68 The lack of awareness of having to make the necessary health-related risk factor modification may be a contributing factor in this low participation rate. Given the increasing use of PCI as the treatment of choice for patients with ACS, it is vital that risk factor modification strategies tailored to this group of patients are developed. Health researchers are continuously looking for effective and cost-effective strategies that will enable risk factor modification as well as overcoming problems related to access, quality and cost of health care.

1.5.1 Smoking cessation

Tobacco smoking is the most significant independent risk factor for the progression of CHD.46 Several studies have provided evidence of the significant favourable effects of smoking cessation.79 The risk of mortality is reduced by about half one
year after cessation, then declines gradually. After around 15 years of abstinence, the risk of CHD is similar to that of never-smokers. A systematic review of cohort studies reported a 36% reduction in crude relative risk (RR) of mortality for those who quit smoking compared with those who continued to smoke (RR 0.64, 95% confidence interval (CI) 0.58 to 0.71). A reduction in non-fatal MIs (crude RR 0.68, 95% CI 0.57 to 0.82) and a rapid decrease in risk of ACS episodes and reduction in hospital readmissions of CHD patients following smoking cessation have been reported. Researchers have indicated that the relative risk of hospitalisation for ACS associated with smoking is reduced by half within the first year after the cessation of smoking. In addition, smoking cessation following the initial AMI reduces the odds of a second non-fatal event by 50% (p<0.01). Smoking cessation after an MI also reduces the risk of sudden death, silent ischaemia, arrhythmias, elevated plasma fibrinogen, coronary spasm and depression of high-density lipoprotein cholesterol (HDL-C). Patients who continue to smoke after coronary revascularisation following an ACS episode also have an increased risk of Q wave AMI and death and a diminished quality of life.

1.5.2 Physical activity

There is strong evidence to indicate that an inactive lifestyle doubles the risk of CHD and that participation in physical activity has cardio-protective benefits, resulting in a better prognosis for ACS survivors compared with their inactive counterparts. These cardio-protective benefits include decreased heart rate during exercise thereby increasing muscular oxygen uptake which ultimately reduces myocardial oxygen demand. In addition, improved physiological function and reduction in blood pressure among those with hypertension has also been reported in patients with CHD who are physically active. Participating in physical activity has also been reported to improve mental function and reduce stress, anxiety and depression. Physical inactivity is also indirectly linked to other risk factors, such as increased weight gain, blood pressure and serum low-density lipoprotein cholesterol (LDL-C) levels and decreased serum HDL-C levels. The NHFA recommends that people with established CHD should participate in at least 30 minutes of moderate intensity physical activity on most if not every day of the week.
1.5.3 Dietary modification

A number of studies have demonstrated the benefits of healthy foods, including low saturated fat diets and fruit and vegetables, on curtailing the progression of CHD. Numerous studies have demonstrated that dietary pattern, in particular dietary fat, is associated with a higher risk of CHD and overall mortality. It is no wonder that strategies for risk reduction in individuals and populations have focussed on healthy diets low in saturated fats and increased fruit and vegetable intake. There are contradictions in the literature about the benefits of low fat diets in reducing risk of CHD, with experts indicating that the risk reduction is due to changes in blood cholesterol levels. A systematic review of 27 randomised controlled trials (RCTs) undertaken to investigate the effect of change in dietary fat intake, which would be expected to result in a lowering of cholesterol concentration, demonstrated small but potentially important reductions in cardiovascular risk. There was also evidence of a benefit of alteration of dietary fat intake on total mortality. A reduction of 9% in cardiovascular mortality and 16% in cardiovascular events was observed.

Numerous cohort studies have demonstrated that fruit and vegetable consumption is inversely associated with the risk of CHD, although the causal mechanism of this association remains uncertain. A meta-analysis of 12 trials involving 278,459 people demonstrated that individuals who had less than 3 servings/day of fruit and vegetables had a 7% risk of CHD compared to those who had 3-5 servings/day (p=0.06) and a 17% risk compared to those with more than 5 servings/day (p<0.0001). This finding indicates that more than 5 servings/day of fruit and vegetables is associated with significant reduction in risk of further CHD events.

1.5.4 Obesity

Obesity has been identified as an independent risk factor for CHD. A common method for measurement of obesity is the body mass index (BMI). BMI is expressed as kilograms per metre squared, and is calculated from the individual’s height and weight. Individuals are classified as being overweight if their BMI > 25 kg/m². The predictive value of BMI for fatal CHD is mediated by the associated factors of increased blood pressure, cholesterol level, and physical inactivity, as harm...
associated with raised BMI takes more than a decade to become evident, in contrast to the classical CHD risk factors. Nevertheless, a recent meta-analysis of 21 trials including 302,296 participants and 18,000 CHD events demonstrated that a five-unit increment in BMI was associated with a 29% increased risk of CHD and, after additional adjustment for blood pressure and cholesterol levels, with a 16% increased risk.

Waist circumference has been postulated to have stronger associations with biomarkers of CHD than BMI. More recently the waist–hip ratio has been identified as the preferred measure of obesity for predicting cardiovascular disease. This finding is based on a large study that looked at BMI, waist-to-hip ratio, waist and hip measurements in more than 27,000 people from 52 countries. Waist-to-hip ratio was three times stronger than BMI in predicting the risk of a heart attack. Larger waist size, which reflects the amount of abdominal fat, was harmful, whereas larger hip size, which may indicate the amount of lower body muscle, was protective.

Reduction in obesity has beneficial effects on other coronary risk factors, including low levels of triglycerides, raised levels of HDL-C and lower arterial pressure. In addition, improvements in exercise capacity and insulin sensitivity have also been reported. A Cochrane review of 18 trials with 2,611 participants concluded that for overweight hypertensive patients, weight loss of 3% to 9% of body weight was associated with 3 mm Hg decreases in both systolic and diastolic blood pressure.

Given the risk of CHD associated with obesity, the NHFA recommends a waist measurement of less than or equal to 94 centimetres (cm) for males and less than or equal to 80cm for females and a BMI between 18.5-24.9 kg/m\(^2\).

Hyperlipidaemia, hypertension and dysglycaemia have all been identified as independent risk factors for CHD requiring pharmacotherapy, and the therapeutic rationale and therapies are discussed below. When developing secondary prevention programs it is impossible to consider pharmacotherapy in isolation from other behavioural therapies because, as often quoted, medications are only effective if people take them.
1.5.5 Hyperlipidaemia

There is strong evidence of a continuous relationship between total serum cholesterol and the risk of CHD.\textsuperscript{112,114} It has been well established that elevated concentration of low-density-lipoprotein cholesterol (LDL-C) plays a causal role in the development of CHD. In addition, a low serum level of high-density lipoprotein cholesterol (HDL-C) is an independent risk factor for an acute coronary event.\textsuperscript{112} Elevated triglyceride concentrations, usually in association with a reduced HDL-C concentration, is also related to increased CHD risk. The increased risk is attributed to the raised levels of LDL-C that accelerates atherogenesis which oxidises and reduces levels of cardio-protective HDL-C. The NHFA guidelines recommend a target total cholesterol level of less than 4.0 mmol/L, LDL-C of less than 2.5 mmol/L, HDL-C greater than 1 mmol/L and triglycerides less than 1.5 mmol/L.\textsuperscript{34}

Epidemiologic studies and recent long-term outcomes trials have demonstrated that lowering LDL-C levels significantly reduces the risk of major coronary events.\textsuperscript{115} RCTs have demonstrated that lipid-lowering therapy, namely statins, significantly reduces the risk of death or cardiovascular events in populations with or without a history of CHD, irrespective of initial lipid profiles. Statins inhibit cholesterol synthesis, resulting in increased LDL-C receptor activity, leading to improved clearance of LDL-C particles and precursors and increased HDL-C concentration.\textsuperscript{116}

Findings from a meta-analysis involving 14 RCTS undertaken on 90,056 participants demonstrated a statistically significant reduction in the 5-year incidence of major coronary events, coronary revascularisation and stroke by about one-fifth per mmol/L reduction in LDL-C, largely irrespective of the initial lipid profile among those randomised to statin therapy.\textsuperscript{117}

A more recent meta-analysis\textsuperscript{118} of RCTs that enrolled more than 1,000 patients with either stable CHD or ACS also demonstrated a significant benefit of intensive lipid lowering with high-dose statin therapy compared to standard-dose therapy for preventing predominantly non-fatal cardiovascular events. The meta-analysis included the four landmark trials: the TNT (Treating to New Targets), the IDEAL (Incremental Decrease in End Points Through Aggressive Lipid-Lowering), PROVE IT-TIMI-22 (Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction-22) and A-to-Z (Aggrastat-to-Zocor) trials. A
total of 27,548 patients were enrolled in the 4 large trials. The combined analysis yielded a significant 16% odds reduction in coronary death or MI (p < 0.00001), as well as a significant 16% odds reduction of coronary death or any cardiovascular event (p < 0.00001). Meta analysis of RCTS that have compared statins (including simvastatin, pravastatin, atorvastatin and fluvastatin) to placebo-for reduction in LDL-C have all concluded that statins reduce coronary events by about 25%–30% over 5 years of treatment.\textsuperscript{119-121}

Five trials, including the Scandinavian Simvastatin Survival Study (4S) Group (n=4,444 patients),\textsuperscript{122} the Heart Protection Study (HPS) (n=20,536 high-risk individuals),\textsuperscript{123} the Collaborative Atorvastatin Diabetes Study (CARDS) trial (n=2,838 patients with type 2 diabetes),\textsuperscript{124} the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER) (n=5804 patients aged 70-82 years),\textsuperscript{125} and the Long-term Intervention with Pravastatin in Ischemic Disease (LIPID) (n=9,000 CHD patients),\textsuperscript{126} demonstrated the efficacy of statins as secondary prevention against mortality from CHD in a broad range of initial cholesterol levels and in the presence of other major coronary risk factors such as hypertension or diabetes.

The Reversal of Atherosclerosis with Aggressive Lipid Lowering (REVERSAL) trial (n=654 CHD patients) demonstrated using intravascular ultrasound assessment technique that high-dose statins halted, or even regressed, progression of atherosclerotic disease.\textsuperscript{127} Likewise, the PROVE-IT trial (n=4126 patients with ACS)\textsuperscript{128} showed an incrementally better cardiovascular outcome overall, associated with a greater reduction in LDL-C concentration in high doses of statins. The PROVE IT–TIMI-22 (n=4,162)\textsuperscript{129} and the TNT (n=10,001)\textsuperscript{130} demonstrated that high-dose statins were more effective than standard-dose statins at reducing cardiovascular events. However, two trials, A-to-Z\textsuperscript{131} and IDEAL\textsuperscript{132}, had non-significant trends toward benefit of intensive statin therapy for their pre-specified primary end point, raising questions regarding the reliability of this observation.

Trials investigating the early use of statins have demonstrated a beneficial effect of early commencement of treatment. The Lescol Intervention Prevention Study (LIPS) undertaken in 1,677 patients demonstrated a significant reduction in the risk of cardiac events in patients started on statin therapy immediately following a successful PCI, independent of baseline cholesterol levels.\textsuperscript{133} Similarly, the
Myocardial Ischemia Reduction with Aggressive Cholesterol Lowering (MIRACL) trial demonstrated that initiation of statin within 24-96 hours after an ACS event successfully reduced recurrent ischaemic events in the following 16 weeks. The PROVE-IT–TIMI-22 study found that patients started on intensive statin treatment within ten days after admission with an ACS achieved lower LDL-C concentrations (1.6 mmol/l v 2.5 mmol/l) than those started on low-dose statin. In addition, there is now good evidence that patient compliance with statin treatment is improved if treatment is instituted during hospitalisation.

1.5.6 Blood pressure level

Hypertension is a common and independent risk factor for CHD which could lead to ACS. Blood pressure values that are above the optimal value but not within the hypertensive range also confer increased risk of ACS. It has been established that almost 30% of deaths from CHD with blood pressure as a contributing factor were in people who were not considered to be hypertensive but had a systolic BP of 120-139 mm Hg or a diastolic BP of 80-89 mm Hg. Therefore, reduction of BP to optimal levels, control of hypertension, and prevention of the age-related increase in BP remain vital to prevent further episodes of ACS.

Secondary prevention trials, such as the Heart Outcomes Prevention Evaluation (HOPE), European trial on reduction of cardiac events with Perindopril in stable coronary artery disease (EUROPA), and the second Australian National Blood Pressure Study (ANBP2), have demonstrated benefits of blood pressure reduction. The HOPE (n=9,297 CVD patients), ANBP2 (n= 6,083 patients) and EUROPA (n= 12,218 CHD patients) studies showed the benefits of ACE inhibitors in the reduction in mortality rates, MI, ACS, stroke, coronary revascularisation, cardiac arrest and heart failure, as well as the risk of diabetes and related complications itself in patients at high risk for cardiovascular events. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) (n=42,418) concluded that thiazide-type diuretics should be the initial treatment for high-risk patients as findings at 5-year follow-up demonstrated that 68.2% of patients achieved their goal blood pressure.

Non-pharmacological methods including reduced salt intake have been demonstrated to reduce high blood pressure. A systematic review of 11 RCTs involving 3,514
participants, with follow-up from six, demonstrated reduction in systolic BP by 1.1 mm Hg and diastolic BP by 0.6 mm Hg in participants with reduced sodium intake. In addition, people with low sodium intake were able to stop their anti-hypertensive medication more often, while maintaining similar blood pressure control.\textsuperscript{142}

### 1.5.7 Dysglycaemia

Dysglycaemia (impaired glucose tolerance) increases the risk of CHD\textsuperscript{113,143} by 2–4 fold.\textsuperscript{62} Even when the blood glucose level is within the normal range, an increase in cardiovascular risk is observed as the glucose increases.\textsuperscript{143} Independent of age, smoking, blood pressure, cholesterol, and occupation, mortality due to CHD for people with a 2-hour post-50-g glucose load of 5.4 mmol/L has been reported to be 1.5- to 2-fold.\textsuperscript{144} People with diabetes have an acceleration of atherosclerosis and atherothrombosis, which is related to endothelial dysfunction, dyslipidaemia, insulin resistance, and chronic hyperglycaemia. In addition, the presence of free fatty acids and glycosylation end products, assists with vasoconstriction, inflammation, and thrombosis.\textsuperscript{145} The in-hospital mortality rate in ACS patients with diabetes is approximately 10%.\textsuperscript{146} ACS survivors who have diabetes have a poor prognosis despite the various methods of coronary revascularisation. Poor prognosis is due to the complex metabolic milieu accompanying diabetes that alters blood rheology, the structure of arteries and disrupts the homeostatic functions of the endothelium.\textsuperscript{147} Therefore, following a coronary event the control of diabetes is vital to prevent further episodes of ACS.\textsuperscript{148}

While each of the risk factors described above are independent risk factors for CHD, the likelihood of coronary events is elevated with the presence of more than one risk factor. Failure to modify risk factors that contribute to ACS\textsuperscript{149} have been associated with disease progression in other coronary arteries\textsuperscript{150-152}, as well as increased risk of restenosis in coronary arteries that have been revascularised.\textsuperscript{153} Secondary prevention strategies, including medications and lifestyle changes to reduce risk factors, have become an important component in the management of patients following an episode of ACS. Given the effectiveness of medications in risk factor reduction, adherence to medications is vital to prevent further cardiac episodes. As lifestyle changes are now advocated as first-line therapy for most of the coronary risk factors, the World Health
Assembly in 2003 adopted the Global Strategy on Diet, Physical Activity, and Health, which targets lifestyle modifications that can combat the increase in CHD.\textsuperscript{154}

1.6 Problem statement
As discussed above, CHD remains the leading cardiovascular cause of mortality and morbidity globally and is responsible for high health care costs and disability.\textsuperscript{9,155} Following an acute coronary event, secondary prevention interventions include adherence to a range of pharmacological and non-pharmacological strategies. Although CR is recommended and highly efficacious, participation rates are low, for a range of system, patient and provider factors.\textsuperscript{39,42,156,157} This has compelled clinicians and researchers to explore innovative methods.

This thesis is premised on the assumption that secondary prevention strategies that are based on principles of chronic disease self-management and theories of behaviour change, (discussed in Chapter 2) and are structured and brief (discussed in Chapter 4) may empower people with CHD with the knowledge and skills to make the necessary lifestyle changes to prevent the recurrence of further acute events.

1.7 Study aims
The aims of this thesis were to:
1. Develop a health-related lifestyle self-management (HeLM) intervention for risk factor modification in patients following ACS, informed by an integrative literature review, assessment of risk factors and key informant consultation.
2. Evaluate the feasibility of the HeLM intervention in patients with ACS.

These aims were achieved by undertaking four discrete yet related studies, as described below.
Aim 1  To develop a health-related lifestyle self-management (HeLM) intervention for risk factor modification in patients with ACS

1.7.1 Study 1  Brief Interventions study

Review the best available evidence relating to brief interventions for risk factor modification in patients with CHD. This study was called the Brief Interventions study and is reported in Chapter 4.

1.7.2 Study 2  ICEBRG study

Assess current practice relating to implementation of the evidence-based guidelines titled “Reducing Risk in Heart Disease 2004. A summary guide for preventing cardiovascular events in people with coronary heart disease” (RRIHD) among CR coordinators. This study was called the Implementation of the Cardiac Evidence-Based Reducing risk in heart disease Guidelines (ICEBRG) study and is reported in Chapter 5.

1.7.3 Study 3  FACT study

Profile patients’ cardiac risk factor status, health-related quality of life (HRQoL), adherence to medications, knowledge relating to CHD and its risk factors and participation in CR programs 12-24 months following PCI. This study was called the Follow-up After Coronary Treatment (FACT) study and is reported in Chapter 6.

Aim 2  To evaluate the feasibility of the HeLM intervention in patients with ACS

1.7.4 Study 4  HeLM study

Undertake a RCT to evaluate the feasibility of an empirically derived intervention, tailored to the needs of patients with ACS. This was called the Health-related Lifestyle self-Management study as reported in Chapter 7.

The relationship of these activities is illustrated in Figure 1.5
Figure 1.5  Flow diagram of the study
1.8 Structure of the thesis

This thesis contains seven chapters and reports four studies, as shown in Figure 1.5, undertaken in a sequential mixed-method design. In order to increase clarity and cohesion for the reader, methodological issues are discussed within the chapter in which the study is reported. The specific contents of each chapter are listed below.

Chapter 1 provides the background to the burden of CHD and the importance of secondary prevention strategies. In addition, this chapter provides the broad aims and objectives of the thesis.

Chapter 2 presents a review of the published literature relating to risk factors and strategies for lifestyle modification including cardiac rehabilitation. In addition, the literature relating to chronic disease self-management is discussed.

Chapter 3 presents the conceptual framework for the study and the overarching research design that was used to achieve the study aims.

Chapter 4 presents the methods and findings of a systematic review of structured brief interventions on risk factor modification for patients with CHD.

Chapter 5 presents the methods and findings from an interview with CR coordinators across NSW to identify the barriers and facilitators to implementing the RRIHD guidelines developed by the NHFA.

Chapter 6 presents the methods and findings from an investigation of the long-term cardiac outcomes of patients following PCI.

Chapter 7 presents the evaluation of the feasibility of the evidence-based HeLM) intervention.

Chapter 8 presents an overall discussion and conclusion to the thesis.

1.9 Significance

Extensive changes are predicted in worldwide patterns of mortality and disability in 2020 compared with 1990, largely related to population ageing as well as increased incidence in low-income and lower-middle-income countries. Based on these projections, epidemiologists predict that CHD will remain the leading cause of death in developed countries. In addition, approximately 5.9% of disability adjusted
life years (DALYs) in 2020 will be attributable to CHD. These predictions have implications not only for individual patients but also for health care systems and society in terms of cost and burden of disease. Therefore, it is imperative that primary and secondary CHD preventive practices based on clearly defined evidence-based guidelines are implemented widely to decrease the associated premature disability and mortality, and lessen the impact on public health. This thesis is significant because it addresses the burden of CHD and applies an empirically-derived, novel solution to promote secondary prevention strategies in survivors of ACS. Further, this thesis has undertaken a series of studies describing the developing and testing of the feasibility of an evidence-based intervention for health-related lifestyle modification.

1.10 Conclusion

This chapter has described the burden of CHD, outlined the importance of cardiovascular risk factor modification and argued for undertaking research to explore novel interventions to effect positive behaviour change. The following chapter provides a discussion of the state of the science relating to secondary prevention programs and provides a background to the studies reported in subsequent chapters.
Chapter 2

Approaches to secondary prevention and behaviour change
2.1 Introduction
The previous chapter has presented the burden of CHD, cardiovascular risk and the aims and significance of the study. Secondary prevention is the attempt to prevent recurrence of disease\textsuperscript{160} and when commenced early also accelerates the recovery process. Within the context of the aims of this thesis, it means reducing the risk factors for an additional cardiovascular event in a person who has already had an episode of ACS, angina or coronary intervention procedure. Secondary prevention interventions for risk factor reduction include appropriate pharmacotherapy and lifestyle modification to eliminate risk factors, after treatment of the acute event.\textsuperscript{160} The RRIHD guideline\textsuperscript{34} recommends a comprehensive approach to secondary prevention that incorporates psychological, social and biomedical factors. When developing secondary prevention interventions, it is important to consider contextual issues such as the health care system, level of evidence for adopting this approach and key conceptual issues underpinning the model of intervention. This chapter seeks to review common theoretical models of behaviour change, evidence to date and the need to explore novel approaches of intervention.

2.2 Australia’s response to secondary prevention
There is extensive scientific evidence confirming that aggressive comprehensive risk factor management improves survival, reduces recurrent events and the need for interventional procedures, and improves quality of life for patients with CHD.\textsuperscript{161} Based on the evidence, guidelines and clinical recommendations have been developed to assist health care providers develop interventions to reduce recurrent cardiovascular events.\textsuperscript{34,161} In Australia, the Council of Australian Governments (COAG) has developed a new National Reform Agenda aimed at health promotion, prevention, and early intervention strategies and investment to reduce the incidence of chronic disease and risk factors, and improve overall health outcomes.\textsuperscript{162}

In addition, the CSANZ and the NHFA have developed the RRIHD evidence-based guidelines,\textsuperscript{34} which clearly describe the optimal targets for behavioural and biomedical risk factors as well as providing information for the medical and psychosocial management of the patient (Appendix 1). These guidelines also clearly
state that following ACS all patients should be actively referred to CR services for ongoing secondary prevention.

Secondary prevention involves appropriate pharmacotherapy and health-related behaviour change to eliminate risk factors, after treatment of the acute event. In the next section these two components are discussed.

2.3 Pharmacotherapy

The use of pharmacological therapies as described in Chapter 1 have been demonstrated in RCTs to be effective in the reduction of risk factors and prevention of restenosis of the treated vessel, and therefore the incidence of mortality and major acute coronary events (MACE) by curtailing the progression of CHD. In addition, pharmacological therapies also prevent restenosis of the treated vessel. The RRIHD guidelines recommend that patients admitted with ACS, unless contraindicated, receive antiplatelet agents, ACE inhibitors, angiotensin II receptor antagonists, beta-blockers, statins, anticoagulants and aldosterone antagonists for long-term management after ACS. Since the underlying cause of ACS is CHD, which is a chronic disease, the majority of these medications have to be continued long-term, often lifelong, therefore adherence to medication regimes is an important aspect in secondary prevention.

2.3.1 Challenges in adherence to medications

Despite compelling evidence about the effectiveness of medications in risk factor reduction, adherence to medications has been recognised as a major problem in patients with CHD. Adherence to medication regimes, described as the extent to which patients take medications as prescribed, is imperative to risk factor reduction. For example, adherence to lipid-lowering treatment is associated with lower risk of recurrent coronary events, while poor compliance with hypertension medications is associated with further episodes of ACS as well as other adverse health outcomes such as stroke and left ventricular hypertrophy. A large proportion of ACS patients become non-adherent at six months. Long-term adherence has been estimated to be between 40% to 70% for hypertensive medications and 37-80% for lipid-lowering medications. Among elderly patients with ACS, adherence to long-term lipid therapy was significantly higher
(40.1%) compared to patients with chronic CHD (36.1%).\textsuperscript{179} Adherence rates at 1-2 year follow-up for aspirin was 83\textsuperscript{177}-88\%,\textsuperscript{178,180} beta-blockers 61\textsuperscript{177}-78\%\textsuperscript{178} and 66\textsuperscript{180}-72\% for ACE inhibitors.\textsuperscript{178}

Rates of non-adherence with any long-term medication treatment vary from 17\% to 60\%, depending on the characteristics of the condition, the treatment, number of medications, the patient, and the setting.\textsuperscript{180,181} Significantly, non-adherence is highest when patients are symptom-free.\textsuperscript{181} This observation is of particular importance in patients with ACS, as many might not have had an MI and therefore do not consider themselves as patients with heart disease.\textsuperscript{182} Likewise, patients with ACS who have been treated with PCI may underestimate the significance of their condition as they have a short hospital stay and less pain, and return to work early.

Lack of adherence to medication results in suboptimal control of risk factors, leading to risk for further ACS events and increased hospital admissions,\textsuperscript{183-185} consequently resulting in increased financial burden on the health care system.\textsuperscript{168,184} It is therefore important that along with education about the illness and medications, interventions targeting behavioural changes to improve medication adherence and thus reduce risk factors are implemented.

### 2.4 Behaviour change

The risk factors described in Chapter 1 underscore the complexity of dealing with behaviour change. Following an acute coronary event, adjustment and lifestyle changes can sometimes be a long and difficult process for many individuals, with many failing to change their health-damaging lifestyles. Various factors have been identified that impact on behaviour change, such as the lack of knowledge\textsuperscript{186,187} and skills to successfully adopt healthy behaviours, and resistance to or the inability to change. A range of approaches, such as the chronic disease self-management, have been developed to address this issue from the perspective of the individual, the health professional and the system. Chronic disease self-management is defined as a “system of coordinated healthcare interventions and communications for populations with long-term conditions in which patient self-care is significant”.\textsuperscript{188} pp. 1
2.4.1 Improving self-management and health behaviour

The increasing burden of chronic disease has compelled researchers and policy makers to consider the approaches varying approaches including disease specific versus generic self management programs and health professional led versus lay led programs. In spite of these emerging trends, one cannot deny the substantial evidence for CR and associated models. 189

Effective self-management following an acute coronary event to prevent the occurrence of another requires not only the knowledge of strategies for risk factor modification, but also commitment and skills to modify behaviour, and problem-solving skills to manage barriers to change and relapse. These skills acquired in self-management are known to complement medical therapy and rehabilitation. Successful self-management and positive changes in health behaviour can be obtained by implementing interventions based on an understanding of human behaviour and motivators for change. Various theories and models to understand self-management attitudes and health behaviour have been developed, tested in clinical research, and found to be useful for predicting health behaviours. Theory-driven interventions, especially those based on social learning and behavioural theories, 190 have been reported to be more successful than those that are not. 101,191,192

2.4.2 Theoretical underpinnings to address behaviour change

A range of theoretical perspectives have been developed to inform the theory of behaviour change. These include the Health Belief Model, 193 the Theory of Reasoned Action, 194 Social Cognitive Theory, 195 and the Transtheoretical Model (TTM). 196 The fundamental constructs underlying these theories, as applied to chronic condition self-management, are similar and applicable to CHD. These constructs include: (1) skills for illness management are learnt and behaviour is self-directed; (2) success of self-management is dependent on the individual’s motivation, confidence and self-efficacy; (3) the individual’s social environment can either support or hinder self-management; and (4) monitoring and responding to changes in disease state, symptoms, emotions and function improve adaptation to the chronic condition. It is not the aim of this thesis to describe each of the theories on which self-management
support models are based; therefore, the commonly used theories have been summarised in Table 2.1. 197

Table 2.1 Constructs of commonly used self-management theories 197

<table>
<thead>
<tr>
<th>Constructs</th>
<th>Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health Belief Model</strong></td>
<td></td>
</tr>
<tr>
<td>Perceived susceptibility</td>
<td>the belief that one has the chance of getting a condition</td>
</tr>
<tr>
<td>Perceived severity</td>
<td>the belief that a health problem is serious</td>
</tr>
<tr>
<td>Perceived benefit</td>
<td>the belief that changing one's behaviour will reduce risk or moderate the impact of the condition</td>
</tr>
<tr>
<td>Perceived barriers</td>
<td>a perception of the obstacles to changing one's behaviour</td>
</tr>
<tr>
<td>Cues to action</td>
<td>events or strategies that increase one’s motivation</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>confidence in one’s ability to take action</td>
</tr>
<tr>
<td><strong>Theory of Reasoned Action</strong></td>
<td></td>
</tr>
<tr>
<td>Behavioural Intention</td>
<td>perceived likelihood of performing the behaviour</td>
</tr>
<tr>
<td>Attitudes</td>
<td>degree to which the person has a favourable or unfavourable evaluation of the behaviour in question</td>
</tr>
<tr>
<td>Behavioural Belief</td>
<td>evaluation of the likelihood that performance of the behaviour is associated with certain outcomes</td>
</tr>
<tr>
<td>Evaluation of Behavioural Belief</td>
<td>assessment of the outcomes</td>
</tr>
<tr>
<td>Subjective Norm</td>
<td>influence of social pressure along with the individual’s motivation to comply with those perceived expectations</td>
</tr>
<tr>
<td>Normative Belief</td>
<td>influence of social pressure that is perceived by the individual</td>
</tr>
<tr>
<td>Motivation to Comply</td>
<td>motivation to do what each personal contact person wants</td>
</tr>
<tr>
<td>Perceived Behavioural Control</td>
<td>the degree to which an individual feels that performance or non-performance of the behaviour is under his or her control</td>
</tr>
<tr>
<td>Control Belief</td>
<td>perceived likelihood of each facilitating or constraining condition occurring</td>
</tr>
<tr>
<td>Perceived Power</td>
<td>perceived effect of each condition in making the performance of the behaviour easier or more difficult</td>
</tr>
<tr>
<td><strong>Social Cognitive theory (previously called Social Learning theory)</strong></td>
<td></td>
</tr>
<tr>
<td>Environmental</td>
<td>factors outside the person</td>
</tr>
<tr>
<td>Situation</td>
<td>individual’s perception of the environment</td>
</tr>
<tr>
<td>Behavioural Capability</td>
<td>for change to occur, the individual must have the knowledge and skills</td>
</tr>
<tr>
<td>Expectations</td>
<td>individual’s anticipation of the outcomes of a behaviour</td>
</tr>
<tr>
<td>Expectancies</td>
<td>value the individual places on the expected result. If the result is important, the behaviour change is more likely to happen</td>
</tr>
<tr>
<td>Self-control</td>
<td>regulation of one’s own behaviour</td>
</tr>
<tr>
<td>Observational Learning</td>
<td>watching someone else perform a behaviour and observing the outcomes</td>
</tr>
<tr>
<td>Reinforcements</td>
<td>reinforcements are either positive or negative consequences of behaviour</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>belief in one's ability to successfully change one's behaviour</td>
</tr>
<tr>
<td>Emotional Coping Responses</td>
<td>strategies used by someone to deal with emotionally challenging thoughts, events, or experiences</td>
</tr>
<tr>
<td>Reciprocal Determinism</td>
<td>dynamic interaction of the person, the behaviour, and his/her environment</td>
</tr>
</tbody>
</table>
Central to this thesis is promoting health-related lifestyle change, which, although complex, is the most effective way to minimise the health burdens of many chronic conditions.\textsuperscript{198} Due to the complexity of health behaviour, some theorists have developed models that include constructs from a number of theories to help understand a specific problem in a particular setting or context. One such model that has been applied to chronic disease self-management\textsuperscript{199} is the transtheoretical model of change, which formed the theoretical basis for the HeLM intervention. The association between the TTM, chronic disease management and the stated problem of health-related risk factor modification is that they all focus on the decision-making by the individual with the illness.

**The Transtheoretical model**

Adoption of health-promoting behaviours is greatly dependent on the patient’s motivation, readiness to change existing risk factor related behaviour, and self-efficacy.\textsuperscript{200,201} The TTM has four dimensions: stages, processes, decisional balance and self-efficacy. Prochaska, Redding and Evers\textsuperscript{196} have indicated that in the process of adopting health-promoting behaviours that reduce the risk of a further coronary event, such as smoking cessation or participation in physical activity, people generally go through several different stages before a new behaviour becomes a habit. The TTM acknowledges that in the process of change, people are not all at the same stage of readiness and some individuals can relapse to a previous stage several times before reaching the final stage of behaviour modification.\textsuperscript{202} Behaviour change is therefore recognised as a continuum rather than a discrete event\textsuperscript{202,203} (Figure 2.1).
According to the TTM, an individual’s willingness to adopt health-promoting behaviours to reduce coronary risk factors aligns with one of the five stages of readiness for change:196,204

**Pre contemplation** patients are not considering changing behaviours that can have a positive outcome on their health, e.g. patients are not eating a low-saturated fat diet, not currently exercising, or are smokers and they are not seriously considering changing their behaviour;

**Contemplation** patients are considering changing their behaviour but are not confident they will do so within the next month;

**Preparation** patients combine intention to change and behavioural efforts and are confident they will make changes within the next month;

**Action** patients have changed their behaviour within the past six months, however they are at high-risk of relapsing because habits are not yet established;

**Maintenance** patients have maintained the change for at least six months. This stage requires motivation and skills to prevent relapse.
Relapse During the process of making changes to lifestyle most people experience relapse. They cycle through the various stages several times before achieving a stable life style change. Therefore, the Stages of Change Model considers relapse as a normal process when making lifestyle changes. Overcoming this stage requires the individual to analyse how the slip happened and use it as an opportunity to learn how to anticipate high-risk situations more effectively, control environmental cues that tempt them to engage in their bad habits and learn how to handle unexpected episodes of stress without returning to the bad habit.

Progression from one stage to another involves decisional balance, deliberating processes of change and self-efficacy. Decisional balance requires the individual to weigh the positive and negative aspects of a risk-related behaviour. According to the TTM, personal discomfort, associated with the risk-related behaviour, may lead to behaviour change. If the consequences of the risk-related behaviour outweigh the benefits, individuals experience less ambivalence and are more likely to take action to change the behaviour.

Processes of change are the activities that people use to progress through the stages. These processes involve experiential and behavioural activities. The experiential activities include consciousness raising (increasing awareness), dramatic relief (emotional arousal), environmental reevaluation (social reappraisal), social liberation (environmental opportunities) and self-reevaluation (self-reappraisal). The behavioural processes include stimulus control (reengineering), helping relationship (supporting), counter conditioning (substituting), reinforcement management (rewarding), and self-liberation (committing).

Self-efficacy involves the confidence of the individual in their ability to change to healthy behaviours. It also evaluates the individual’s capacity to relapse when faced with high-risk situations. Researchers have reported that strategies tailored to the individual’s stage of change have produced improved outcomes. Recent trials undertaken to assess the effect of stage-based intervention have reported statistically significant improvements in self-care and diabetes control, fruit and vegetable intake and adherence to medications. In spite of this, criticisms of the TTM have been reported, such as the use of arbitrary dividing lines in order to differentiate between the stages, classifying individuals and assuming that they make coherent and stable plans. These criticisms may in part reflect the application of the TTM. To date, the TTM...
remains the only model that incorporates constructs from other theories and is dedicated to studying entire populations, particularly unmotivated individuals who need the most assistance,\textsuperscript{216} such as those patients who would not attend traditional CR programs. Therefore it is considered that this model has applicability to this thesis.

The TTM, through its various stages, provides a model for health professionals to understand the reasons why people do not change.\textsuperscript{217} It also assists them in delivering programs targeted at particular stages of change or for enabling individuals to progress through the different stages.\textsuperscript{197} Even where there is good initial compliance to a health-related behaviour change, a relapse to previous behaviour patterns is very common. Undertaking and maintaining a behaviour change, requires different types of programs and self-management strategies. Intervention strategies directed at behavioural and attitudinal change produce greater results than traditional educational approaches to health promotion, particularly when tailored to the individual’s readiness to change.\textsuperscript{202} The TTM is well-suited to developing tailored interventions based on individualised assessments along with other strategies for behaviour change. The evidence-based guidelines developed by the NHFA and CSANZ clearly indicate that a behavioural change assessment, based on the TTM, is a recommended component for lifestyle and risk factor management.\textsuperscript{54}

\section*{2.5 Approaches to patient empowerment in chronic disease}

The evidence from the literature is strongly indicative of risk factor reduction in patients with ACS to prevent the occurrence of further acute events. In response to the emerging epidemic of CHD, barriers to participation in CR, lack of funding for traditional CR programs\textsuperscript{218,219} and the inability of the health system to deal with this significant health problem, a shift to more contemporary patient-centred approaches is warranted. This is where CHD is seen as a biopsychosocial condition rather than as simply a physical illness. Therefore, following the initial treatment for ACS, long-term management of the underlying CHD has been identified as a national priority area for chronic disease self-management.\textsuperscript{220} Evidence of the benefits of chronic disease self-management programs have been reported in patients with CHD, relating to improvements in processes of care, quality of life and functional status, and
reduction in admissions to hospital. The main characteristics of effective self-management programs are those that have been based on social learning and behavioural theories. These models have also included: collaborative problem between individual, carers and health professionals; goal setting and care planning; a continuum of self-management training and support services; and active and sustained follow-up initiated by the health professional.

Difficulty in achieving and maintaining lifestyle changes following an acute coronary event has been well-established. However, with appropriate tools, skills and support from health care professionals, patients can make changes that reduce their risk of further coronary events. From evidence to date, it is clear that knowledge alone is not sufficient to drive behaviour change strategies, therefore clinicians and researchers continually strive to develop novel models of interventions to improve secondary prevention. It is increasingly apparent that a systems-based approach is necessary. Much of this approach is based upon the work of Wagner et al who advocates considering systems, patients, and provider issues in planning and implementing care.

2.5.1 Chronic disease self-management

As discussed in Chapter 1, there is a burgeoning incidence of chronic conditions, particularly CHD. Of the total disease burden in Australia, chronic disease is expected to increase from 70-80% by 2020 and has therefore been identified as a national priority area. Coronary heart disease and the disability associated with it are proving to be among the greatest health challenges both in Australia and globally in terms of resources and financial costs.

Promoting self-management has provided the impetus for this study. The chronic disease self-management (CDSM) framework was selected as a useful framework because ACS reflects the spectrum of CHD resulting in acute myocardial ischaemia. Although ACS maybe treated in hospital with revascularisation, the underlying CHD pathology of atherosclerosis that caused the acute event is a long-term process and continues to remain a chronic problem. Therefore, the Australian Institute of Health and Welfare (AIHW) have included CHD in their list of chronic diseases.

Four crucial approaches to chronic disease management, including prevention, early detection and treatment, continuation of prevention and care, and self-management,
have been identified in the National Chronic Disease Strategy, which is an initiative of the Australian government.226

Self-management, derived from social-cognitive theory and the concept of self-efficacy,227 is not a new concept and is a term that has been used extensively to describe patient education, patient behaviours, and health promotion programs.228

Self-management is a holistic approach that acknowledges the medical and psychosocial components of a condition229 and therefore involves a collaborative relationship between the individual with the disease, their families and health professionals.230 Self-management involves support from health care professionals to enable people to make informed choices, adopt healthy behaviours and develop problem-solving skills.231 Self-management empowers individuals with chronic disease to be more proactive in managing their illness and take more control of their lives through changing existing behaviours to incorporate more health-enhancing behaviours, effective communication, shared decision-making and improved knowledge and skills.232 In recent times, the role of self-management in chronic care has gained significant support and is now widely recognised as a necessary part of effective chronic disease management. Therefore, the National Chronic Disease Strategy has recommended the integration and support of self-management programs at all entry points into the health care system.1

**Factors impacting on self-management**

For people treated for ACS, self-management involves engaging in coronary risk reduction behaviours to prevent recurrence of the acute episode, adhering to medication regimes, being proactive in monitoring and managing symptoms and signs of illness, and managing the impact of illness on functioning, emotions and interpersonal relationships.233

It has been well established that clinicians traditionally rely on "informational power" (health-related information) and their "expert power" (professional status) to facilitate patients to modify their behaviour.234 Knowledge about the disease provides the means to increase health-promotive behaviours and to decrease the impact of risk factors.64,186 However behaviour change does not result from increasing knowledge alone.191 Risk perception alone is a poor predictor of behaviour change.63 Other contextual factors that influence an individual’s behaviour change include cognitive,
sociocultural and environmental factors and expectations, educational factors and age. In addition, adoption of healthy behaviours and the degree to which individuals self-manage depends greatly on their capacity, motivation and circumstance. Therefore, changing health-related behaviours requires two separate processes that involve motivation and volition respectively. For that reason, it is vital that the choice of behaviour change activities for individuals following an acute coronary event extends beyond conventional communication and includes self-management support such as skills training, health systems support, evidence-based information and policies and empowerment of the individual.

For some individuals with CHD, especially the elderly and those with more chronic health conditions, self-management is a lifetime task and remains challenging. Therefore, critical aspects for improving health outcomes and quality of life include strengthening and supporting self-management by collaboratively helping patients and their families acquire the skills and confidence to manage their chronic illness, providing self-management tools, and routinely assessing problems and accomplishments.

2.5.2 Program models

Self-management strategies have been implemented with varying success rates. Examples of these self-management strategies include generic models, cardiac specific models and bibliotherapy. The generic models include the Stanford University CDSM program, the Flinders Model of Chronic Condition Self-Management, and the Australian Government Sharing Health Care Initiative. Cardiac specific models include the Coaching patients On Achieving Cardiovascular Health (COACH) program, and traditional and contemporary CR programs including those that use telemonitoring (standard telephones, internet and mobile phones).

The Stanford CDSM model

This self-management model was developed by the researchers at Stanford University and was based on Bandura’s theory of self-efficacy. The Stanford program was originally developed for arthritis, and has since been modified for people with a range of chronic conditions. The Stanford CDSM program is a group-based six week course, facilitated by lay leaders or health professionals.
meetings are highly interactive, focussing on increasing knowledge and building core skills that are the fundamentals of self-management programs, including problem-solving skills, decision-making, sharing experiences, forming a patient-health care provider partnership and taking action and support.247 A key feature of the model is the teaching strategies that enhance self-efficacy.248

Findings from studies that have used this model indicate that the individuals’ change in health status resulted from enhanced self-efficacy experienced by participants of self-management programs.248 In Australia, Stanford CDSM self-management is widely used in Arthritis agencies and training to deliver the Stanford CDSM course is provided under licence to Stanford Education Centre, California.

The Flinders Model
This self-management model, developed at the Flinders University Adelaide, teaches health care providers the skills to promote patient self-management based on a collaborative, motivational counselling framework.249 The aim of this model is to link the general practitioner (GP), other health professionals and their patients with community delivered self-management education programs. The course offers health care providers a structured interview format and written tools to assess self-management behaviours and personal barriers to self-care among individual patients.249 The Flinders Model has been trialled in patients with diabetes and chronic pulmonary disease. The findings at 12-month follow-up demonstrated significant improvements from baseline in self-management ratings,249 HbA1c,249 quality of life250 and exercise tolerance.251 However, it should be noted that these findings are based largely on descriptive reports and one pilot study involving 38 participants.

The Australian Government Sharing Health Care Initiative
The Australian Government Sharing Health Care Initiative220 includes the Stanford University CDSM program, stages of change model and telephone coaching for chronic disease self-management education. Evaluation of this initiative has demonstrated that educational interventions using flexible methods for both program content and delivery have the greatest health impact compared to those that are not flexible.220
Strengths and Limitations of generic chronic disease self-management programs

Although the potential to adopt a generic approach is appealing, particularly in the elderly who have multiple conditions, and despite encouraging results from participants in the trials, the three models described above have not provided convincing evidence of the generalisability of the program, given that women and ethnic groups were greatly under-represented in most studies. Extensive debate and tension exist between disease-specific and generic models of interventions. An example of a disease-specific approach is discussed below. Yet it is important to note that if interventions are conceptually sound it is likely that they can be extrapolated to other chronic conditions with modification of the content.

Coaching patients On Achieving Cardiovascular Health (COACH) – example of a disease-specific model

The COACH program which is a self-management training program that is empowering and monitors patients with CHD has been recently adopted for patients with chronic obstructive pulmonary disease. In the program, a health professional coaches patients to aggressively pursue the target levels for their particular coronary risk factors while working in partnership with their GP. Regular coaching sessions are provided to patients using the telephone and mail following discharge from hospital. Coaching requires a median time of 30 minutes for the first session and 20 minutes thereafter. Prior to commencement of the coaching sessions, the coach determines the patients' knowledge of their risk factors, the targets for their risk factors, their knowledge and practice of lifestyle measures and drug treatment, and provides appropriate information. The coach urges the patient to make appropriate requests for treatment from their own doctor.

Evaluation of this self-management model in 792 patients from 6 university teaching hospitals demonstrated that coaching was significantly better than usual care in lowering total cholesterol (TC), LDL cholesterol, blood pressure, and body weight, reducing dietary intake of total fat, saturated fat and cholesterol, increasing regular walking habits, reducing patient anxiety and cardiac symptoms, and improving quality of life. Detailed results from this study are presented in Appendix 8.
However, this study has some limitations that may impact on the findings. The patients’ readiness to change was not assessed at baseline, therefore it could be assumed that the participants were all motivated to adopt healthy behaviour, which is a common attribute of trial participants.\textsuperscript{252} Secondly, the success of the coaching program is highly dependent on the qualities of a good coach, which include assertiveness, initiative in working with patients to achieve their risk factor targets, excellent problem-solving skills, excellent written and verbal communication, computer skills, organisational skills, commitment to improving performance, the ability to work autonomously, and flexibility in working hours. The absence of these qualities could result in failure of the program. In addition, the absence of a behavioural or social learning model for coaching indicates an authoritarian technique for risk factor modification.

2.6 Evidence of self-management programs in people with CHD

In people following ACS, the aim of self-management programs is to assist with recovery from the acute event, revascularisation procedure, prevent cardiac events and manage angina in the long term. This is achieved through education about lifestyle modification and risk factor reduction, monitoring of coronary risk factors, and psychosocial support.\textsuperscript{253} Empowering the individual will increase their confidence to resume an active, productive life and includes the promotion of behaviours that reduce the risk of further events.\textsuperscript{191,254}

The evidence surrounding the benefits of self-management for a number of chronic conditions has been well established.\textsuperscript{241,242,246,255} These benefits include significant improvements in health-related behaviours (e.g. increases in physical activity), an active and emotionally satisfying life due to symptom reduction, improved communication with physicians, reduced health care utilisation and increased self-efficacy.\textsuperscript{241,242,246,255} However, these findings are mainly from studies on self-management concentrating on asthma, arthritis, heart failure or diabetes.\textsuperscript{228} Limited literature has focussed upon benefits of self-management for people with CHD.
2.6.1 Bibliotherapy

Various health-related publications for behaviour modification and self-management have been published.\textsuperscript{256-261} However, the effect of generic health publications on risk factor modification remains poor. Tailored health messages are therefore becoming increasingly common in risk factor modification and self-management strategies.\textsuperscript{262} Tailored communication is a combination of strategies and information that is intended to target a specific person rather than a population.\textsuperscript{263} The tailored communication is unique to the individual and based on the needs of the person following assessment of risk factors and risk-related behaviours.\textsuperscript{263} A systematic review of 56 published studies indicated that tailored interventions are effective in motivating health behaviour change of small magnitude.\textsuperscript{262}

Each of these self-management strategies applies similar principles: identifying the individual’s main problems, assessing and reviewing their health status and risks, collaborative goal and priority setting relating to their problems or risks,\textsuperscript{232} providing self-management interventions using behaviour theory to support the required behaviour and providing ongoing monitoring, review and feedback on progress.\textsuperscript{264}

2.7 Evidence for disease management approaches

The theoretical perspectives described above have informed a range of secondary prevention interventions. A range of interventions have been implemented to reduce the incidence of risk factors among patients following an acute coronary event. These lifestyle modification strategies either focus on single or multiple risk factors; for example, the lifestyle and pharmacotherapy for obesity trial.\textsuperscript{265}

Many of the trials have been incorporated in a number of systematic reviews. Systematic reviews are useful because they summarise the best available evidence based on predetermined criteria. An explanation of systematic reviews is presented in chapter 4. A systematic review of 12 RCTs with 9,803 patients\textsuperscript{266} was undertaken to determine whether multidisciplinary disease management programs for patients with CHD improved processes of care and reduced morbidity and mortality. Studies included in this review were those that evaluated interventions that were comprehensive disease management systems, had more than 50% patients with CHD, had a sample size of more than 50 participants and reported outcomes for
patients with CHD separately. Studies that evaluated single modality interventions (such as exercise programs or telephone follow-up), tested inpatient interventions, or enrolled fewer than 50 participants, were excluded. In all trials, patients randomised to the control groups received usual care which was generally not defined.

The findings demonstrated that disease self-management programs improved processes of care, reduced admissions to hospital, and enhanced quality of life or functional status in patients with CHD. A detailed description of the findings is presented in Table 2.2. Although this systematic review demonstrates the benefits of chronic disease management programs, these results should be interpreted with caution, mainly because of the small number of trials with small sample sizes and the poor reporting of the specific elements of the intervention in many of the trials.

A further systematic review included five RCTs published after 1994 that involved CDSM interventions in 1,033 adults over 18 years for CHD. The participants in these five studies were patients recruited from hospital or medical clinics. Four of the five studies were group-based programs of four to eight weeks’ duration. The fifth study was an individual and telephone-based cognitive-behavioural counselling intervention. Four studies also included social support, two included stress management, and one included CR as part of the intervention. The control groups in all five studies received usual care which consisted of either verbal or written information.

The findings demonstrated that CDSM interventions reduced health service usage, enhanced quality of life, and improved physical activity status and symptoms of angina in patients with CHD. Although all the publications included were RCTs, the findings from this systematic review should be interpreted with caution. Firstly, there was less than 60% uptake among eligible individuals in two trials; and secondly, the studies were insufficiently powered to compare differences in events.

The evidence from these two systematic reviews, however, demonstrates that self-efficacy, which is the strength of belief in one’s capability, is an important mechanism responsible for changing and maintaining healthy behaviours. Therefore, self-management programs should include strategies for enhancement of self-efficacy to increase the patient's sense of mastery and confidence in managing their chronic condition.
Table 2.2  Evidence from systematic review of CDSM interventions

<table>
<thead>
<tr>
<th>Author</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>MacAlister 266</td>
<td>No significant difference in reinfarction rate between groups 1/10 trials demonstrated a significant survival benefit * 2/6 trials reported a significant reduction in readmissions to hospital * 2/4 trials showed shorter lengths of hospital stay * 5/7 trials showed significantly greater improvements in cardiovascular risk factors * Patients were more likely to be prescribed lipid-lowering drugs, beta-blockers and antiplatelet agents * 5/8 trials had better outcomes relating to quality of life or functional status 2/3 trials demonstrated cost savings *</td>
</tr>
<tr>
<td>Shaw 228</td>
<td>Decrease in service use for heart-related hospital admissions (p&lt;0.05) and inpatient days (p=0.02) * (n=3 trials) No difference in self-reported health usage Decrease in lower mean number of CHD outpatient appointments All 5 trials reported improvements in quality of life; however, the findings were statistically significant in only 3 4 trials reported statistically significant improvements in physical activity 3/5 trials reported improvements in the number, frequency, severity, and “bothersomeness” of angina symptoms and physical functioning, and a reduction in the use of nitrates</td>
</tr>
</tbody>
</table>

*benefit among patients in the intervention group

Although a range of secondary prevention strategies have been described above, a specific discussion of cardiac rehabilitation is warranted for a number of reasons. Firstly, the evidence of the effectiveness of CR, and secondly, this model of intervention is strongly advocated within the context of the Australian health care system. In addition, it is useful to consider the limitations of this model of intervention before developing novel or hybrid models.
2.8 Cardiac Rehabilitation

The RRIHD guidelines recommend that all patients following ACS are actively referred to CR for secondary prevention. Cardiac rehabilitation is an organised evidence-based approach that can reduce mortality and modify risk factors for subsequent coronary events and cardiovascular disease. Cardiac rehabilitation describes “all measures used to help people with heart disease return to an active and satisfying life and to prevent recurrence of cardiac events”. Contemporary CR programs are multifactorial and include patient education and advice relating to risk factors, lifestyle modification, relaxation, drug therapy, and psychosocial counselling. This shift from older programs that were mainly exercise-focussed to promote cardiac reconditioning is primarily due to the advancement in technology that has prevented prolonged bed rest and subsequent physical deconditioning. In addition, contemporary CR programs complement the support and individual medical care given by specialists and GPs in an attempt to reduce subsequent morbidity and mortality due to cardiovascular illness and enhance the psychosocial and vocational status of patients.

2.8.1 Benefits of participation in CR

Improved survival

Comprehensive multifactorial CR programs have been reported to slow the progression of CHD, leading to reduction in the incidence of ACS. In addition, there is extensive scientific literature supporting the value of CR in improving life expectancy by 0.202 years during a 15-year period, mortality and morbidity, including recurrent MI, quality of life and decreasing cardiac risk factor burden, compared to non-CR participants.

Much of the evidence that supports the benefit of CR programs is based on trials that focussed primarily on supervised exercise-based CR. For example, findings from a recent systematic review of 48 RCTs (8,940 patients) that investigated the effectiveness of exercise-based CR programs in patients with CHD demonstrated that compared with usual care, CR was associated with a 20% reduction in all-cause mortality and 26% reduction in cardiac mortality among patients who participated in
exercise-based CR compared to usual care. The effect of CR on total mortality was independent of CHD diagnosis, type of CR, dose of exercise intervention, length of follow-up, trial quality, and trial publication date.\textsuperscript{278}

An Australian cohort study based on data linkage has demonstrated that CR attendees had a 35\% improvement in 5-year survival.\textsuperscript{219} This reduction in mortality is also attributed to the extensive advances in technology, surgical and medical management over the decades for patients with CHD.

**Comparison between CR programs with and without exercise components on mortality and morbidity**

Contemporary CR programs are not restricted to supervised exercise but include patient education and advice relating to risk factors, relaxation, drug therapy, and psychosocial counselling.\textsuperscript{272-275,284,285} Therefore, identifying the effect of different contemporary CR programs, particularly those with and without a structured exercise component, is vital for developing interventions for secondary prevention.

A systematic review of 63 randomised trials\textsuperscript{189} involving 21,295 patients with CHD was undertaken to assess the effect of CR programs with and without exercise components on mortality and morbidity. Twenty-four trials in this review included risk factor education or counselling along with a structured exercise component, 23 trials included risk factor education or counselling along without a structured exercise component, and 17 trials involved only a supervised exercise program. The findings from this systematic review demonstrated that overall there was a 15\% reduction in all-cause mortality and that the risk reduced by up to 50\% after two years.\textsuperscript{189} A subgroup analysis revealed that for all-cause mortality there was a 13\% risk reduction in programs without exercise, 12\% risk reduction in programs with exercise and 28\% risk reduction in programs with structured exercise programs alone (Table 2.3). Results from the systematic review also indicated that overall there was a 17\% risk reduction relating to MI at one year follow-up. A subgroup analysis revealed a 14\%, 38\%, and 24\% risk reduction relating to MI in programs without exercise, programs with exercise and in programs with structured exercise programs alone, respectively (Table 2.3).
Table 2.3 All-cause mortality and MI in trials evaluating secondary prevention programs

<table>
<thead>
<tr>
<th>Type of CR</th>
<th>Mortality</th>
<th>MI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relative risk</td>
<td>95% CI</td>
</tr>
<tr>
<td>CR programs without exercise</td>
<td>0.87</td>
<td>0.76 to 0.99</td>
</tr>
<tr>
<td>CR programs with exercise</td>
<td>0.88</td>
<td>0.74 to 1.04</td>
</tr>
<tr>
<td>CR programs that were solely exercise-based</td>
<td>0.72</td>
<td>0.54 to 0.95</td>
</tr>
</tbody>
</table>

This systematic review indicated no difference in mortality rates between CR programs with and without an exercise component, although CR programs without exercise may reduce total health care costs. Nevertheless, a wide variety of secondary prevention programs to improve health outcomes in patients with CHD is required. Although this systematic review included all types of CR programs, the limitations of this review need to be considered. All trials included in the review enrolled highly select samples that were low-risk, which prevents generalisation of the findings to all the ACS population. Seventy-one percent of the included trials (n=45) recruited patients after MI or a coronary revascularisation procedure. The redefinition of ACS includes patients with unstable angina, who were a minority in the trials. In the clinical situation, these patients represent a large proportion (up to 41%) of the ACS patients, therefore the findings cannot be generalised to these patients. Approximately half the trials (n=45) included only younger patients, and in all but two trials women constituted less than half of the sample, thereby precluding generalisability. In addition, the majority of the trials were intensive and are potentially not feasible in most health care settings without additional resources.
Risk factor reduction

Smoking cessation
The evidence strongly indicates that patients who participate in multifactorial CR with well-designed educational and behavioural components and includes a quit smoking intervention are more likely to cease cigarette smoking. In a meta-analysis of RCTs, lower rates of self-reported smoking (OR = 0.64; 95% CI: 0.50 to 0.83) were reported among participants in exercise-based cardiac rehabilitation programs compared to usual care. Individual RCTs also indicate that patients were almost twice as likely (P<0.01) to remain abstinent if they participated in some form of CR compared to those who did not.

Improvement in lipid profile
Comprehensive CR programs and exercise training have been shown to produce significantly favourable changes in the lipoprotein profile in patients with CHD. Participation in CR programs also significantly enhances the lipid-improving effects of pharmacological therapy. Significant increases in serum hHDL-C, decreases in serum triglyceride level and reductions in serum TC and LDL-C have been reported in patients participating in some form of CR. Findings from a systematic review of RCTs demonstrated greater reductions in total cholesterol level (weighted mean difference [WMD], -0.37 mmol/L [-14.3 mg/dL]; 95% CI -0.63, -0.11 mmol/L [-24.3 to -4.2 mg/dL]), triglyceride level (WMD, -0.23 mmol/L [-20.4 mg/dL]; 95% CI -0.39, -0.07 mmol/L [-34.5,-6.2 mg/dL]) among participants in exercise-based CR compared to nonparticipants.

It should be noted that most of these studies have investigated the effect of participation in CR along with the use of pharmacological agents on lipid profile. Although one trial that investigated the effects of CR independent of the improvements observed with the use of pharmacologic agents also demonstrated significant beneficial effects of CR on lipid profile.
Weight loss
Studies of CR and exercise training generally have also reported significant improvements in obesity indices such as weight, body mass indices, and body fat percentage. \(^ {296-298}\) Savage \(^ {298}\) demonstrated that participants had reductions in total body weight (-4.6 kg), fat mass (-3.6 kg), percent body fat (-2.9%), and waist circumference (-5.6 cm) (all P < .001) while maintaining fat-free mass. Subcutaneous adipose tissue was reduced by 12% (P < .001) and visceral adipose tissue was lowered by 14% (P < .001). \(^ {110}\)

Hypertension
Significant reductions in systolic blood pressure (WMD -3.2 mm Hg; 95% CI -5.4,-0.9 mm Hg) were reported among participants in exercise-based CR programs. Other studies have reported that even when lifestyle modifications alone are not adequate in controlling hypertension, they may reduce the number and dosage of antihypertensive medications needed to manage the condition as well as reduce other cardiovascular risk factors in hypertensive patients. \(^ {299}\)

Improved psychosocial risk factors and quality of life after participation in CR
Participation in CR has been reported to decrease the prevalence of depression, which is an independent risk factor in the pathogenesis of cardiovascular disease, \(^ {90,149,300-303}\) by 40% to 50% and cause marked improvements in the overall coronary risk profile. \(^ {304}\) Participation in CR programs has also demonstrated significant reductions in anxiety \(^ {305-307}\) and stress. \(^ {61,306,308}\) Current data suggest that participation in some form of CR programs, irrespective of whether or not they were exercise-based, helped to reduce cardiac risk factors in patients with CHD by increasing functional capacity and improving quality of life \(^ {281-283}\) and self-efficacy. \(^ {189,278,282}\)

Financial benefits
With the increasing focus of attention on the cost of health care, a number of recent studies have shown there is convincing evidence that the benefits of CR also include financial savings. Findings from cost-effectiveness studies undertaken in the USA \(^ {279}\) and UK \(^ {218}\) have demonstrated that cardiac rehabilitation is more cost-effective when
compared with other post-MI treatment interventions, thrombolytic therapy, coronary bypass surgery, and cholesterol lowering drugs.\textsuperscript{279} It should be noted that these trials were undertaken in patients selected to participate in CR. An Australian trial that investigated the cost-effectiveness of CR in a broad cross-section of patients with ACS reported that rehabilitation costs of $631 per patient were offset by a reduction in follow-up costs of $236, resulting in a net incremental cost per patient of $395,\textsuperscript{67} demonstrating the beneficial effects of CR. A summary of the benefits of lifestyle modification programs is presented in Table 2.4.

<table>
<thead>
<tr>
<th>Table 2.4</th>
<th>Summary of the benefits of lifestyle modification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decrease in cardiovascular and total mortality by between 20% and 25%</td>
</tr>
<tr>
<td></td>
<td>Decrease in cardiovascular morbidity</td>
</tr>
<tr>
<td></td>
<td>Reduction in subsequent cardiac events</td>
</tr>
<tr>
<td></td>
<td>Reduction in serum lipid levels</td>
</tr>
<tr>
<td></td>
<td>Reduction in cigarette smoking</td>
</tr>
<tr>
<td></td>
<td>Improvement in exercise tolerance</td>
</tr>
<tr>
<td></td>
<td>Stress reduction</td>
</tr>
<tr>
<td></td>
<td>Improvement in psychosocial well-being and function</td>
</tr>
<tr>
<td></td>
<td>Improved quality of life</td>
</tr>
<tr>
<td></td>
<td>Early return to work</td>
</tr>
<tr>
<td></td>
<td>Reduction of inappropriate readmissions to hospital and cost for re-hospitalisation</td>
</tr>
<tr>
<td></td>
<td>Increased adherence to medications</td>
</tr>
</tbody>
</table>

2.8.2 Limitations of the studies

Although these studies have demonstrated beneficial effects, the majority of RCTs of CR were based in hospital settings and were predominantly exercise focussed. These trials were also limited in scope, enrolling predominantly low-risk middle-aged men after MI or CABG.\textsuperscript{309} Identification of the ethnic origin and the sociodemographics of the participants was seldom reported. It is possible that patients who would have benefited most from the intervention were excluded from the trials on the grounds of age, sex or comorbidity. Given the fact that the population in Sydney South West Area Health Service (SSWAHS) is considered to be of a lower socioeconomic status,\textsuperscript{310} these limitations are vital to generalising the findings in this region. What is clear from these studies is that exercise-based CR should not be ruled out due to lack
of resources or costs, as there are benefits of exercise-based CR within the context of today's cardiovascular service provision.\textsuperscript{278}

\section*{2.8.3 Barriers to participation in CR}

As described in the previous section, the physical, psychological and social benefits of participation in CR following a coronary event have been established.\textsuperscript{219,288,311,312}

Patients who have survived an episode of ACS and those who have undergone revascularisation, irrespective of the method, are all suitable candidates for CR, with beneficial outcomes from CR services reported in these groups. Despite these benefits, there is evidence that participation in CR remains less than optimal, ranging between 21\% and 75\% of the target group.\textsuperscript{36,37,39,40,219,313}

Various factors have been associated with low CR participation rates. Demographic characteristics of patients, CR service provision, components of the CR programs and medical diagnosis have been reported to be directly associated with CR participation rates.\textsuperscript{69,157,314,315} A higher uptake of CR has been reported in men,\textsuperscript{313,316-318} younger patients,\textsuperscript{315,318-320} and in those who are married or living with a partner.\textsuperscript{39,313,316,320} Published studies also demonstrate that people who are less educated,\textsuperscript{39,315,320} unemployed,\textsuperscript{313-315,320} or of lower socioeconomic status\textsuperscript{38,69,313,315} are less likely to participate in CR programs. It is evident that participation in CR programs is largely influenced by sociodemographic factors. However, it should be noted that the majority of these studies that provide evidence of demographic disparities in relation to participation in CR involved patients following MI and CABG.

Other barriers associated with participation in CR programs include limited availability and accessibility, length of the program (ranging from 4 weeks to 1 year),\textsuperscript{9,38,69,316} lack of referral by physician or cardiologist,\textsuperscript{39,42,69,157,321-324} long waiting lists,\textsuperscript{9,321} language barriers,\textsuperscript{36} distance to the programs from home or work and transportation,\textsuperscript{9,38,69,315,316,318,325} and scheduling of classes.\textsuperscript{9,38,69,316} Many patients following PCI return to work early and therefore are unable to participate in programs that are scheduled during working hours.

It is evident that participation in CR programs is also influenced by elements of the program.\textsuperscript{326} For example, patients have reported that positive relationships with health professionals, family support,\textsuperscript{70} and lack of pain during exercise were key
motivators to participation in CR programs. These components however, have been based on health regimen compliance literature rather than on the patients’ views of important components. Preference concerning certain features of the CR program may be related to demographic factors, and strong preference concerning certain features of the CR program may affect the patterns of cardiac rehabilitation attendance. There is a need to take clients’ preferences into consideration in health service delivery, if participation rates in CR are to be increased. Lack of patient motivation and low self-esteem\textsuperscript{38,69,315,318} have also been identified as challenges to participation in CR programs.

It is clear from the evidence that notably less than 25\% of post-PCI patients participate in CR compared to those who have had CABG or MI.\textsuperscript{318,320,327} Findings from a UK study identified that 33-56\% of patients enrolled in CR after CABG and this reduced to 14-23\% following MI and 6-10\% following PCI.\textsuperscript{328} Similar rates of participation in CR programs have been reported in Australian studies.\textsuperscript{68,219,323} In a large cohort study based on data linkage, 15\% of patients participated in CR following AMI. Of these, 37\% had undergone CABG and 14\% had PCI.\textsuperscript{219} A second cohort study\textsuperscript{68} published earlier demonstrated that overall only 32\% of eligible patients participated in CR, with CABG patients participating on average at a rate of 53.1\% compared with 27.2\% of AMI patients and only 10.3\% of PCI patients. A third study,\textsuperscript{323} in contrast, identified a higher participation rate among patients discharged following coronary revascularisation procedures.

Lack of participation in CR among ACS patients who have been revascularised with PCI could be due to the rapid procedural technique, shorter hospital length of stay, and immediate potential success of PCI without requiring open-heart surgery.\textsuperscript{151} These patients often underestimate the severity of their cardiovascular disease.\textsuperscript{329} The shorter hospital stay often means a reduced opportunity for patient education and referral to outpatient CR programs. In addition, many of the patients who have PCI may not have had a cardiac event and therefore believe that they do not have heart disease.\textsuperscript{182}

Percutaneous coronary intervention is now performed twice as often as cardiac surgery\textsuperscript{330} and therefore nonparticipation in CR programs among these patients has serious implications for clinical practice. The numerous barriers to participation in
traditional facility-based CR programs have prompted people to consider the content, timing and mode of delivery of CR programs and the identification of alternate approaches for the delivery of CR services.

2.8.4 **Alternate approaches to cardiac rehabilitation**

Given the challenges discussed above, it is necessary to consider different models of interventions. These alternate models for delivery of CR services include home-based CR, nurse-directed cardiac clinics, incorporation of community health workers (CHW) who are characteristically indigenous to the community being served, telecommunication, modular approaches and brief interventions.

**Telecommunication**

Advances in communication and information technology combined with challenges related to low participation rates have led to the introduction of telecommunication which can broaden the availability of CR services by extending beyond the traditional supervised setting. Using these methods, health care professionals can continue to offer prompting and reinforcement of favourable behavioural change leading to risk factor reduction and adherence to therapy.

Electronic communications include telephone interventions, office-based interventions involving touch screen computers, and the internet, and emphasise goal-setting, feedback, counselling and social support. A recent meta-analysis of 37 RCTs that included telephone and computer interventions indicated that electronic communication was effective in bringing about behaviour change. This method for the delivery of CR services has also been reported to be cost-effective either independently or in conjunction with traditional cardiac rehabilitation.

The delivery of information and motivational support by telephone to people with CHD has several advantages. Motivational support provided using a telephone has been reported to be less confronting and threatening to patients compared with in-person or group counselling. Secondly, the use of the telephone overcomes the limitations of geographical boundaries and transportation barriers that are common in traditional CR programs. Using the telephone to provide information and motivation is a method to deliver support when it is convenient for the patient rather
than at the convenience of the counsellor. In addition, telephone counselling provides a greater sense of privacy and anonymity, compared with group or in-person counselling. Delivery of an intervention for risk factor reduction using the telephone enables individualised services to a wide range of patients with CHD. Limitations of telephone counselling include the complete absence of non-verbal cues and therefore there is no opportunity to evaluate body language or facial expressions. Telephone counsellors therefore need to be attuned to every sound, every silence, inflection and qualities of speech including tone, pitch and speed.

Brief interventions
As demonstrated above, CR programs are intensive and lengthy, which is a major barrier to adopting these programs, given that patients have a short hospital stay and return to work early following the advances in medical and interventional treatment. The aim of secondary prevention is to reduce risk factors through behaviour change, improve quality of life and increase survival. The brief intervention is another method that has been used to motivate people to adopt healthy behaviours. Researchers have demonstrated beneficial outcomes of brief interventions for patients with alcohol problems, HIV, diabetes, and stroke related risk behaviours. The effect of brief structured interventions and minimal contact for smoking cessation have also been demonstrated to improve smoking cessation rates in the short term. The evidence supports that brief intervention of one to three sessions for health-related behaviour modification is more effective than no intervention, and could be comparable with more extensive interventions.

As discussed above and in Chapter 1, implementing effective secondary prevention programs remains a challenge, and a range of approaches have been adapted. In spite of the benefits of CR participation, attendance is limited. Developing a suite of interventions that can be tailored to the needs of individuals is appropriate. Many people do not attend CR because of an inability to attend daytime sessions and transport difficulties. In addition, some people do not like group programs or are not convinced of the benefit of the approach. Implementing brief interventions is conceptually alluring, from not only the perspective of consumer preference but also cost-effectiveness, should these interventions be evaluated favourably. To date, the bulk of the evidence for the brief intervention is in the areas of addiction. In order to
inform intervention development a review of the effectiveness of brief interventions for risk factor modification in patients with CHD has been undertaken and is described in Chapter 4.

2.9 Conclusion

This chapter has described the key approaches to secondary prevention and discussed the challenges and potential solutions. The following chapter will describe a conceptual framework for the study and the overarching research design that was used to achieve the study aims.
Chapter 3

*Overall research methods and conceptual framework*
3.1 Introduction

Chapter 2 has described the importance and existing strategies for risk factor modification in patients with CHD. This chapter presents the overall research design for the study and the conceptual framework of the project and illustrates how these issues contribute to the study design. As stated in Chapter 1, this project comprises four discrete yet related studies, each undertaken using a different research design, therefore detailed descriptions of each study design and the methods used are presented in the corresponding chapters.

3.2 Overall Research Design

Increasingly, multiple research designs such as multi-method, mixed-methods and mixed model methods are used to enable a multidimensional view of a phenomenon. Although these three methods have differences, the terms are often used interchangeably. Multi-method design is the conduct of two or more research methods, each conducted rigorously and complete in itself, in one project, after which the results are triangulated to provide a complete picture. The multi-method research is one of the fastest growing interest areas in research methodology and is becoming a widely accepted approach in recent years to investigate organisational phenomena, such as the process and organisational consequences of implementing a new device for managing surgical patients. On the other hand, mixed-method research is an approach used for the collection and analysis of data using qualitative and quantitative research designs (e.g. focus groups and surveys) in a single study of which one is the core design. The non-core design is supplemental to the major core method and assists to interpret and support findings, provide corroborative evidence and add depth or breadth to a study. The major difference between multi-method and mixed-method design is that in multi-method design all projects are separate but complementary processes. Mixed model research is the mixed combination of methods in many or all the stages of the study.

It is vital in any research process that the design chosen is suitable to investigate the aims of the project. This HeLM project was undertaken using a multi-method design to achieve the aims as described below.
Aim 1  To develop a health-related lifestyle self-management (HeLM) intervention for risk factor modification in patients with ACS

In order to achieve the first aim, the development of an evidence-based health-related lifestyle self-management intervention, three discrete yet interrelated studies using different designs were undertaken. These three studies were carried out to obtain evidence from the literature, clinical experts and the patients, as these are the three main aspects of evidence-based practice. Evidence from the literature investigating the effect of brief interventions on risk factor modification in patients with CHD was obtained by using a systematic review design. Evidence from the clinical experts was attained by conducting a qualitative interview investigating CR coordinators’ perceptions of the barriers and facilitators to the adoption of the recommendations from the RRIHD guidelines published by the NHFA and CSANZ\(^{34}\) and a survey to obtain information about the CR programs. Evidence from patients about their cardiac risk factor status, HRQoL, adherence to medications, knowledge relating to CHD and its risk factors and participation in CR programs 12-24 months following PCI was obtained by using a survey design. These approaches were chosen because using either quantitative or qualitative processes for the development of the intervention was not sufficient to investigate the broader context. The application of different methods for data collection and analysis would provide rigour and evidence for the HeLM intervention.

Aim 2  To evaluate the feasibility of the HeLM intervention in patients with ACS

The second aim was to investigate the feasibility of the HeLM intervention that was undertaken using a randomised controlled trial design. The RCT design was selected to investigate the feasibility of the HeLM intervention, as it has been considered as the gold standard according to the hierarchy of evidence in medicine and other biosciences.\(^{362}\)
According to the multi-method design, each of the four studies was conducted rigorously, with conceptual congruence and complete in itself\textsuperscript{361} and have been presented as separate chapters. Table 3.1 presents the research designs used for each of the studies that constituted the multi-methods. A detailed description of the rationale for each of the studies, the research design and the methods used are presented in the related chapters.

**Table 3.1  Research designs used for each of the studies that constituted the multi-methods**

<table>
<thead>
<tr>
<th>Aim of the study</th>
<th>Evidence Source</th>
<th>Research Design</th>
<th>Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>To develop a HeLM intervention</td>
<td>Literature</td>
<td>Systematic Review</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>\textit{investigate the effectiveness of brief interventions for lifestyle modification in patients with CHD.}</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinicians</td>
<td>Qualitative and quantitative design</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>\textit{investigate the barriers and facilitators for the implementation of evidence-based guidelines.}</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patients</td>
<td>Quantitative design (Survey)</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>\textit{follow-up patients 12-24 months post PCI.}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To investigate the feasibility of the HeLM intervention</td>
<td>Patients</td>
<td>Quantitative design (RCT)</td>
<td>7</td>
</tr>
</tbody>
</table>
3.3 Conceptual framework

The principles of evidence-based practice, chronic disease self-management and the TTM\textsuperscript{203} were used to develop the conceptual framework for this study (Figure 3.1).

3.3.1 Evidence-based practice

Evidence-based practice (EBP) is defined as an approach to health care where health professionals use the current best available evidence to make clinical decisions for individual patients.\textsuperscript{366} In Australia, although research evidence obtained from RCTs is considered the highest level of evidence according to the National Health and Medical Research Council (NHMRC) and other peak bodies, it is only one aspect of developing evidence-based interventions. EBP is not restricted to research evidence but values, enhances and builds on clinical expertise, knowledge of disease mechanisms, and pathophysiology.\textsuperscript{366} It involves complex and conscientious decision-making based not only on the available evidence but also on patient characteristics, situations, and preferences.\textsuperscript{366} Recently, researchers have indicated that development of evidence-based interventions requires input from clinical experts regarding how they could improve clinical outcomes and the pros and cons of implementing evidence obtained from RCTs.\textsuperscript{367} The other aspect in developing evidence-based interventions is information obtained from the user; namely the patient.\textsuperscript{367} Although there is a great deal of controversy about involving patients in decision-making and care planning, exploring their preferences should be considered as an important source of evidence.\textsuperscript{368} In this study this approach was used as interventions developed using evidence-based approaches have been reported to be more successful compared to those that were not. Following the deliberations and strengths of this approach, the HeLM intervention described in Chapter 7 was developed using a complementary process of research evidence, CR coordinators and patients.
3.3.2 Chronic disease self-management
The CDSM framework\(^{220}\) was selected because ACS reflects the spectrum of CHD resulting in adverse health outcomes, including heart failure.\(^{22}\) Although ACS is treated in hospital with revascularisation, the underlying CHD pathology of atherosclerosis that caused the acute event is a chronic process requiring self-management. In recent times, the role of self-management in chronic care has gained significant support and is now widely recognised as a necessary part of effective chronic disease management.\(^1\) The HeLM intervention was therefore designed as a self-management strategy involving information provision, effective communication, shared decision-making and improved knowledge and skills, to empowering patients with CHD to be more proactive in managing their illness and take more control of their lives.

3.3.3 Transtheoretical model
As discussed in Chapter 2, the TTM has four dimensions: stages, processes, decisional balance and self-efficacy. Successful self-management and positive changes in health behaviour can be obtained by implementing interventions based on an understanding of human behaviour and motivators for change. Theory-driven interventions, especially those based on behavioural theories,\(^{190}\) have been reported to be more successful than those that are not.\(^{101,191,192}\) The HeLM intervention was therefore embedded in the TTM for behaviour change. Application of this model to the HeLM intervention consisted of: (1) the development of the “Take the HeLM” booklet that targeted all four TTM dimensions: stages, processes, decisional balance and self-efficacy; (2) feedback; (3) supportive telephone calls; and (4) goal-setting. The HeLM intervention was designed to increase motivation, provide knowledge and skills, and thereby enable behaviour change resulting in risk factor reduction. A detailed description of the HeLM intervention is presented in Chapter 7.
3.4 Summary

In this chapter, a description of the overarching methods used in the study was presented. Multi-methods are used to augment understanding of an experience or issue through confirmation of conclusions, extension of knowledge or by initiating new ways of thinking about the subject of the research. The use of a single method for developing the HeLM intervention would be limiting and the important evidence that was obtained from the other research would have been missed. Therefore, the use of a multi-method approach was novel and the integration of the results led to a more in-depth conceptual development of the HeLM intervention, the feasibility of which was tested in a RCT. The multi-methods design also offered the opportunity to go beyond the traditional typical independent research design. A conceptual framework for the study and the overall research design has been presented. The conceptual model was based on evidence-based practice, chronic disease self-management and the TTM for behaviour change.

Figure 3.1 Conceptual model for the HeLM intervention
Chapter 4

Effect of brief structured interventions on risk factor modification for patients with coronary heart disease – A systematic review
4.1 Introduction

In this chapter, brief intervention and the methods and findings of the systematic review will be presented. The systematic review has been based on a framework developed by the Cochrane Collaboration, and the accepted standards for systematic review methods as determined by the Joanna Briggs Institute (JBI) and the handbook of the Cochrane Collaboration were employed to inform the methods used in this review.

4.2 What is a Brief Intervention?

A brief intervention (BI) is a simple effective tool that involves motivating and encouraging people to change behaviour and generally integrates important constructs from various behavioural theories. The main aim of BI is to impact on patients’ motivation to change, following which patients may continue to change their behaviour with minimal additional assistance. The brief intervention is targeted at the patient’s stage of readiness to change, thus enabling the patient to achieve personal health-related goals.

4.3 Methods for delivery of brief interventions

A brief intervention usually refers to time-limited structured advice focusing on changing and/or increasing desirable patient behaviour. The time-limited advice can range from five to one hour and is delivered by a general medical practitioner, health professional or nurse. The frequency of advice to ensure success of the strategy has been reported to range from single through to multiple sessions of motivational interviewing or some other form of counselling accompanied by repeated follow-up either through clinic visits or telephone consultations. The use of intervention workbooks as a self-help material for patients has also been reported as a useful tool for facilitating and recording behaviour change. Miller and Rollinick have indicated that brief interventions that use the principles of motivational interviewing are more beneficial to the patient than no treatment at all. Patients have been reported to have changed behaviour within a few minutes when interventions using brief motivational interviewing were used. Although the efficacy of this cost-effective intervention
has been demonstrated in patients with drug and alcohol problems, stroke and diabetes, the benefits of this method is yet to be demonstrated in secondary prevention trials of CHD patients.

4.4 Elements of Brief Interventions

Brief interventions include elements proposed by Miller and Sanchez\(^ {376} \) that initiate motivation to change. These elements are summarised by the acronym FRAMES and include feedback, responsibility, advice, menu, empathy, and self-efficacy.\(^ {346,377} \)

Other elements that have been reported to enhance effectiveness of interventions targeted at behaviour change include goal-setting, follow-up, and timing.

4.4.1 Description of FRAMES

**Feedback to the individuals of their personal risk**

A strong motivator for an individual to adopt healthy habits is the provision of personal, individualised feedback.\(^ {210,378,379} \) It is of utmost importance that this feedback be based on objective assessments and delivered in a structured, non-confrontational, non-threatening and constructive manner.\(^ {358} \) The feedback should be easy to understand without the use of medical jargon. Biomedical risk assessment is the process of giving individuals feedback on the physical effects of their health-related behaviours by physiological measurements.\(^ {379} \) The individual’s coronary risk status is compared with evidence that is considered to be gold standard; for example, the person’s weight compared to the recommendation from the NHFA guidelines for weight management. The objective of the feedback is to help the patient identify the presence of an unhealthy behaviour and the importance of change. Feedback is also important to highlight the progress made towards the adoption of healthy behaviour.

**Responsibility – making the individual responsible for change**

The evidence suggests that when people feel empowered and believe that they are in control of themselves they are more likely to adopt/adhere to their new behaviour.\(^ {358} \) Although the health care professional should be involved in the decision-making process, the final determination of what is best for the patient is both the right and responsibility of the individual patient.
**Advice to adopt healthy behaviour by changing**

Providing advice to change in a non-judgemental manner can promote positive behavioural change.\(^{358}\) A motivational approach to offering advice may be either directive (making a suggestion) or educational (explaining information). Educational advice is based on credible scientific evidence supported in the literature. Simple advice given according to the individual’s level of understanding at the appropriate time and matched to their readiness to change has been demonstrated to be beneficial.\(^{207}\)

**Menus of self-directed choices available for change**

The role of the health professional is to enhance the individual’s ability to make informed choices; therefore, they may offer patients a variety of strategies from which to choose. Behaviour change is improved when individuals can choose from a menu of options.\(^{207}\) Providing a menu of options is consistent with the motivational principle that clients must choose and take responsibility for their choices. Patients are often given self-help materials with strategies they could adopt to make the necessary changes. Self-help materials often include diaries to help patients monitor their progress.

**Empathy – showing warmth, respect, and understanding**

A warm, supportive, sympathetic, reflective, attentive and understanding approach to delivering BI has been demonstrated to have a positive impact compared to an aggressive, confrontational, or coercive style.\(^{207,359}\) Empathy usually entails reflective listening – listening attentively to each client statement and reflecting it back in different words so that the client knows you understand the meaning. A 77% reduction in alcohol intake was reported when an empathetic counselling style was used, compared to a 55% reduction using a confrontational method.\(^{380}\)

**Self-efficacy – empowerment of the client**

Behaviour change requires empowerment of the client to undertake the necessary tasks and skills to bring about change. Therefore, fostering hope and optimism in the client’s abilities is vital.\(^{207}\)
4.5 Brief interventions and Motivational interviewing

Motivational interviewing is a client-centred, supportive, respectful approach that is persuasive without being coercive, and it is used to assist people to recognise their problems and increase their motivation to make changes.\(^{237}\) In this method, the emphasis is on individuals helping themselves. The health professional therefore assists the individual to develop their own motivational and coping strategies and take responsibility for any change.

Motivational interviewing and brief interventions have been used widely in the literature interchangeably, although they are not the same. Many of the elements of BI and motivational interviewing are similar, however the applications of some of these elements differ.\(^{381}\) Providing advice is one such application where there is a major difference between brief interventions and motivational interviewing. In this study, the term motivational support has been used because one of the aims of the intervention was increasing the readiness to change. Motivational support is a method used to facilitate the progress along the different stages of change.\(^{381}\)

4.6 Systematic Reviews as a research method

Systematic reviews are undertaken to assist clinicians keep abreast of the large volumes of biomedical literature by summarising the evidence and helping to explain differences among studies on the same question.\(^{382}\) A systematic review is an objective analysis of scientific studies in which the methodology and the findings are systematically assessed and summarised according to predetermined criteria. Used increasingly to inform clinical decision making, plan future research agendas, and establish clinical policy, systematic reviews strengthen the link between best research evidence and optimal health care.\(^{382}\)

4.7 Research question and objectives

This systematic review was undertaken to answer the following question: for patients with CHD, what is the effect of brief interventions for the modification of the following risk factors – smoking, physical inactivity, lipid profile, high blood pressure (BP), high fat diet and diabetes?
The objective of this review was to determine the effect of brief intervention on risk factor modification in patients with CHD. The following comparisons were made: (1) BI vs usual care for single risk factor modification; (2) BI vs extensive interventions for single risk factor modification; (3) BI vs usual care for multiple risk factor modification; and (4) BI vs extensive interventions for multiple risk factor modification.

Definition of terms For the purpose of this systematic review, the following definitions were used:

**Brief intervention** – verbal or written communication provided to patients by a health care professional to modify risk factors. Interventions included provision of advice with or without the use of written, audio or video information during a single consultation lasting up to 30 minutes, with up to seven follow-up contacts.

**Extended interventions** – communication that extended more than half an hour.

**Continuous abstinence** – smoking no more than five cigarettes since recruitment and not smoking at all in the past week. An expired carbon monoxide (CO) reading < 10 ppm or a salivary cotinine concentration < 20ng/ml.

**Point prevalence abstinence** – a self report of not having smoked at all for the past week and an expired CO reading < 10 ppm or a salivary cotinine concentration < 20ng/ml.

### 4.8 Criteria for considering studies for this review

All randomised, quasi-randomised controlled trials and clustered trials evaluating the effects of brief interventions for modification of risk factors in patients with CHD were included in the review. Reports in all languages were considered in this review. Trials that investigated self-monitoring or other reports of smoking, cholesterol level, physical activity, dietary habits including fat and fish intake, blood sugar levels, blood pressure levels, body mass index, incidence of admission for acute coronary syndrome, chest pain and stroke, patient satisfaction with method of intervention, patient knowledge relating to risk factors and behaviours required to modify risk factors, health-related quality of life and economic measures and cost effectiveness in adults (age >18 years) with risk factors for CHD were included. Studies undertaken for primary prevention were excluded. Trials undertaken in children to
promote healthy lifestyle were excluded. Trials that include the following methods for delivery of the brief intervention were included: face to face interview; telephone; electronic and postal. Trials that included brief intervention as part of an extended program were excluded. In addition, trials that compare types of diets or exercises were excluded. Population-based trials and those undertaken for health promotion were also excluded.

4.9 Searching the literature

To avoid duplication of research, searches should be conducted to establish whether a review is required by searching for existing and ongoing reviews. Therefore, prior to commencing this review, the Cochrane Library and the JBI database were searched to ensure that a systematic review on this subject had not been undertaken.

A preliminary literature search of the MEDLINE and CINAHL databases was performed to help identify the range and type of studies potentially available for synthesis. A large number of potential studies were identified and therefore a decision was made early in the review process to restrict the initial search to RCTs and clinical controlled trials only. In addition, RCTs are considered to be the gold standard to provide the evidence for the effectiveness of interventions.

The aim of the search strategy was to undertake a comprehensive literature search to facilitate retrieval of all published and unpublished clinical trials relating to interventions for risk factor modifications for patients with CHD. Therefore, in consultation with a qualified health librarian, the Ovid databases were searched to identify key words used in the titles and abstracts. As each database has its own unique indexing terms, individual search strategies were developed for each database. During the development of the search strategy, consideration was given to the diverse terminology used and the spelling of key words as this would influence the identification of relevant trials. No restrictions were placed on date of publication and each database was searched as far back as possible.

The databases searched included Current Controlled Trials register, DARE, MEDLINE (1966-2006), CINAHL (1982-2006), EMBASE (1980-current) and the Cochrane Library up to and including 2006 Issue 2 (see Appendix 3 for search strategies). In addition, the reference lists and bibliographies of all possible trials and
reviews were searched for further references. To complement the search strategies, relevant conference proceedings and the grey literature were searched, experts and company representatives contacted to identify any further trials or research in progress, and key word searching of the world wide web was conducted (Table 4.1).

Table 4.1  Overview of the searching techniques

<table>
<thead>
<tr>
<th>Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>• keyword searches of electronic databases</td>
</tr>
<tr>
<td>• scanning of reference lists</td>
</tr>
<tr>
<td>• citation searching of key papers</td>
</tr>
<tr>
<td>• contact with organisations and individuals via the Internet and through personal communication</td>
</tr>
<tr>
<td>• keyword searching of the world wide web.</td>
</tr>
</tbody>
</table>

4.10 Methods of the review

The references and abstracts identified from the search were imported into the bibliographic software Endnote Version 6. All duplicate references were removed and the remaining were assessed against the inclusion/ exclusion criteria independently by two reviewers and the full text was obtained of relevant reports. If the title and abstract were inconclusive, full text was obtained for further assessment. Studies that were reported in more than one publication were included only once. Decision for study eligibility was made by two reviewers. Any disagreements were resolved by discussion with a third reviewer.

4.10.1 Assessing the methodological quality of the trials

The methodological quality of the eligible randomised controlled trials was assessed independently by two reviewers using the Joanna Briggs quality assessment tool for experimental studies (Appendix 4). Any disagreements were resolved by discussion with a third reviewer. Each study was critically appraised and the methodological quality was assessed for the following: (a) detailed description of inclusion and exclusion criteria used to obtain the sample; (b) evidence of allocation concealment at randomisation; (c) the validity of methods of outcome assessment; (d) description of withdrawals and dropouts; and (e) the potential for bias in outcome assessment.
4.10.2 Extracting data from the trials

Data extraction from the included trials was undertaken and summarised independently by two reviewers using a data extraction tool (Appendix 6) that was piloted prior to use. Piloting was undertaken by two independent reviewers using three trials. Amendments to the tool were made based on their comments. The final data extraction tool was used to collect data from the studies relating to: patient demographics; patient inclusion/exclusion criteria; description of the interventions; method and frequency of delivery of the BI; content of the BI; whether the BI was targeted at the patient’s stage of change; description of the outcomes; follow-up period and the number and reasons for withdrawals and dropouts. If any data were missing from the trial report, attempts were made to obtain them by contacting the authors. Discrepancies between reviewers were resolved by discussion.

4.10.3 Synthesising the data

All calculations were made using the Cochrane statistical package Review Manager (RevMan) Version 4.1. Clinical heterogeneity was assessed by considering the populations, interventions and outcomes between the studies. Statistical heterogeneity was investigated by calculating the $I^2$ statistic, and if this indicated a high level of heterogeneity among the trials included in an analysis, a random effects meta-analysis was chosen for an overall summary. Where high levels of heterogeneity were found, they were explored by the subgroup analyses and by sensitivity analyses excluding the trials most susceptible to bias. Fixed effects meta-analysis was used for combining study data if the trials were judged to be sufficiently similar. Relative risks and 95% CI were calculated for dichotomous data. Analysis of continuous data was undertaken using the mean and standard deviation values to derive WMD and their 95% CIs. Where synthesis was inappropriate, a narrative overview was undertaken.

For cluster randomised controlled trials, it was anticipated that if the analysis accounted for the cluster design then a direct estimate of the desired treatment effect was extracted, e.g. RR plus 95% CI. If cluster-specific analysis was not undertaken, data would be extracted for all individuals in each intervention group, relating to the number of clusters randomised to each intervention, the average cluster size in each intervention group, and the outcome data (e.g. number or proportion of individuals...
with events, or means and standard deviations), ignoring the cluster design. Next, using an external estimate of the intracluster coefficient, a design effect would be estimated. It would then be possible to enter the data into RevMan and combine the cluster randomised trials with individually randomised trials in the same meta-analysis, using generic inverse variance methods of meta-analysis. However, this method was unable to be applied due to the limited number of trials undertaking the same comparison.

4.11 Description of studies included in the review
Approximately 16,000 trials were identified from the search strategy. Following removal of duplicates, the majority were excluded based on a review of the title and abstract of the citation against the inclusion criteria. Thirty-six trials were considered to be potentially eligible and full text of these trials was obtained. Nineteen trials were further excluded as they did not meet the inclusion criteria or were published in duplicate. Appendix 7 presents the reasons for why these studies were excluded. Seventeen trials, involving a total of 4,725 participants, were included in the final review. Three trials compared the effects of brief structured interventions on diet modification,\(^385,386,387\) seven on smoking cessation,\(^287,355,388,392\) and seven on multiple risk factors.\(^44,297,393-397\) The trials were conducted in the USA,\(^297,387,388,391-393,397\) Australia,\(^44,389,395\) United Kingdom,\(^287,385,394,396\) the Netherlands,\(^355\) Denmark,\(^386\) and Canada.\(^390\)

4.11.1 Sample sizes
The number of participants in trials comparing the effect of brief structured interventions for diet modification ranged from 13\(^385\) to 63,\(^387\) with a total of 112 participants in the studies. There were 2,274 included in trials that compared brief structured interventions for smoking cessation, with the number of participants in individual trials ranging from 100\(^388\) to 789.\(^355\) In the trials that assessed the effect of the brief structured interventions on multiple risk factors, the number of participants ranged from 104\(^297\) to 792.\(^44\)

4.11.2 Trial design
Six of the seventeen trials were conducted in multiple centres.\(^44,297,355,391,394,395\) All seventeen trials utilised a parallel group design, and the trial by Mahler\(^397\) had three comparison arms.
4.11.3 Participants
The age of the trial participants ranged from 37 to 86 years. With one exception, all the remaining trials included both genders, although in most trials the majority of the patients were males.

4.11.4 Reasons for hospital admission
The main reasons for hospital admission were myocardial infarction, coronary artery bypass grafts, coronary artery disease, coronary angiography and percutaneous coronary interventions.

4.11.5 Interventions
A clear description of the intervention protocol was reported in all trials, however a description of the components of usual care was not reported in one trial. The interventions consisted of written, visual, and audio self-help educational and behavioural information, postal reminders, telephone support and personalised risk factor cards. In all trials participants were provided with advice on risk factor modification. In six trials the interventions were based on theoretical behaviour change principles. The number of telephone calls for supportive counselling ranged from 1 to 7 with a mean number of three calls for the duration of the study. The length of the interventions varied from 10-30 minutes with a mean of 17 minutes. In one trial, the intervention was delivered through the internet, and in others through audio or video tapes. The interventions were delivered by nurses, a psychologist, dieticians, a case manager, research assistants and a health educator. Only four trials reported that education was provided for the staff delivering the interventions.

4.12 Methodological quality of the included trials
All trial reports were evaluated against the criteria outlined in the methods of the review to assess methodological quality. There was 100% concordance between the reviewers in this respect. Overall, the quality of the trials was excellent with a mean of 10 criteria being described (Appendix 5). Only two of the seventeen trials described all eleven aspects of methodological quality as determined by the JBI criteria (Appendix 4). This demonstrates the poor reporting styles and therefore the assessment of the strengths and weaknesses of the study. Details regarding statistical
power and sample size calculations were reported in six trials. The alpha level used in their statistical tests was also reported.

4.12.1 Randomisation
The method of randomisation involved random numbers tables in nine trials, block randomisation in three trials, alternation and permuted tables in one trial each, and the method of randomisation was not reported in two trials. None of the trials reported on the method for allocation concealment.

4.12.2 Intention-to-treat analysis
An intention-to-treat analysis should ideally include data from all those who were randomised. Inclusion of those patients who withdraw or drop out from a trial is important as losing their data could result in attrition bias. Analysis on an intention-to-treat basis was reported in only eight trials.

4.12.3 Follow-up
More than 80% of the participants were followed up in all except one trial.

4.12.4 Baseline comparability of groups
A description of the patients’ baseline characteristics is essential when assessing comparability between the groups because it indicates if randomisation was successful. It also assists the reader in deciding if the results are applicable to their situation. Baseline comparability relating to age, gender, education level, comorbidities, risk factors, and reasons for hospital admissions were presented. All but one trial indicated that there was baseline comparability between the groups.

4.12.5 Blinded outcome assessment
Due to the nature of interventions, blinding of the patient, care provider and assessor was not possible in most of the trials. However, four trials reported that those assessing outcomes were blinded to the intervention. This finding highlights the possibility of a detection bias.

4.12.6 Methods to assess outcomes
A wide range of outcome measures was used in the included trials. The effect of the intervention on dietary habits was assessed using validated instruments to measure...
fat scores and laboratory assessment of lipid profiles of the participants. Participation in various types of physical activities and the mean time spent walking were used to assess physical activity. The methods used to assess smoking cessation included measuring expired CO levels, cotinine levels and self reports. Smoking cessation was assessed as continuous and point prevalence abstinence (see definition of terms). Blood glucose level (BGL) was examined using fasting BGL or A1C.

The duration of follow-up ranged from 3 weeks to 30 months after treatment. Cost analysis was reported in only one trial. For further descriptions see Summary Tables (Appendix 8).

### 4.13 Results

#### 4.13.1 Brief structured intervention vs usual care for dietary modification

Two trials compared the effect of a brief structured intervention to usual care for dietary modification. However, meta-analysis was restricted due to the limited information available and the different outcome assessment timings between the trials. One small trial assessed outcomes 12 weeks following the intervention and reported a significant reduction in fat intake among participants who received the brief structured intervention (Figure 4.1).

<table>
<thead>
<tr>
<th>Study or subcategory</th>
<th>N Treatment Mean (SE)</th>
<th>N Control Mean (SE)</th>
<th>WMD (95% CI)</th>
<th>Weight</th>
<th>SE WMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (all trials)</td>
<td>8</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advice (C1506)</td>
<td>8</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity (not applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: z = 3.09 (P &lt; 0.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95%)</td>
<td>8</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity (not applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: z = 3.09 (P &lt; 0.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 4.1** Mean change in fat intake at 12 week follow-up
The trial also demonstrated no statistically significant change from baseline to follow-up in the lipid profile between the two groups (Figure 4.2).

![Figure 4.2 Mean change in lipid profile at 12 week follow-up](image)

Likewise, there was no statistically significant change in weight loss between the two comparison groups, although participants in the intervention group lost more weight compared to those in the control arm (Figure 4.3).

![Figure 4.3 Mean change in weight at 12 week follow-up](image)

The second trial assessed outcomes at six months and reported that only a few patients randomised to the intervention group did not achieve their target LDL-C at the 6 month follow-up. However, these results were not statistically significant (Figure 4.4).

![Figure 4.4](image)
Participants randomised to the intervention group also had a significant reduction in their LDL-C (p=0.02) and TC levels (p=0.02) from baseline to follow-up compared to no changes in their counterparts. However, the difference in the reduction in the LDL-C and cholesterol levels between the two groups was not statistically significant (p=0.059). 387

4.13.2 Brief structured intervention vs extensive intervention for dietary modification

One trial386 compared the effect of a brief structured intervention to an extensive intervention for dietary modification and reported outcomes at one year follow-up. The findings demonstrated significant improvements from baseline to follow-up in participants randomised to the extensive intervention in the percentage of energy from fat (33% to 28%), saturated fat (12% to 9%) and carbohydrate (51% to 54%) consumed by them. The corresponding values among participants randomised to the brief intervention did not differ significantly (31% to 32%, 11% to 12%, and 53% to 52% respectively). The differences from baseline to follow-up between groups were statistically significant for fat, saturated fat and carbohydrate intake. However, these results should be viewed with caution as the data in all comparisons were few and hence the confidence intervals were all wide (Table 4.2).
Table 4.2 Mean change in dietary intake from baseline to follow-up

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Difference from baseline to follow-up between groups</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensive intervention (n=19)</td>
<td>Mean 95% CI</td>
<td></td>
</tr>
<tr>
<td>Brief intervention (n=17)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

% of energy from

<table>
<thead>
<tr>
<th>Intake</th>
<th>Mean</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat intake</td>
<td>6.4</td>
<td>2.1, 10.7</td>
</tr>
<tr>
<td>Saturated fat intake</td>
<td>3.8</td>
<td>1.5, 6.1</td>
</tr>
<tr>
<td>Carbohydrate intake</td>
<td>-5.8</td>
<td>-10.1, -1.5</td>
</tr>
<tr>
<td>Protein intake</td>
<td>-0.2</td>
<td>-2.2, 1.8</td>
</tr>
</tbody>
</table>

The median intakes of fish, fruits, and vegetables at follow-up among participants in the extensive intervention group did not significantly differ from those randomised to the brief intervention group.

### 4.13.3 Brief structured intervention vs usual care for smoking cessation

Six trials included in this review investigated the effects of a brief structured intervention and usual care for smoking cessation. The trials assessed outcomes at various intervals and used different methods to assess smoking cessation, which precluded the use of a meta-analysis for the majority of the trials. Smoking cessation was assessed at 3 weeks, 6 weeks, 3 months, 6 months, 12 months, 24 months and 30 months. The methods used to assess smoking cessation included measuring expired CO levels, cotinine levels and self reports. Smoking cessation was assessed as continuous and point prevalence abstinence (see definition of terms). As these outcome measurements are disparate, the results have been reported separately.

#### Smoking cessation at three week follow-up

One trial investigated the effect of a brief structured intervention compared to usual care on rates of smoking cessation at three week follow-up and reported no statistically significant difference in the cessation rates between the two groups (Figure 4.5).
Figure 4.5 Number of patients who continued to smoke at three week follow-up

**Smoking cessation at six week follow-up**

A single trial investigated rates of smoking cessation at six week follow-up. The findings demonstrated no significant difference in smoking cessation rates between the two groups using both the continuous and point prevalence abstinence assessment methods (Figure 4.6).

Figure 4.6 Number of patients who continued to smoke at six week follow-up

**Smoking cessation at three month follow-up**

One cRCT assessed this outcome using both continuous and point prevalence self reports. The results demonstrated a significant benefit of the structured brief intervention on smoking cessation rates. The odds of remaining a smoker as assessed using the continuous and point prevalence criteria decreased by up to 70% and 60% respectively for those receiving the intervention (Figure 4.7).
Figure 4.7  Number of patients who continued to smoke at three month follow-up

Smoking cessation at six month follow-up
This outcome was assessed in two trials\textsuperscript{388,391} using different outcome measures. The trial by Dornelas\textsuperscript{388} that assessed smoking cessation using self reports demonstrated a statistically significant decrease in the number of participants in the intervention arm who continued to smoke. However, in the second trial\textsuperscript{391} that assessed outcomes using cotinine levels, there was no statistically significant difference in the smoking cessation rates between the two groups (p=0.07) (Figure 4.8).
Smoking cessation at 12 month follow-up

Four trials assessed smoking cessation at the 12 month follow-up. Trials that used objective measures such as expired CO levels and cotinine levels were combined. The findings demonstrated a statistically significant reduction in the number of participants who continued to smoke at the 12 month follow-up (Figure 4.9). The trial that used self reports as an outcome measure also demonstrated significant difference in the intervention group.

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Intervention (n)</th>
<th>Control (n)</th>
<th>OR (fixed) 95% CI</th>
<th>Weight %</th>
<th>OR (fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>W: Assessed using expired CO levels and cotinine levels</td>
<td>36/82</td>
<td>36/82</td>
<td>1.00 (0.36, 1.67)</td>
<td>36.01</td>
<td>6.00 (0.36, 1.00)</td>
</tr>
<tr>
<td>Fedor, Q, 2001</td>
<td>40/79</td>
<td>44/62</td>
<td>0.92 (0.40, 2.27)</td>
<td>27.20</td>
<td>2.03 (0.40, 1.27)</td>
</tr>
<tr>
<td>Shiao-Food/Beer</td>
<td>74/124</td>
<td>77/132</td>
<td>1.19 (0.40, 3.27)</td>
<td>37.70</td>
<td>6.78 (0.40, 1.27)</td>
</tr>
<tr>
<td>Total events: 151 (Intervention) 194 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: CH² = 15.04, df = 2, P = 0.0005, I² = 96.2%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 3.07 (P = 0.0029)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X: Assessed using self reports</td>
<td>10/40</td>
<td>14/40</td>
<td>0.59 (0.22, 1.17)</td>
<td>199.00</td>
<td>6.29 (0.22, 0.72)</td>
</tr>
<tr>
<td>Total events: 12 (Intervention), 24 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 3.86 (P = 0.0001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.9 Number of patients who continued to smoke at the 12 month follow-up

Smoking cessation at 24 and 30 month follow-up

In the only trial that assessed this outcome at 24 and 30 month follow-up, there were no statistically significant differences in the smoking cessation rates between the two groups (Figures 4.10 and 4.11).

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Intervention (n)</th>
<th>Control (n)</th>
<th>OR (fixed) 95% CI</th>
<th>Weight %</th>
<th>OR (fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>B: Assessed using self reports</td>
<td>65/127</td>
<td>69/129</td>
<td>1.00 (0.56, 1.93)</td>
<td>130.00</td>
<td>6.31 (0.56, 1.49)</td>
</tr>
<tr>
<td>Shiao-Food/Beer</td>
<td>127</td>
<td>129</td>
<td>1.00 (0.56, 1.49)</td>
<td>127.00</td>
<td>6.31 (0.56, 1.49)</td>
</tr>
<tr>
<td>Total events: 15 (Intervention), 19 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.27 (P = 0.78)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X: Assessed using self reports</td>
<td>177</td>
<td>129</td>
<td>1.00 (0.56, 1.49)</td>
<td>199.00</td>
<td>6.31 (0.56, 1.49)</td>
</tr>
<tr>
<td>Total events: 32 (Intervention), 99 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.37 (P = 0.71)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.10 Number of patients who continued to smoke at 24 month follow-up
4.13.4 Brief structured intervention vs. Extensive intervention for smoking cessation

Smoking cessation at 3 and 12 month follow-up

One trial investigated the effect of brief structured interventions and extensive interventions on smoking cessation rates. The findings demonstrated no statistically significant difference in outcomes at either the three month or the 12 month follow-up (Figures 4.12 and 4.13).
Figure 4.13  Number of patients who continued to smoke at 12 month follow-up

4.13.5  Brief structured intervention vs. usual care for multiple risk factor modification

Seven trials assessed the effects of brief structured intervention and usual care for multiple risk factor modification.\textsuperscript{44,297,393-397} The outcomes assessed included blood pressure,\textsuperscript{393} changes to physical activity, diet and weight. Only one of the seven trials\textsuperscript{397} assessed outcomes after one month and three months;\textsuperscript{397} the remaining six reported outcomes at the six month follow-up.

**Blood pressure at 6 month follow-up**

Three trials\textsuperscript{44,297,393} reported on the effect of a brief structured intervention on blood pressure at the six month follow-up. However, due to the different reporting methods used the trials could not be included in a meta-analysis.

One trial\textsuperscript{393} reported no statistically significant difference in the number of participants who had an elevated blood pressure at the 6 month follow-up (Figure 4.14).
The trial by Vale\textsuperscript{44} reported increases in systolic and diastolic BP from baseline measurements in both the intervention and the control group. However, the increase was significantly more among participants in the control arm of the study (p=0.001 systolic BP; p=0.005 diastolic BP). In contrast, the trial by Southard\textsuperscript{297} demonstrated a reduction in systolic and diastolic blood pressure in both groups from baseline to follow-up. However, the difference in reduction between the two groups was not statistically significant.

**Lipid profile at 6 month follow-up**

Four trials investigated the lipid profile of participants at the six month follow-up.\textsuperscript{44,297,393,395} Two trials\textsuperscript{44,297} reported reductions in TC, LDL-C, and triglycerides in both groups from baseline to follow-up. However, the reductions relating to TC, LDL-C, and triglycerides between the two groups were reported to be statistically significant in only one trial.\textsuperscript{44} Both trials reported no statistically significant difference in the mean HDL-C levels between the two groups at the six month follow-up. In the trial by Heller,\textsuperscript{395} there was no difference in the mean cholesterol and HDL-C levels between the two groups (Figure 4.15).

![Figure 4.15 Lipid profile at six month follow-up](image)

The final trial\textsuperscript{393} reported no statistically significant difference in the number of participants who had raised triglycerides and LDL-C between the two groups at the six month follow-up (Figure 4.16).
Physical activity status

At 1 month follow-up

One three-arm comparison trial investigated this outcome. Patients were randomised to receive a mastery or coping tape or standard hospital information prior to discharge. The mastery tape was designed to provide information and was supplemented by patient narration of the descriptions of their experiences. The mastery tape was made to depict these patients as calm and confident at the time of release. The coping tape had the same information as the mastery tape but patients expressed concerns about hospital release.

Participants who viewed the coping tape engaged in significantly more moderate exercise (p<0.02) than participants who received the mastery tape and the control group. There was no statistically significant difference in the amount of light and strenuous exercise between the three groups. As the exact number of participants randomised to each group was not stated, the data could not be presented as a visual representation.

At 3 month follow-up

In the only trial that assessed this outcome at three month follow-up, participants who viewed the coping tape reported having engaged in significantly more (p<0.05) strenuous activity than their counterparts.
At 6 month follow-up

Four trials included in this review investigated the effects of a structured intervention at the 6 month follow-up.44,297,395,396 All four trials used different outcome measurements; therefore the results could not be combined in a meta-analysis. The findings indicated that a significantly greater number of participants randomised to the intervention group reported walking three times/week395 had taken up walking following discharge from hospital44 and had tried to increase the amount of exercise.396

No statistically significant difference in the number of participants undertaking vigorous activity once a week396 or increasing their amount of exercise297 was reported. However, the trial by Southard297 reported that participants in both groups increased the number of minutes of weekly exercise from baseline to follow-up.

Changes to diet, medications and exercise at 6 month follow-up

In the only trial394 that assessed these combined outcomes, there was no statistically significant differences between the two groups (Figure 4.17).

<table>
<thead>
<tr>
<th>Study or cell category</th>
<th>Treatment n=111</th>
<th>Control n=109</th>
<th>OR (95% CI) Weight %</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever, 0.1999</td>
<td>52/111</td>
<td>39/109</td>
<td>1.60 (1.10, 2.30)</td>
<td>100.00</td>
</tr>
</tbody>
</table>
| Total events: 90 (Treatment), 66 (Control) Test for heterogeneity: not applicable Test for coxie effect: Z = 0.12 (P = 0.90)

Figure 4.17 Changes to diet, medications and exercise at six month follow-up

Weight at 6 month follow-up

The effect of the intervention on participants’ weight at 6 month follow-up was reported in three trials.44,297,396 Two trials reported statistically significant reductions in weight among participants in the intervention group (Vale p<0.01; Southard p=0.003) compared to the control group. The third trial396 reported that although a greater number of participants in the intervention group seriously tried to lose weight, the difference was not statistically significant (Figure 4.18).
Figure 4.18  Number of patients who lost weight at six month follow-up

Body Mass Index

The BMI of participants was investigated in two trials at the six month follow-up. Both trials demonstrated a significant decrease in BMI among participants in the intervention group (Southard p=0.003; Vale p<0.001). Due to lack of reporting of standard deviations (SD), the data cannot be presented visually.

Fat intake

Four trials included in this review investigated this outcome. Data, however, could not be combined in a meta-analysis due to the different follow-up periods and outcome measures.

At 1 month follow-up

Mahler reported that participants who viewed either the coping tape or the mastery tape before hospital release had significantly lower cholesterol and saturated fat consumption scores (p < 0.05) at the 1 month follow-up compared to those in the control group. As the exact number of participants randomised to each group was not stated the data could not be presented as a visual representation.

At 3 month follow-up

Participants in both experimental arms of the study tended to consume less saturated fat at the three month follow-up compared to those in the control group. However, the difference was not statistically significant.
At 6 month follow-up

Three trials assessed this outcome at the 6 month follow-up, but trials could not be combined due to lack of data. The findings indicated that the fat intake score and the total amount of fat, saturated fat and cholesterol for participants in the intervention group was lower compared to those in the control group. However, the results were significant in only two trials. Data from one trial has been presented in Figure 4.19.

![Figure 4.19 Mean fat intake at 6 month follow-up](image)

### Blood glucose level

This outcome was investigated in two trials at the six month follow-up. Both trials demonstrated no statistically significant difference between the two groups in fasting glucose level or mean A1C between the two groups (Figure 4.20).

![Figure 4.20 Blood glucose level](image)
Smoking status at 6 month follow-up

Five trials that investigated the effect of a brief structured intervention on multiple risk factors included the smoking status of the participants.\textsuperscript{44,297,394-396} This outcome was assessed in all five trials using self reports and was therefore combined in a meta-analysis. The findings demonstrated a statistically significant reduction in the number of participants who continued to smoke at the six month follow-up (Figure 4.21).

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>OR (Fixed) 95% CI</th>
<th>Weight</th>
<th>OR (Fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Number of patients who continued to smoke at 6 month follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heider, P 1995</td>
<td>180/348</td>
<td>261/457</td>
<td>0.36 (0.25, 0.52)</td>
<td>16.36</td>
<td>0.36 (0.25, 0.52)</td>
</tr>
<tr>
<td>Heider, P 1999</td>
<td>272/485</td>
<td>261/457</td>
<td>1.03 (0.42, 2.43)</td>
<td>16.36</td>
<td>0.93 (0.45, 1.90)</td>
</tr>
<tr>
<td>Lewin, R 2002</td>
<td>11/929</td>
<td>11/932</td>
<td>1.05 (0.55, 2.00)</td>
<td>9.40</td>
<td>1.01 (0.29, 3.54)</td>
</tr>
<tr>
<td>Southard, B 2002</td>
<td>22/393</td>
<td>26/427</td>
<td>0.97 (0.44, 2.17)</td>
<td>26.61</td>
<td>0.97 (0.44, 2.17)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>45%</td>
<td>83%</td>
<td>0.99 (0.64, 1.53)</td>
<td>1.00</td>
<td>0.97 (0.64, 1.53)</td>
</tr>
</tbody>
</table>

**Figure 4.21** Number of patients who continued to smoke at six month follow-up

One trial\textsuperscript{396} also investigated the number of participants who tried to give up smoking and demonstrated no statistically significant difference in this outcome between the two groups (Figure 4.22).

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>OR (Fixed) 95% CI</th>
<th>Weight</th>
<th>OR (Fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Number of patients who tried to give up smoking at 6 month follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lewin, R 2002</td>
<td>29/54</td>
<td>34/75</td>
<td>0.82 (0.45, 1.49)</td>
<td>109.60</td>
<td>0.86 (0.41, 1.81)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>54%</td>
<td>34%</td>
<td>0.87 (0.47, 1.62)</td>
<td>109.60</td>
<td>0.86 (0.41, 1.81)</td>
</tr>
</tbody>
</table>

**Figure 4.22** Number of participants who tried to give up smoking at the six month follow-up
4.13.6 Costs

Costs of the intervention was investigated in one trial.\textsuperscript{297} The findings demonstrated a gross cost savings of $1,418 per patient as fewer cardiovascular events occurred among participants in the intervention group (15.7%) compared to the control group (4.1%) (p=0.053). The authors reported an estimated 213\% return on investment.

4.14 Discussion

Several trials have investigated the effect of brief structured interventions or simple counselling programs for risk factor modification in secondary health care however the results remain inconsistent. This inconsistency could be attributed to all the study design elements previously identified and the various definitions of the term ‘brief’ when describing the intervention programs. Brief interventions in one study could be considered as an extensive method in another. This systematic review clearly defined the terms ‘brief’ and ‘extensive’ and thereby reduced any inconsistency in the types of interventions that were compared.

This systematic review was undertaken to investigate the effectiveness of brief structured interventions for risk factor modification in patients with coronary heart disease, and has summarised the best available evidence at the time of the report. A systematic search of the literature resulted in 17 published trials that were eligible for inclusion in this review. The trials involved both male and female adult patients. The majority of the trials were reported according to the guidelines set out in the CONSORT statement,\textsuperscript{398} which lists the essential criteria that need to be reported so as to enable readers to determine the validity and reliability of the results. While all 17 trials met the methodological criteria for inclusion in the review, only 10 trials\textsuperscript{44,287,297,355,387,389,391,393,394,396} stated that participants were blinded to the intervention groups, although that could be due to the nature of the intervention.

Meta-analysis was restricted to trials of the same intervention that assessed the same outcome and was consequently limited by the lack of replication studies, thereby reducing the ability to extract definitive conclusions from the trials detailed in this review. The lack of measures of dispersion (e.g. standard deviations) also prevented the use of many of the data in the meta-analyses. Only trials using similar outcome measures were formally combined statistically for a particular outcome, however the
data from all trials addressing the same question for that outcome were presented as subtotals in the figures. This method of presenting the data might be questionable, however it does allow for identification of a pattern. As a result, this report is mainly in the narrative form with figures utilised to highlight particular findings. These findings should be interpreted cautiously, given the heterogeneity in terms of the follow-up period and the potential for the results of small trials like those reported here to over- or underestimate treatment differences. A discussion relating to each comparison is presented below.

4.14.1 Brief structured intervention vs usual care for dietary modification

Two trials involving 76 patients compared brief structured intervention with usual care for dietary modification. Although one trial demonstrated a significant decrease in fat intake in the intervention group, the trials were generally consistent in demonstrating no statistical difference in the lipid profile between the intervention and control groups. There was a tendency, however, for more participants in the intervention arm to lose weight at the 12 week follow-up and achieve target cholesterol levels at the six month follow-up. However, due to the small sample sizes of these studies these findings should be viewed with caution as the results may be attributable to Type 2 error. Dietary modification is a long-term commitment and the decrease in fat intake could be due to the Hawthorne effects of the study, therefore long-term follow-up is essential to demonstrate the beneficial effects of the intervention.

4.14.2 Brief structured intervention vs extensive intervention for dietary modification

Only one trial, involving 36 patients, compared brief structured intervention and extensive intervention for dietary modification. The evidence demonstrated a significant reduction in the percentage of energy obtained from fat and saturated fat intake among participants receiving extensive intervention. However, no difference in fish, fruit and vegetable intake between the groups was evident. Although the follow-up period to demonstrate effectiveness of the intervention was sufficiently long (1 year), the small sample size resulted in wide confidence intervals which complicate and limit conclusions.
4.14.3 Brief structured intervention vs usual care for smoking cessation

Six trials involving 2,020 patients compared brief structured intervention with usual care for smoking cessation. However, data could not be combined in a meta-analysis due to heterogeneity relating to outcome measures used and length of follow-up between the trials. Unlike the other two comparisons, one of the six trials consisted solely of women. As might be expected, there was no difference in the smoking cessation at the three and six week follow-up. This could be due to the fact of the nature of addiction. There is, however, evidence of a benefit of brief structured interventions for smoking cessation at the three and six month follow-up based on self reports. There is also strong evidence based on carbon monoxide and cotinine levels to support the effectiveness of brief interventions for smoking cessation at the 12 month follow-up.

In women particularly, the length of time they remained smoke-free was significantly greater in the intervention group (p=0.038) than the control group. There was also a tendency for fewer women in the intervention group to continue smoking at the 6, 12, 24 and 30 month follow-up, although the results were statistically significant only at the 12 month follow-up. This could be due to the fact that this study was undertaken in older women with limited social and financial resources, which resulted in long-term success rates.

4.14.4 Brief structured intervention vs extensive intervention for smoking cessation

In the only trial that compared brief structured intervention to extensive intervention for smoking cessation, in 254 participants, there was no clear difference of a likelihood of smoking cessation between the two groups.

4.14.5 Brief structured intervention vs usual care for multiple risk factor modification

Trials that undertook this comparison for multiple risk factor modification demonstrated a benefit of the intervention on behavioural changes such as fat intake, weight loss and consequently on reduction in the BMI, smoking cessation and physical activity among the participants. In spite of these findings, the effects on the blood pressure, blood glucose levels and the lipid profile remain inconclusive. This
could be due to the fact that outcome measurements related to behaviour change were assessed using self reports which could falsely inflate the results.

### 4.15 Limitations of the trials

Despite the high methodological quality score assigned to the brief intervention studies, 6/17 trials failed to provide a power calculation, nine did not perform an intention to treat analysis, only four reported blinded assessment and there was no reference to concealment of randomization from the investigators in any trial. In addition, to this the rather modest numbers studied, the heterogeneity of the studies and that a third of the patients were from two trials one of which the findings were inconclusive and the other contain significant amount of self reported data warrants caution during interpretation of the results. In addition, the majority of the studies included in the review required participants to have access to a telephone and to speak English, thereby systematically excluding a potentially vulnerable and underprivileged population. The proportion of men compared to women in the study groups was larger and the women were older, which is expected in the CHD population, although this might have influenced results. Furthermore, education for the persons performing the intervention was reported in only four trials, which could also influence the results.

Only one study undertaken in the USA provided cost data, which makes it difficult to generalise the health economic results to an Australian setting. Economic modelling is therefore vital to inform decision-making.

### 4.16 Implications for practice

The limited evidence obtained from the review does not provide a concrete base for the development of practice guidelines. However, based on the randomised trials undertaken to date, there is strong evidence to support the use of brief structured intervention for long-term (up to 1 year) smoking cessation. Currently, there is insufficient evidence to either support or undermine the effectiveness of brief interventions for modification of other coronary risk factors related to diet. There is also no evidence of the effect of brief interventions on single compared to multiple risk factor reduction.
The evidence for assessing the effect of brief interventions on physical activity and multiple risk factors is limited. Until stronger evidence becomes available, practices relating to interventions for risk factor modification will continue to be dictated by local preferences and cost factors.

4.17 Implications for research
This review has provided a guide to future priorities for research:

1. Consensus methods to standardise definitions related to brief interventions will not only inform comparison of studies but also promote application to clinical practice;

2. Further randomised trials using sample sizes based on power calculations to detect a clinically meaningful difference are needed to address the questions and to allow secondary analyses amongst discrete subgroups, including women, people from lower socioeconomic groups and people with heart failure;

3. The strongest evidence for whether brief intervention is an effective strategy for risk factor modification is likely to be provided by trials in which the outcomes are well-defined, assessed using validated methods and have an adequate follow-up period;

4. Large multicentre trials are needed to compare the clinical benefits and cost-effectiveness of different forms of brief interventions for risk factor modification in patients with CHD;

5. Similarly, randomised trials using sample sizes based on power calculations to detect a clinically meaningful difference are needed to provide robust evidence of the effects of brief interventions on BGL and BP;

6. Given the costs associated with the development and delivery of the interventions, future trials should undertake economic evaluations to assess the impact of brief interventions;

7. Prospective trials in this subject need to be more robust in order to assist clinicians and policy makers in making informed decisions about the appropriate use of brief structured interventions for risk factor modification.
4.18 Conclusion
In this chapter, the effect of structured brief interventions for lifestyle modification in patients with known CHD has been reported. Although 17 trials were included in the review, the effectiveness of brief structured interventions for risk factor modification in patients with CHD is limited due to the small number of studies assessing each outcome. However, there is suggestive but inconclusive evidence that brief interventions targeted at multiple risk factors may lead to risk factor modification in patients with CHD. Findings from this review also provide a guide for the optimal length and frequency and the mode of delivery of the brief intervention. These findings were used for the development of the HeLM intervention.

4.19 Implications for the development of the HeLM intervention
Given that the benefits of brief intervention for risk factor reduction warrant further investigations the HeLM was designed

1) to be a brief structured intervention based on motivational support and the FRAMES strategy
2) to have three telephone calls over a 6-week period each lasting 15-30 minutes for motivational support
3) to have telephone support delivered by a health professional who received some training in motivational interviews.
Chapter 5

Implementation of the Cardiac Evidence-Based Reducing risk in heart disease Guidelines (ICEBRG)
5.1 Introduction
This chapter reports the findings of the ICEBRG (Implementation of the Cardiac Evidence-Based Reducing risk in heart disease Guidelines) study. The chapter will present the findings of this study using a mixed-methods approach to identify the barriers and facilitators to implementing the “Reducing Risk In Heart Disease (RRIHD) 2004: A summary guide for preventing cardiovascular events in people with coronary heart disease evidence-based guidelines” (Appendix 1). In brief, these guidelines provide health professionals with evidence-based information for coronary risk factor modification following an acute cardiac event. This study was undertaken as part of describing the context and generates information for informing the HeLM intervention, discussed in Chapter 6.

5.2 Cardiac rehabilitation within the Australian context
The cardiac rehabilitation model of secondary prevention has been described in Chapter 2. The provision of CR services has gradually increased in Australia over the past 15-20 years. According to the NHFA, there are approximately 300 programs across the country. A system of universal health coverage exists in Australia and participation in CR is endorsed by policy and best practice guidelines. These services are available across a range of settings, and in many facilities, referral of patients following a cardiac episode is automatic. With the exception of those CR programs provided in private hospitals, the majority of CR programs are offered at no cost to the participants. Given that the small population in Australia is distributed over a vast geographic expanse, there is a wide variation in the distribution of programs and levels of service provision. The majority of CR services are group outpatient-based programs conducted in hospitals and community centres. In rural areas, home-based and outreach programs have been developed in response to variable resources and issues in accessibility. Generally CR programs are conducted by a team of multidisciplinary health professionals. Most of these programs include an exercise component, as well as psychological and educational interventions. The programs range from 6 weeks to 6 months, with some programs
Partners and other family members are encouraged to attend the programs with the participants.

In spite of an impressive evidence base informing practice, as discussed in Chapter 2, a number of barriers exist in ensuring participation in CR services.\textsuperscript{9,38,69,316} As a consequence a large number of people may not have access to evidence based practice guidelines. Coordinators of CR programs are well positioned to have an understanding of the barriers and facilitators to service delivery. Describing these factors is important in informing future health interventions and models of health care intervention.

5.3 Aim of the Study

The aim of the ICEBRG study was to identify the perceptions of CR coordinators regarding the barriers and facilitators to adhering to evidence based guidelines, specifically the RRIHD Guideline.\textsuperscript{401}

This study was undertaken to answer the following questions:

1. What are the barriers and facilitators to the implementation and adoption of the RRIHD guidelines?
2. What strategies do CR coordinators adopt to facilitate implementing best practice guidelines?
3. What are the perceptions of CR coordinators about the reasons for low participation in CR programs.

5.4 Mixed-methods as a research design

The study used a mixed-methods (qualitative and quantitative), descriptive and exploratory approach to address the research questions. Mixed-methods were used for this study as they provide distinct yet complementary information\textsuperscript{402} for the implementation of the evidence-based guidelines. Quantitative methods allowed generating data describing program characteristics and whilst qualitative data allowed the exploration of the individual CR program’s perspectives of the barriers and facilitators to optimal service provision. Several advantages have been reported from using a combination of different methodological perspectives. Firstly, research involves both theoretical and applied knowledge, and the application of findings in

having a maintenance stage.\textsuperscript{318}
clinical practice. Using combined methodologies increases the potential of the research to address these discrete yet interrelated facets of clinical practice. In addition, this method adds rigour to the study as it allows the researcher to address practice and policy issues with integration and synthesis of data obtained from both perspectives. This approach was used to identify the barriers and strategies adopted by CR program coordinators in implementing the recommendations from the evidence-based guidelines to reduce risk in people with established CHD. Quantitative methods are useful in identifying relationships and patterns, using reductionist methods. This method was used to describe characteristics of CR program participants.

The framework used for reporting the results of the qualitative interview and the survey is in accordance with a sequential exploratory mixed-method design, where collection and analysis of firstly qualitative data was undertaken, and then quantitative data. This design was used to confirm information emerging from the qualitative analysis.

5.5 Sampling Strategy

In order to obtain information from CR coordinators from both rural and metropolitan areas, a comprehensive sampling strategy was selected to include all CR programs in New South Wales (NSW). NSW has the highest population of all Australian states, and is a heavily urbanised and industrialised state. The CR programs in NSW were identified from the directory maintained by the NHFA (NSW Branch). These programs were then classified according to the Accessibility/Remoteness Index of Australia (ARIA+), which is widely accepted as Australia's most authoritative geographic measure of remoteness and is also endorsed by the Australian Bureau of Statistics (ABS). The ARIA+ category is calculated from measures of road distance between populated localities and service centres. These road distance measures are then used to generate a remoteness score for any location in Australia. ARIA+ is a continuous varying index with values ranging from 0 (high accessibility) to 15 (high remoteness) (Table 5.1). This classification system was used because it has been reported to be purely a geographic measure of remoteness, excluding any consideration of socioeconomic status, rurality and population sizes. This system of classification also provides a measure of remoteness.
that is suitable for a broad range of applications, including assisting in service planning, demographic analysis and resource allocation.  

5.5.1 Method used for calculating ARIA+ Score

The software available on the ARIA+ website was used to calculate the ARIA+ Score. The software required the operator to enter the postcode of the CR program centre and then the ARIA+ score was calculated for each centre using a formula embedded in the software. Postal codes for all CR programs were obtained from the CR program directory. Following the calculation of an ARIA+ Score, all CR programs were classified as Highly Accessible, Accessible, Moderately Accessible, Remote and Very Remote, using the breakpoints developed by the ABS (Table 5.1, Figure 5.1).

Table 5.1 ARIA+ Categories

<table>
<thead>
<tr>
<th>Score</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 0.2</td>
<td>Highly Accessible</td>
</tr>
<tr>
<td>0.2 - 2.4</td>
<td>Accessible</td>
</tr>
<tr>
<td>2.4 - 5.92</td>
<td>Moderately Accessible</td>
</tr>
<tr>
<td>5.92 - 10.53</td>
<td>Remote</td>
</tr>
<tr>
<td>10.53 - 15.00</td>
<td>Very Remote</td>
</tr>
</tbody>
</table>

Figure 5.1 NSW map according to ARIA+ categories  

5.5.2 Justification for the sample size

Purposive sampling was adopted, selecting participants who had first-hand experience with the phenomenon under investigation.\(^{405}\) A sample size of 4-10 organisations has been previously recommended for a qualitative multiple site study.\(^{410}\) Based on this information, a decision was made to include 25% of the CR programs within each ARIA+ category. It was considered that the sampling strategy, achieving representation of a range of service delivery perspectives, together with the extant literature would provide illuminating information to develop the HeLM intervention described in Chapter 7.

5.5.3 Selection of CR programs

The allocation of CR programs for inclusion in the study was undertaken by a researcher not associated with the conduct and transcription of the interviews and data analysis. A two-stage approach was used to select CR programs for the project. Firstly, the names of all CR programs, including their ARIA+ category, were entered into a software package, Statistical Package for the Social Sciences (SPSS) 13.0. Secondly, each CR program was then allocated a random number which was generated by the software program. The names of the CR programs were removed and the list was sorted according to the ARIA+ category. Twenty-five percent of the CR programs within each category were then randomly selected using the random selection features of the software. This method was selected in order to obtain representation from all five geographical categories.

5.5.4 Recruitment of CR coordinators

Two methods were used to invite the randomly selected CR coordinators to participate in the study. Firstly, a personally addressed cover letter, along with a participant information sheet (Appendix 9), outlining the aims and method of the study as well as the interview process was mailed to all randomly selected CR coordinators. Secondly, as approximately 10% of the letters were returned as recipients could not be located, an electronic version of the cover letter and the participant information sheet was sent using email addresses from the CR program directory two weeks following the initial invitation. A date and time for the interview was organised for those who responded.
Overcoming issues with recruitment

Cardiac rehabilitation coordinators who did not respond to the mailed information were contacted by telephone. If they agreed to participate, an interview date and time was arranged. Three attempts were made to contact the non-responding coordinators and messages were left on their answering service. In some areas, the CR coordinator listed in the directory no longer worked in the area; therefore, attempts were made to identify the CR coordinator for that area and the person was invited to participate in the study. This method did not bias the selection process, as CR sites rather than CR coordinators were randomly selected.

5.6 Ethical considerations

Approval was obtained from the Human Research Ethics Committee Sydney South West Area Health Service (Western Zone) to protect the safety, rights and freedom of the participants. Approval was obtained from the Human Research Ethics Committee Sydney South West Area Health Service (Western Zone) to protect the safety, rights and freedom of the participants.405 (Appendix 10).

5.6.1 Informed consent

A participant information sheet was developed explaining the aims and design of the study as well as the interview process and the ethical approval. Cardiac rehabilitation coordinators were informed that participation was voluntary and their decision not to participate would have no effect on their professional or personal relationship within their Area Health Service. All participants were mailed a consent form (Appendix 11). The consent form included details according to the NHMRC requirements, regarding the purpose and methods of the study, length of time for the interview, form of publication of research results and the freedom to withdraw at any time during the study. Establishing a date and time for the interview was considered as a form of consent. On the day of the interview, prior to commencing, verbal consent was obtained, permission to voice record was confirmed, and this agreement was also voice recorded.

5.6.2 Maintaining privacy and confidentiality

Numerical unique identifiers and password-protected files were used to maintain participant privacy and confidentiality. The master list for these unique identifiers was stored in a locked filing cabinet, accessible only to the researcher and destroyed at the end of data collection. Completed questionnaires, interview recordings and
transcripts of the personal interviews are stored in locked filing cabinets at the Centre for Applied Nursing Research (CANR) and are accessible only to designated research personnel. The results are reported in a de-identified manner to protect the rights of the individual participants.

5.7 Methods of data collection
The data collection methods were designed to seek information regarding:

1. the barriers and facilitators to the implementation and adoption of the RRIHD guidelines?
2. strategies adopted by CR coordinators to facilitate implementing best practice guidelines?
3. the perceptions of CR coordinators about the reasons for low participation in CR programs.

The two methods used to collect data included qualitative telephone interviews (Appendix 12) and a self-administered survey (Appendix 13).

5.7.1 Interviews as a data collection method
Qualitative interviewing is a method of data collection that is widely used in health research, including nursing, allied health and social work. While interviews have mainly been used to provide the whole or majority of the data needed in qualitative research, interviews of exploratory nature have also been conducted to determine suitable questions for the development of questionnaires. With the growing use of mixed-methods research, qualitative interviews are now being used increasingly for data triangulation, to augment the comprehensiveness and validity of a single study and to obtain further information on interesting or unexpected findings.

For this study, interviews were conducted using the telephone rather than face-to-face or using focus groups in order to assist the inclusion of CR coordinators from a wide geographical area. In addition, this method also enabled coordinators to participate at a time suitable to them without the need to travel long distances. Although the telephone interviewing method has benefits, it also has some disadvantages. Firstly, telephone interviews do not allow for visual cues and the ability to view the participant’s body language, which provide valuable information
in a qualitative study. As this study focussed primarily on health service delivery related information, the need to explore personal perspectives was not a key focus of the study minimising the need for face to face interviews. Secondly, as the participants in this study were professionals in CR, the telephone interview method was therefore appropriate as it maintained some form of anonymity, which added richness to the data.

5.7.2 Surveys as a data collection method
Data relating to the diagnosis of patients, staff working in the CR programs were collected and barriers to participation in CR programs was collected using a postal survey as participants were not able to provide this information over the telephone. The postal survey is a commonly used data collection method that has been reported to have numerous advantages. Firstly, this method allows access to widely scattered samples across local, regional and national geographic locations, which was particularly important for this study as the participants worked within a 1,000 km radius from the research centre. Secondly, postal surveys can be conducted at a low cost relative to other traditional methods of surveying. It has been reported that postal surveys cost half the price of a telephone survey and a quarter of the cost of administering face-to-face surveys. Thirdly, postal surveys allow the respondent to complete them at their own convenience, which for this study was imperative given the busy schedules of the participants. In addition, respondent anonymity could be protected through various methods. Fourthly, postal surveys do not allow for personal contact with the respondent, therefore there was minimal chance for personal bias based on first impressions to alter the responses to the survey. Finally, by using the postal survey method, the same instrument can be sent to all participants, thus minimising the risk for interviewer bias.

The qualitative telephone interviews were conducted using an interview schedule and the survey was conducted using a self-administered questionnaire.

5.7.3 Design of the interview schedule
The interview questions were designed to encourage participants to provide details of the strategies, barriers and facilitators in the implementing of best practice guidelines process, and other strategies they would use in an ‘ideal world’ to adhere with recommendations. The interview schedule consisted of structured questions with an
opportunity to extend beyond the prepared questions. Questions were both closed and open-ended. The interview topics were informed by the RRIHD evidence-based guidelines\textsuperscript{401} and the NSW Policy Standards for Cardiac Rehabilitation.\textsuperscript{416}

The interview schedule consisted of 13 sections. The first section comprised of two questions that were designed to identify the CR coordinators’ knowledge of the guidelines and whether patients were assessed for their stage of change. Sections 2 to 9 comprised five questions each and were targeted at smoking cessation, nutrition, reduction in alcohol consumption, physical activity, weight management, lipids, blood pressure and diabetes control. The first question in each section was aimed at identifying strategies currently used to address the risk factor, e.g. smoking. This open-ended question allowed the CR coordinator to describe all the strategies used to address the risk factor. The second question involved rating the seven predetermined processes to implement the key guideline recommendations\textsuperscript{401} on a five-point itemised rating scale, anchored from 1 = very poor at the lowest end of the scale, to 5 = very good at the highest. The third question comprised six items and was based on the stages of change.\textsuperscript{205} This question related to monitoring the number of patients who have modified their risk factors. The fourth question was open-ended and CR coordinators were asked to describe the barriers they perceived in implementing guideline recommendation. The fifth question related to the strategies CR coordinators would implement if they were given the resources they perceived to be necessary to deliver effective services and meet guideline recommendations. Both positive and negative experiences relating to implementing the guidelines were explored including barriers and available resources. Monitoring of the patients’ employment status and strategies for return to work were investigated in section 10.

Questions in Sections 11 and 12 aimed to identify the extent to which the pharmacological and non-pharmacological, including lifestyle recommendations, were implemented and the barriers to these interventions. Section 13 was designed to investigate psychosocial assessment undertaken within programs and support strategies used by CR coordinators.
5.7.4  Design of the self-administered questionnaire

The items in the self-administered questionnaire (Appendix 12) were generated from a comprehensive literature review and consultation with key informants. Principles of questionnaire development were used, such as the items reflected area of interest and the questionnaire was relatively simple and unambiguous. Stringent efforts were made to avoid long questionnaires that would be relevant to only small proportions of the sample.\textsuperscript{417} Likert scales were included so respondents could rate the level at which they agreed or disagreed with a given statement.\textsuperscript{418} A questionnaire comprising of 19 items that explored the following attributes was developed:

a)  \textit{Demographic data} included the location and commencement year of the CR program, professional designation of the coordinator, the number and type of professionals working in the program and the amount of time each dedicated to the program. Information describing program participants was also sought.

b)  \textit{Attendance at CR programs} Number of patients who attended and completed a program in 2004.

c)  \textit{Referral patterns} for enrolment and attendance at programs in 2004.

d)  \textit{Barriers to referral} to an outpatient CR program. Factors influencing barriers to referral were identified from the literature\textsuperscript{38,69,316} and seven barriers to referral were scored on a five-point itemised rating scale, anchored from 1 = strongly agree to 5 = strongly disagree. In addition, CR coordinators were also asked to identify other barriers to referral that were not listed.

e)  \textit{Barriers to attendance at an outpatient CR program}. Factors influencing barriers to attendance were identified from the literature.\textsuperscript{69,316} CR coordinators were asked to score the 15 barriers to attendance on a five-point itemised rating scale, anchored from 1 = strongly agree to 5 = strongly disagree. In addition, the coordinators were also asked to identify other barriers to attendances that were not listed.

5.7.5  Pilot testing the interview schedule and the self-administered questionnaire

Pilot testing a data collection instrument is vital prior to implementation to reduce ambiguity and redundancy.\textsuperscript{419} The self-administered questionnaire and the interview
schedule were piloted to ensure comprehension and accuracy of the technical terms used. It also made certain that the questions were clear and unambiguous to the respondent. In addition, undertaking the pilot test established whether the data collection tool was a burden for the respondents.405,414,420

Approach to pilot testing
Pilot testing was done using three CR coordinators randomly selected from the CR directory, one of whom no longer practised in the area. All three had extensive experience in CR. Based on their comments, several significant amendments were made in the format as well as the phrasing of the interview questions. They also confirmed the estimated time required for the self-administered questionnaire and the interview schedule. Data obtained from these pilot participants were not included in the final analysis.

5.7.6 Conducting the qualitative interview
This study adopted an interview guided approach,402 a widely used format for qualitative interviewing. This approach enabled the interviewer to have a list of questions on the various topics that were to be explored during the interview to ensure that all of the key issues were explored with each participant. Using this method, the interviewer was able to vary the phrasing and order of the questions without compromising the study.402 In addition, this method also allowed for data collection to be more methodical and comprehensive compared to traditional informal conversational interviews, while the style remained fairly conversational and informal.402 All participants were sent an electronic copy of the interview guide (Appendix 12) when the appointment for the interview was scheduled. The researcher felt that if respondents read the questions before the interview, they would have time to think and plan their responses and reflect on the CR activities performed at their centre. All interviews were conducted in a closed, quiet office by the researcher who is skilled and experienced in conducting telephone interviews.414 Prior to commencing the interviews, participants were informed that since the interviews were long they could ask the interviewer to take a break at any time during the conversation. It is important in qualitative studies that participants and researchers develop a trusting relationship that fosters sharing sensitive information.421 Extensive efforts were made while setting up the interviews to
promote a greater sense of relationship between the participant and the researcher. In addition, during the interviews the trust was strengthened by addressing the issues of concern to the participants. All participants were engaged in the interviews as valued, informed, and active members of the study. During the interview, probing for more in-depth responses or to guide the conversation was also undertaken at the interviewer’s discretion to ensure that all topics on the outline were covered. Interviews lasted from 60-90 minutes.

5.7.7 Establishing the trustworthiness of information

Establishing trustworthiness of qualitative data is an essential component of the study design and conduct. Trustworthiness is established by strategies that are set up before information gathering begins, and is monitored throughout the conduct of investigation. The strategies used in this study are discussed below.

Engagement of the researcher with the research issues and potential participants

Investing sufficient time in developing a thorough understanding of study participants and the issues they face is vital to the production of credible qualitative data. Therefore, prior to commencing the interviews, the researcher established rapport with the participants by discussing the purpose of the study and also immersing herself in the issues facing CR coordinators and key informant interviews with the NHFA, Cardiac Rehabilitation Association (NSW), NSW Health Chronic Care Unit to identify key issues faced by CR coordinators. Item generation for the survey and interview schedule were generated by integrative review methods and key issues outlined in Chapter 2. A respectful attitude to the needs, vulnerabilities of the study participants was made by the research team. The researcher also clearly articulated her biases that might have crept into the study during the interview for example the barriers faced by her in encouraging PCI patients to participate in CR.

Methodological triangulation

The most important issue is that trustworthiness of findings is checked and cross-checked by triangulation which is a process using a combination of research methods. One type involves the convergence of multiple data sources. Another type is methodological triangulation, which involves the convergence of data from multiple data collection methods. A third triangulation procedure is investigator
triangulation, in which multiple researchers are involved in an investigation. For this study methodological triangulation which is an attempt to improve validity by combining various methods in one study was used. The techniques used in this study were interviews and surveys.

**Feedback and discussion with the participants**

Providing feedback to the participants is a method commonly used to enhance the quality of the data. This feedback is generally conducted by member checking which involves sending complete transcripts to the participants for confirmation. However, it has been argued that member checking is often complicated by the varied social experiences of individuals that qualitative nursing research endeavours to clarify, thus often raising more questions than demonstrating confirmation or conclusion of analyses. In addition, member checking has been reported to be impractical and unethical at times and as well can make reporting of unpleasant findings difficult. Therefore in this study following discussions with the supervisors member checking was not undertaken. In this study, following the interview the researcher provided the participants with a short verbal summary of the discussion to ensure that their experiences had not been misrepresented. In addition, concepts that appeared to be of greater importance to participants were discussed in greater detail during the summary discussions at the conclusion of the interviews.

**Peer review/checking**

Peer review/checking is a method used to ensure that rigour has been maintained. This is done by presenting the process of data analysis to supervisors and colleagues not directly involved in the investigation processes. Criticisms obtained from this process assists in the clarification, decision-making and, if necessary, changes of direction during the conduct of the study. As a doctoral thesis, this investigation has been subject to scrutiny by supervisors, academics from the UWS School of Nursing and members from the NHFA (NSW Branch).

**Bracketing**

There is extensive literature that indicates a researcher may have had similar experiences within the context of proposed research objectives that remain highly significant to the data. In this study bracketing was used in which the researcher
set aside her prejudgements or biases during the data analysis in order to fully explore the information in the data itself, while putting previous knowledge aside.\textsuperscript{423} This posed a challenge to the researcher to separate any past knowledge or experience that she may have had in CR and then use that experience by connecting it interpretatively to the meanings of the respondents. To overcome this, the data was cross checked by an independent researcher.

**Maintaining an audit trail**

An audit trail consists of evidence of how the data were collected, analysed, and interpreted.\textsuperscript{423} For this study, the researcher maintained a diary throughout the project that included her ideas, motivations and discussions held with colleagues, which provides evidence of how and why decisions were made in the process of working with the data.\textsuperscript{423} Paper copies of the interview data have been retained in a secure location.

### 5.8 Managing the interview data

Managing the interview data is important as qualitative interviewing generally generates large volumes of information.\textsuperscript{414}

#### 5.8.1 Note taking and audio taping the interviews

In order to capture the content of the interview, notes were written, as it is not possible to write a complete transcript of the conversation.\textsuperscript{402} However, taking notes has been reported to distract the interviewer from the focus of the conversation, resulting in loss of critical information.\textsuperscript{424} In addition, the notes taken might not provide adequate information if the researcher needs to review the original conversation. Therefore, the interviews were audio recorded\textsuperscript{425} to assist the researcher to recall discussions during data analysis.\textsuperscript{412} When compared to taking notes of a conversation, this method significantly decreases the likelihood of error or misinterpretation of the responses during data analysis. This method also enabled the process of confirmation and validation. It is well known that interviewing is a time-consuming process\textsuperscript{424} and the ability to reobtain any lost data is minimal, therefore high quality recording\textsuperscript{424} using a digital audio recorder Samsung YH 820 was undertaken.
5.8.2 Transcribing interviews

Transcribing an interview can be undertaken using various methods. For example, if the subtle communicative interaction between researcher and the participant is of interest, verbatim transcription is mandatory.360 This method includes transcription of all words as well as the manner in which they are spoken, that is, including pauses, interruptions and volume of speech. This level of detailed transcription is commonly used for conversation analysis and some types of discursive analysis. For the purpose of this study, content transcription of all recordings426 rather than verbatim or near verbatim was undertaken as the aim of the study was to identify the barriers and facilitators to the implementation of the evidence-based guidelines, therefore the researcher was solely interested in the content of the interview. Content method involves transcription of what is being said (i.e. the words alone) and ignoring the non-linguistic features of the interview.427 Transcription was undertaken by the researcher and a research assistant. The transcripts were then reread against the recording and corrections made as necessary.427 The length of the transcriptions varied from 15-25 pages.

5.8.3 Within-case analysis

A commonly used method for the analysis of multiple programs is to first conduct a within-case analysis. In this study each interview was treated as a case428 and a detailed description of each individual program and discussions with each CR coordinator was undertaken. All notes were reviewed within 72 hours after the interview and the within-case analysis428,429 was performed as soon as possible while the information was still fresh in the mind of the researcher. This preliminary analysis assisted in developing a thorough understanding of the contextual elements of CR programs as well as the perceptions of CR coordinators.429

5.8.4 Cross analysis

Within-case analysis was followed by a cross analysis to identify similar themes and patterns across all programs.428 Analysis was undertaken using a qualitative (Nvivo) program to determine emerging themes.430 Preliminary content analysis using free or tree nodes within Nvivo were used to specify barriers and strategies identified by CR coordinators for the implementation of the guidelines. A second member of the research team, who was not involved with the data collection, reviewed the
preliminary content analysis against the transcripts and the audio tapes. There were no discrepancies and undertaking this process validated the themes that emerged from the data. In the final stage of analysis, essential changes to the established themes were made and illustrative examples were identified by relistening to the audio recordings and reviewing the transcripts. The illustrative examples demonstrated the significance of the themes from the participants’ views.

5.9 Managing the data obtained from the postal survey

Following telephone interviews a postal survey was administered to the CR coordinators who participated in the telephone interviews to obtain information regarding their CR programs and services provided. Data obtained from the self-administered questionnaire was analysed using SPSS. Frequency distributions were utilised to describe the data in terms of nominal scales, such as the program demographics (Questions 1-8) and attendance at CR programs (questions 9-17). Means and standard deviations were used in analysing the Likert scale data, such as the barriers to referral and nonattendance at CR programs.

5.10 Findings

While the information from the telephone interviews provided a rich and lucrative data source to describe the barriers and facilitators to implementing the guidelines, the survey informed the issues arising from the telephone interviews such as participation rates in CR programs. Findings from the two data collection methods have been reported together to allow convergence and confirmation of the data generating the study themes.

5.10.1 Classification of CR programs and participation rates

A total of 126 programs were identified from the CR program directory maintained by the NHFA (NSW Branch) and were classified according to the ARIA+ categories. Approximately half the programs (43%) were located in moderately accessible areas and a quarter was located in highly accessible and accessible areas (Table 5.2). Following selection of 25% of the CR programs, 37 coordinators were invited to participate in the study.
Issues relating to nonparticipation

Twenty CR coordinators were available for the interview (Table 5.2). Various reasons for nonparticipation in the study were identified. Funding for one program had ceased and another had closed due to lack of patient participation. One coordinator initially indicated that she would participate, however was unavailable at the time of the appointment. Three refused due to lack of time, which is a common reason for nonparticipation in trials by health professionals. One coordinator refused as their policies were recently updated, another indicated that they sent their patients to other centres and the third refused because they were only recently appointed and lacked the experience. Despite having achieving a participation rate of 54%, the data obtained from the participants were considered critical in developing the HeLM intervention as these data gave a voice to practitioners working in the field striving to implement evidence based practice.

<table>
<thead>
<tr>
<th>Category</th>
<th>Total No. of CR Centres</th>
<th>25% selected</th>
<th>Participated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly Accessible</td>
<td>30</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Accessible</td>
<td>33</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Moderately Accessible</td>
<td>55</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Remote</td>
<td>7</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Very Remote</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>126</strong></td>
<td><strong>37</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>

5.10.2 Profile of CR coordinators

Registered Nurses (RNs) coordinated seventeen of the 20 CR programs. The remaining three programs were individually coordinated by a physiotherapist, occupational therapist or a speech pathologist. The number of years of experience as a CR coordinator ranged from 1-15 years. Half had undertaken a post graduate course in cardiac rehabilitation. Table 5.3 presents the profile of the CR coordinators.
<table>
<thead>
<tr>
<th>CR Coordinator</th>
<th>ARIA+ Classification</th>
<th>Year program commenced</th>
<th>Designation of CR program coordinator</th>
<th>Years of experience as a coordinator</th>
<th>Cardiac course undertaken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant 1</td>
<td>Accessible</td>
<td>1998</td>
<td>RN</td>
<td>7 years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 2</td>
<td>Accessible</td>
<td>2003</td>
<td>PT</td>
<td>3 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 3</td>
<td>Accessible</td>
<td>2000</td>
<td>OT</td>
<td>5 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 4</td>
<td>Accessible</td>
<td>2003</td>
<td>RN</td>
<td>2 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 5</td>
<td>Accessible</td>
<td>1995</td>
<td>RN</td>
<td>3 ½ years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 6</td>
<td>Accessible</td>
<td>1996</td>
<td>RN</td>
<td>3 ½ years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 7</td>
<td>Accessible</td>
<td>1996</td>
<td>RN</td>
<td>6 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 8</td>
<td>Accessible</td>
<td>2002</td>
<td>RN</td>
<td>1 ½ years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 9</td>
<td>Accessible</td>
<td>1988</td>
<td>RN</td>
<td>2 years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 10</td>
<td>HA</td>
<td>1997</td>
<td>RN</td>
<td>1 ½ years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 11</td>
<td>HA</td>
<td>1999</td>
<td>RN</td>
<td>3 years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 12</td>
<td>HA</td>
<td>2002</td>
<td>RN</td>
<td>3 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 13</td>
<td>HA</td>
<td>1997</td>
<td>RN</td>
<td>8 years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 14</td>
<td>MA</td>
<td>1997</td>
<td>RN</td>
<td>3 ½ years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 15</td>
<td>MA</td>
<td>1996</td>
<td>RN</td>
<td>9 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 16</td>
<td>MA</td>
<td>1998</td>
<td>RN</td>
<td>15 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 17</td>
<td>MA</td>
<td>2002</td>
<td>SP</td>
<td>3 years</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 18</td>
<td>MA</td>
<td>1994</td>
<td>RN</td>
<td>12 years</td>
<td>Cardiac Cert.</td>
</tr>
<tr>
<td>Participant 19</td>
<td>MA</td>
<td>N/A</td>
<td>RN</td>
<td>filling in</td>
<td>No course</td>
</tr>
<tr>
<td>Participant 20</td>
<td>MA</td>
<td>1998</td>
<td>RN</td>
<td>1 year</td>
<td>Cardiac Cert.</td>
</tr>
</tbody>
</table>

Highly Accessible (HA); Moderately Accessible (MA); Occupational therapist (OT); Certificate (Cert.); Speech pathologist (SP); Physiotherapist (PT); Not Available (NA)
5.10.3 Description of the programs
Fifteen of the 20 CR programs were located in the hospital setting. The remaining programs were located in the community setting or were home-based. Five CR coordinators indicated that they provided both hospital and community-based CR services. The length of the programs varied between three days and 12 weeks. The majority of the coordinators (n=13) indicated that their programs were conducted over six weeks. Only three coordinators, all from the highly accessible areas, reported that they provided CR services five days of the week. The remaining stated that they were funded to offer services for four (n=1), three (n=1), two (n=6), and one (n=7) day each week. One coordinator indicated that they provided services on a needs basis and another stated that they conducted four programs per year. All programs were conducted during normal working hours, although three coordinators indicated that they also offered programs in the evenings (n=2) and on weekends (n=1).

5.10.4 Staffing in the CR programs

Nursing staff
The CR coordinators were employed from 8 hours/week to 40 hours/week. Aside from the nurse CR coordinators, only five other programs had RNs employed in the program. These RNs were employed from one hour/week to 24 hours/week. In two programs where the coordinator was not a nurse, patients were referred to nursing services for nursing management. Eighteen coordinators indicated that they had no Enrolled Nurses (ENs) in their program; however one indicated that they appointed an EN to conduct the exercise program 2 hours/day for 2 days of the week and the other had an EN work for 56 hours/year in the program. None of the programs included Assistants in Nursing in the team.

Allied health staff
Seventeen coordinators indicated that they did not have an exercise physiologist (EP) in the program, although seven had access to referral to an EP. Almost all had access to a PT, ranging from 1 hour every 6 weeks to a full-time PT. Three coordinators indicated that they had no immediate access to an OT, however they could refer patients to private OTs. Sixteen coordinators indicated that they had some access to a
dietician. Some dieticians participated in the program for 1 hour every 6 weeks, while in some programs a dietician was available only for referral services. Ten coordinators indicated that they had no pharmacist in the team, one indicated that they was only one pharmacy in town, while another stated that the “pharmacist was old-fashioned and not interested in education”. The remaining stated that the pharmacist provided education on medications during the CR sessions. Access to a social worker varied among the programs ranging from no access to access for one hour every 3-8 weeks. Only one coordinator indicated that a cardiologist was part of the team and conducted sessions for one hour every 6 weeks. Another coordinator indicated that the nearest cardiologist was 100 km away. Similarly access to a psychologist was limited with the majority (n=14) of the coordinators indicating that they had no access to a psychologist.

5.10.5 Waiting lists for CR participation
The majority of the participants (n=12; 60%) indicated that there were no waiting lists for participating in CR programs. One coordinator indicated that there was a waiting period at certain times of the year, while another stated that patients could join at any time. Four reported that they had a waiting list and therefore they referred patients to other programs closest to the patients’ home. When questioned about the longest time patients had waited to participate, two coordinators indicated that patients had to wait for no longer than two weeks, four said that patients had to wait for a month, and one stated that patients had to wait up to 22 weeks.

5.10.6 Referral to CR
According to the RRIHD guidelines all patients should be actively referred to CR following an acute event, therefore participants were asked if they felt that all patients were referred to CR. Only five of the 20 participants indicated that all patients were referred. The majority (n=8) reported that all patients were not referred and the remaining (n=7) were unsure. The majority of the participants reported that patients were referred by nurses from other hospitals that were within other ARIA+ regions. Table 5.4 presents the health professionals who refer patients to CR.
### Table 5.4 Health professional who refer patients to CR

<table>
<thead>
<tr>
<th>Referral by</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse on the ward</td>
<td>8</td>
</tr>
<tr>
<td>Nurse from other hospital</td>
<td>13</td>
</tr>
<tr>
<td>GP</td>
<td>6</td>
</tr>
<tr>
<td>Cardiologist</td>
<td>9</td>
</tr>
<tr>
<td>Community nurse</td>
<td>2</td>
</tr>
<tr>
<td>Self-referral</td>
<td>2</td>
</tr>
</tbody>
</table>

#### 5.10.7 Participation in CR according to diagnosis

Only three coordinators were able to provide data about the participation rates according to the patients’ diagnoses. The remaining stated that they were unable to maintain databases of patients’ participation due to lack of resources. Patients who had CABG and myocardial infarction were the main participants in CR.

#### 5.10.8 Reasons for nonparticipation in CR programs

Only 11 of the 20 participants responded to the question relating to reasons for patients not participating in CR programs. There was a wide variation among the coordinators in their ratings for reasons for nonparticipation in CR programs. As the data in each cell were too few, the strongly agree and agree cells were collapsed as were the strongly disagree and disagree cells. A large proportion of coordinators agreed that not being informed of a program and not being contacted by staff were the main reasons for nonparticipation. Coordinators disagreed that nonparticipation was due to waiting lists and fear of pain. A detailed description of the reasons for nonparticipation is presented in Table 5.5.
Table 5.5 Reasons for nonparticipation in CR programs

<table>
<thead>
<tr>
<th>Reason</th>
<th>Strongly agree</th>
<th>Unsure</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not informed</td>
<td>6 (30%)</td>
<td>5 (25%)</td>
<td></td>
</tr>
<tr>
<td>Waiting list</td>
<td></td>
<td>11 (55%)</td>
<td></td>
</tr>
<tr>
<td>No contact by staff</td>
<td>9 (45%)</td>
<td>2 (10%)</td>
<td></td>
</tr>
<tr>
<td>Lack of support</td>
<td>5 (25%)</td>
<td>3 (15%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Dr said it was unnecessary</td>
<td>3 (15%)</td>
<td>3 (15%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Unnecessary personally</td>
<td>3 (15%)</td>
<td>8 (40%)</td>
<td></td>
</tr>
<tr>
<td>Class not suitable</td>
<td>6 (30%)</td>
<td>5 (25%)</td>
<td></td>
</tr>
<tr>
<td>Do not like groups</td>
<td>5 (25%)</td>
<td>3 (15%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Too far from home</td>
<td>6 (30%)</td>
<td>1 (5%)</td>
<td></td>
</tr>
<tr>
<td>Do not have time</td>
<td>5 (25%)</td>
<td>6 (30%)</td>
<td></td>
</tr>
<tr>
<td>Lack of family support</td>
<td></td>
<td>11 (55%)</td>
<td></td>
</tr>
<tr>
<td>Lack of motivation</td>
<td>4 (20%)</td>
<td>5 (25%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Fear of pain</td>
<td>1 (5%)</td>
<td>3 (15%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Language difficulties</td>
<td>1 (5%)</td>
<td>3 (15%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Conflict with work</td>
<td>5 (45%)</td>
<td>4 (36.4%)</td>
<td>2 (18.2%)</td>
</tr>
</tbody>
</table>

% relates to overall participants

5.10.9 Knowledge of the RRIHD guidelines

Nineteen CR coordinators (95%) indicated that they knew about the RRIHD guidelines. However during the telephone interview it was established that some CR coordinators were not aware of the target lipid, blood pressure and referral to CR recommendations reported in the guidelines.

5.10.10 Stage of change assessment

Only two CR coordinators reported that they assessed the patient’s stage of change as recommended in the RRIHD guidelines. The remaining indicated that informal assessment was undertaken as they believed that formal assessment was not an appropriate strategy and that the stages of change questionnaire was too formal. Other reasons for not assessing the patient’s stage of change were the lack of resources that were available to manage any results that might arise from the assessment. For example assessment of the patient’s stage of change for fat intake could reveal the lack of finances to purchase healthy food and CR coordinators had no resources to support these patients.
5.10.11 Performance indicators for CR
All CR coordinators indicated that they had very good processes in place within the limited resources to assist patients with risk factor modification. For patients who smoked, CR coordinators indicated that they encouraged them and their families to stop smoking and provided them with facts on the ill-effects smoking, referred them to the quit line and provided them with behavioural and psychosocial support. They also indicated that patients were advised to visit the GP for Nicotine replacement therapy. CR coordinators indicated that they encourage patients to choose healthy foods and referred patients to a dietician when necessary. All CR coordinators indicated that alcohol consumption was assessed at entry to the CR program however only half indicated that they advised patients about potential interactions with alcohol and their medications. CR coordinators indicated that they encouraged patients with hypertension who drank alcohol to limit their intake to 2 or less standard drinks per day. All CR coordinators reported that they discussed the need for physical activity and monitored patients’ progress, although few indicated that they provided written guidelines for everyday physical activity tasks. Monitoring both waist circumference and body mass index as a measure of weight management was reported by the majority of the participants, however only a few indicated that they set intermediate achievable goals for weight reduction and advised patients to see their GP for pharmacotherapy. All CR coordinators indicated that they assessed patients for diabetes and made appropriate referral when necessary.

5.10.12 Barriers, strategies and facilitators to implementation of the guidelines
This section presents results of the barriers, strategies undertaken to overcome the barriers and facilitators identified by the CR coordinators to implement the RRiHD guidelines. A range of factors were identified by coordinators and these were organised thematically into issues related to: (1) the Health Care System; (2) Professional and Provider Issues; (3) Program Characteristics (influenced by the health care system and profession and provider issues) and (4) Individual and Family characteristics. Examples of barriers and facilitators are summarised in Figure 5.2. In general, coordinators identified facilitators and barriers to the implementation of the guidelines that were opposite poles of the same construct. For example, lack of
funding limits the services provided and is therefore considered as a barrier, while adequate funding enables services to be provided and is therefore a facilitator. Figure 5.2 is a pictorial description of the barriers and facilitators to guideline implementation.

Figure 5.2  Pictorial description of the barriers and facilitators

The major themes identified clearly fitted across more than one of the three constructs relating to the health care system, health care professionals and the CR programs, therefore an integrative approach has been used to present these results. However, themes that related specifically to the individual and family have been presented separately.

5.10.13 Barriers to implementation of the guidelines

Themes that related to the health care system, health care professionals and the CR programs included obstacles to delivering cardiac rehabilitation services, challenges in achieving continuity and coordination, complexities in delivering evidence-based health care, commitment to best practice and striving to overcome the odds. Each of these are discussed below.

Obstacles to delivering cardiac rehabilitation services

A major theme emerging from the data was the number of obstacles the CR coordinators faced in delivering optimal services. This theme related mainly to the
program and the health care system characteristics, and included shortages of dedicated CR personnel, frustration with service inadequacies, lack of dedicated funding, and lack of access to equipment, GPs, specialists and risk reduction services.

Shortages of dedicated CR personnel
Many programs faced staff shortages and dealt with the challenges of fractional appointment of program staff. The majority of the CR coordinators reported that they were employed only part-time as their services were not perceived to be important by administrators. One CR coordinator stated:

“the way the program works here is that I work one day a week only in the program.”

Frustration with service inadequacies
CR coordinators from rural areas reported feeling frustrated that patients in their area were not receiving adequate health services. CR coordinators recognised that the problems relating to heart disease in the country and the city were the same and indicated that neither the government nor the NHFA had put enough resources into the programs run in country areas. One coordinator was annoyed and stated:

“the country people have just been left out.”

Implementing the guidelines requires the CR coordinator to assess the patient, provide education and evaluate patient outcomes. Participants disclosed that workforce and time shortages prohibited them from undertaking initiatives to assist implementation of the recommendations. Participants reported being “frustrated” as they could see the importance of patient assessment and maintaining electronic records as a useful tool for continuity of care. One CR coordinator expressed that:

“You know it is all very nice to maintain a database but if I was here full time it would work out well.”

Lack of dedicated funding and equipment
Few CR programs have dedicated funding, therefore suspension of services due to lack of funding is a frequent occurrence. One CR coordinator reported the inability to participate in the study as the CR service was suspended. In addition, maintaining
initiatives to provide services was reported to be difficult due to lack of dedicated funding.

“just getting funding to have this [working book] continued printing is a big thing for us.”

Another barrier that was frequently mentioned was the lack of sufficient physical resources and equipment to cover all aspects of comprehensive CR services. The NHFA recommends that a minimum data set be maintained for patients participating in a CR program. However, less than half the coordinators reported having appropriate resources to maintain the database. They indicated that although they would like to comply with the recommendations, limited access to office space and equipment prevented them from doing so. To meet the requirements of the NHFA the coordinators said that they wrote in patients’ notes and maintained paper copies of patients’ participation. One coordinator stated:

“I don’t have a computer at my work, I have to enter the information on my home computer.”

In addition to lack of resources for CR coordinators, limited equipment for patient use impacts on the quality of care. In some programs the coordinators do not have the necessary equipment to enable patients to modify their risk factors although patients were willing to attend programs:

“Over here we have only some old equipment which the patients use. It would be really nice to get the modern equipment, maybe then more patients will come.”

**Challenges in accessing health providers**

General practitioners are an integral part of patient care particularly in rural and remote areas, and patients generally rely on the GP for their health care and medication management. CR coordinators reported that in some areas patients found it difficult to make appointments with the GP and had to wait up to a month to make an appointment with the GP. Patients thus felt frustrated and did the next best thing, which was:

“turning up at the hospital which would in turn refer him/her back to the GP”.
They felt that this was a vicious cycle and as a consequence patients managed their illness and medications themselves, which could be detrimental.

The RRHID guidelines recommend referral to specialist services when required, yet referral to specialists and access to health services, such as drug and alcohol workers, pharmacists and dieticians was reported to be a major difficulty for many CR coordinators, particularly in the moderately and less accessible areas. As a result, coordinators reported feeling discouraged as they were not able to provide adequate services. They discussed how visits by an allied health specialist were “spasmodic” and that there were times when there was no access to services. One coordinator stated:

“They have to travel nearly 200 km to [name of place] to see an allied health specialist.”

Many coordinators also spoke about patients not being willing to travel long distances to see a specialist or attend a service, consequently these patients frequently developed complications, such as heart failure. Some coordinators pointed out that there were private clinics that offered services, however the lack of private insurance meant that patients had to remain on the waiting list to access a service or to see a specialist. One mentioned:

“We do the education but cannot go into depth like the pharmacist does and would appreciate the services of someone who is expert on the field.”

They also talked about having to inform patients who were motivated enough to adopt healthy habits, e.g. ceasing smoking, that frequently it was quite difficult to contact the referral services, which they felt discouraged participation. Coordinators reported that patients were willing to modify their behaviour, however there was no support that was readily accessible during this vulnerable stage.

**Continuity and coordination: a challenge**

The process of cardiac care usually involves many different settings and people. The second major theme identified as a barrier to implementing the recommendations was the lack of communication and continuity of care. These included referral from tertiary and procedural centres, gate keeping, and inadequate communication.
between providers and coordinators. Each of these sub-themes has been reported below.

**Referral from tertiary and procedural centres**

Effective communication between health care providers is essential to provide optimal care. Many coordinators discussed how referral from procedural hospitals to other hospitals was often poor or non-existent:

“"The bigger hospitals are not good at referring to smaller centres like myself.""

Others mentioned that they often experienced a delay in referral from tertiary centres:

“"The procedural hospitals wait till they get a whole heap of referrals and then fax [to the coordinator].""

They also discussed how the post-discharge letters from hospitals to GPs often lacked information about eligibility for CR. Some coordinators indicated that due to the lack of referral from tertiary centres, they focussed on primary prevention as many patients admitted to hospital with risk factors such as hypertension or diabetes with or without heart disease did not receive CR services. They suggested interventions to improve referral before hospital discharge, such as automatic referral to CR, routine systematic CR health education and information about local programs.

**Gate keeping**

Policies in some CR centres require the patient to obtain a referral from the GP, however despite efforts to have patients referred to CR services, coordinators identified another barrier, which was “getting past the receptionist”. They felt that the administrative staff at GP surgeries were unsupportive in referrals and frequently indicated that the GP was busy and that patients “would have to wait in queue”. Given the long waiting time to see a GP, particularly in the rural area, CR coordinators felt annoyed at the “gate keeping” attitude of the administrative staff.

**Inadequate communication between providers**

Poor communication between providers was another obstacle frequently mentioned by coordinators. They spoke about how it precluded them from assessing patients
who would benefit from CR. They discussed the difficulty in targeting patients who were transferred to other hospitals for cardiac procedures. One coordinator stated:

“We don’t know who have gone off to a cardiologist, then for an angiography up north and come back again.”

**Inadequate communication between CR coordinators**

Lack of support between the CR coordinators was reported to be another barrier to the adoption of recommendations. This was particularly the experience of those in the less accessible areas. They identified professional isolation as a problem, particularly when associated with geographic isolation; the issues being that they “had no one to bounce off” if clarification was required:

“I work in isolation and I don’t have anybody to discuss things with and brush shoulders with.”

They also stated that it was often not possible to attend professional development seminars “due to lack of resources”. Almost all coordinators in the less accessible areas revealed that they felt isolated and were frequently not informed of the recent developments in CR, and therefore were uncertain if they provided patients with the latest information. For example, one coordinator stated that:

“I tell my patients that a cholesterol level of 6.5 is fine, until now.”

**Complexities and challenges in delivering evidence-based care**

The third major theme that emerged from the discussions with the CR coordinators was the complexities in the delivery of evidence-based care. These complexities mainly related to the health care professional due to the unfavourable impact of the health care system and program-related characteristics shown in Figure 5.2. These complexities included variations in clinical practice patterns, lack of support from GPs, inadequate knowledge and skill level of clinicians, limited knowledge relating to the utility of CR and awareness of locally available programs, inability to access clinical guidelines and education and a lack of mechanisms for accountability and clinical governance.
Variations in clinical practice patterns

Wide variations in clinical practice among doctors that impacted on the delivery of evidence-based care were reported by coordinators. These variations related to referral of patients to CR, assessment and treatment of patients.

Referral and clearance from the GP are required for access to and participation in some CR programs. Coordinators reported reluctance by some GPs to refer patients to secondary, tertiary, specialist and CR services because individual GPs thought referring patients with multi-system problems or comorbidities was inappropriate, and considered themselves to be a “one stop shop”. Many of the coordinators also perceived that some GPs would delay referring patients because of the extra time and effort required to facilitate a referral. They felt that standard criteria for referral are needed if patients are to receive best available care. They also discussed their experiences of GPs who did not provide comprehensive care for the patients and only addressed the presenting problem. One coordinator reported that:

“The patient had a fractured knee but the GP just watched her getting bigger and bigger.”

Insufficient resources also influence the services provided. Some coordinators indicated that they did not refer patients to services if they felt that the patient was not motivated to change behaviour:

“If they don’t want to do it, I’m not going to waste my time.”

Others felt that if they made the appointment for the patients, the patient would feel compelled to attend, and would therefore have made the “first step towards behaviour change”. Some CR coordinators indicated that they believed in self-referral to health services if patients were keen to reduce their risk of further heart disease:

“I give them the phone number and they can call up.”

Some coordinators felt that referring patients to services was not part of their role and that management and follow-up of risk factors was the responsibility of the GP:

“I think that there is much more room for the GPs to be recommending quitting [of smoking] or referral to the quit line because I think that a lot of the time they are too hurried to take the time do that.”
Variability in assessment and treatment according to guidelines

Only two coordinators had positive attitudes towards formal assessment of patients. The remaining indicated that informal rather than formal assessment was undertaken because they believed that the latter was not an appropriate strategy as they would not able to provide services in case they identified a problem. Some coordinators discussed how they did not assess patients as they felt that it was not their responsibility:

“I do not assess the patient’s medication for potential interactions with alcohol; it is up to the GP.”

The lack of concordance between treatment and the best practice guidelines was reported by some coordinators who felt that this was directly related to individual clinical decision-making. Participants stated that some of the recommendations in the guidelines were beyond their scope of practice, e.g. prescribing medications, and that they had to rely on the GP to make the necessary changes. They felt that the RRIHD guidelines for treatment of cardiovascular risk factors in primary health care were not always carried out, as GPs were often reluctant to alter treatment for patients who had returned from tertiary hospitals following an investigation or procedure as:

“They [GPs] don’t like going against the cardiologist”.

In addition, they complained how many GPs, particularly in rural areas, under-prescribe medications, resulting in suboptimal care. They felt perturbed that patients were not receiving optimal treatment yet could not do anything as some of the GPs were also the patients’ visiting doctor at the local hospital. They reported having no formal strategies in place to assist their access to contact a cardiologist.

Engaging GPs is a challenge

Despite the numerous service-related challenges, coordinators stated that they made extensive efforts to deliver evidence-based care, but encountered lack of support from the GPs. They described how in many instances CR personnel had to wait until the GP ordered a consultation or referred a patient before making contact with the patient. In order to facilitate the referral process, some coordinators reported that they had discussions with the GP about the benefits of patients participating in CR.
Providing patients with information about their health has been reported to equip them with knowledge to modify their behaviour. Coordinators discussed how GPs were reluctant to provide patients with results of their blood pressure, cholesterol and blood glucose levels. A few CR coordinators reported that GPs:

“say it is fine or they increase their medication but do not tell them the numerical value.”

Coordinators felt that this resulted in an increased workload for them as they would have to contact pathology services, GP surgeries and hospitals to obtain results so that they could empower the patients. They also discussed how GPs did not trust their judgement and clinical skills:

“sometimes the GPs do not accept that the patient's BP is high and blame the technique or equipment used by nurses to measure BP.”

**Acknowledging the importance of skill and knowledge development**

Many participants were open about their lack of knowledge of evidence-based care. They acknowledged that providing evidence-based CR services required keeping up-to-date with the continuing advancement in health care technologies and described some challenges and an openness to address their self-perceived limitations. Some coordinators discussed how they were lagging behind in knowledge of the recent guideline developments and felt that it was harder to keep abreast of the literature due to numerous other work-related issues. In particular, one coordinator, who was not a nurse and did not have any other staff working with her, stated:

“I should know about cardiac medications but I just don’t have confidence into looking at someone’s medications and say why you are on this.”

The importance of coordinated relationships between the clinical areas and the teaching facilities was stressed. Collaborative efforts to promote knowledge transfer between guideline developers and the health professionals were clearly articulated by the majority of participants. Participants indicated that they used various assessment and education methods, such as patient information booklets and were not certain if these were evidence-based. Those coordinators who had a nursing background
indicated that their nursing skills assisted them during patient assessment. Those who did not have a nursing background felt that they could not always provide adequate assessment for the patients:

“I write down all medications. That is all about it, I guess I put my reliance on the GP which particularly might not be a good thing. I don’t know.”

The minimal availability of information and support to provide CR services was frequently noted by coordinators in non-metropolitan areas. They felt that if they were adequately resourced they would have better access to ongoing professional development opportunities and thus provide evidence-based care.

One participant discussed concerns regarding the level of staff working in the program. They felt that in some areas the programs were coordinated by non-specialist nurses with limited experience in coronary care. They felt that these nurses were working to the best of their ability but should be supported with rigorous training and coronary care skills to undertake comprehensive assessment of the patient and detect signs of complications.

All patients who have had an ACS are suitable for CR, according to the NHFA guidelines. Several coordinators expressed concern that some GPs were not aware of the benefits of CR for the different types of cardiac population, including the local availability of these programs. Although patients were encouraged either in hospital or by the coordinators to ask about CR, they were seldom referred. There was a concern that GPs did not see the importance of CR for the modification of single risk factors; rather, they only referred patients who were following bypass surgery. Some coordinators indicated that physicians not affiliated with a CR program lacked motivation to refer patients, believing that CR was not a priority.

Dissemination of guidelines should ideally include educational strategies to promote their implementation. A large proportion of the coordinators indicated that they found out about the guidelines from colleagues or when attending conferences. A few stated that they would have liked to receive formal notice of the guidelines. They felt that to implement some of the recommendations in the guidelines they would require further training, however the facility for education was not available. Some discussed how they did not have any formal training in CR and felt that to carry out
the role effectively they required specific cardiac education. They felt that education would provide them with the knowledge and skills to carry out their role. All coordinators stated that providing patients with motivational support would facilitate changing their risk-related behaviour, however most of them reported that they had received insufficient training in their undergraduate degree and in clinical practice and as a consequence did not have the necessary skills to promote behavioural change.

Some participants reported that some GPs are not motivated to refer patients to CR as they do not consider it a priority and there is minimal accountability and absence of incentives for them to do so. They were also concerned that primary care physicians did not see referring patients to CR as their role. One coordinator indicated that:

“So many of them have practice nurses, who give all the education – those practice nurses can’t know it all. GPs take control [for the patients care] and the patients don’t know.”

**Patient and family related factors to implementing evidence-based guidelines**

A range of patient and family factors related to adhering with the RRIHD guidelines. The themes identified included: coming to terms with a diagnosis of heart disease, personal barriers, challenges in changing behaviour, and having heart disease is costly. Each of these themes is discussed below.

**Coming to terms with a diagnosis of heart disease, acquiring knowledge, assuming responsibility and challenging recommendations**

Denial and desensitisation by overexposure to a number of health-related risk factors were identified as problems contributing to patients’ non-acceptance of their chronic medical conditions. This was another issue that posed a barrier to rehabilitation efforts. One CR coordinator indicated that:

“It is amazing that a number of people are obese or overweight but they don’t think they have weight problem.”

Half the coordinators reported concerns about the attitudes of clients towards CR services. They were particularly alarmed that in an attempt to have a healthy lifestyle, clients abandoned medical treatment and embraced alternate methods for
risk factor modification that might not have been based on evidence. One CR coordinator stated that clients talked about:

“strange girls doing things with natural packs of stuff and alternative lifestyle and they feel that they don’t need CR”.

The coordinators felt powerless because they could not convince the clients that CR was important as “they thought that [alternate treatment] is their bible”.

Numerous challenges in changing patients’ health-related behaviours were identified by participants.

The majority of the coordinators perceived a lack of self-responsibility among clients as they felt that patients were not adhering to treatment advice. Others indicated that clients depended on other people rather than being self-sufficient:

“You expect the government to spend thousands [of dollars] on your health but what are you doing towards your health?”

There was a perception amongst some coordinators that clients did not consider risk factor modification and health care immediate concerns. They felt that they should be more proactive to build a sense of self-responsibility among patients. One coordinator point out that alcohol and smoking were given priority by some patients over risk factor modification and health care services:

“I have offered him a referral to the [name of specialty] and he said he has got [name of illness] and smoking is what he wants to do.”

A lack of knowledge regarding risk factors for coronary heart disease among clients was another major barrier to providing evidence-based care. Some coordinators indicated that “it is not their [clients] fault that they don’t have the knowledge”, as this was a failure of the health care system. They discussed how “patients do not know their blood pressure or cholesterol levels” and therefore are unaware of the need for personal risk factor modification.

Other coordinators indicated that patients were aware of the risk factors but had limited knowledge about the strategies for modification of the risk factors. They discussed how patients thought that “pushing their boats up the ramp and then sitting and fishing all day” was exercise. In addition, some participants stated that clients
often gained information from their friends and families which frequently led to inappropriate strategies:

“they find out that statin is for lowering cholesterol then they stop it if their cholesterol is normal.”

In addition to the lack of knowledge about risk factors for CHD, coordinators felt that patients were not appropriately informed about their condition and that they came out of the procedural hospital “with the concept that they were cured”. Having to educate them that “it is not a cure but a repair job done” was reported to be a difficult task for the coordinators. They indicated that patients were more accepting of the information given to them while in hospital.

Changing behaviour is well known to be challenging, and coordinators discussed how sometimes patients lacked the motivation to adopt healthy lifestyles. They also talked about clients who felt that they were not able to engage in risk factor modification strategies due to their low socioeconomic status, which was a major barrier to guideline implementation. Some coordinators perceived that patients’ motivation to adopt healthy behaviour was influenced by their level of stress, medical and physical condition and comorbidities.

**Having heart disease is costly and access is not always easy**

Another theme that emerged from the interviews concerned the costs associated with accessing and using health services and following treatment recommendations for patients with heart disease. Some coordinators identified lower socioeconomic status and the costs associated with accessing health services as barriers for clients. Barriers in adhering to guideline recommendations relating to economic issues have been categorised into service-related costs, prescriptions-related costs and travel-related costs.

General practice consultations in many areas in NSW are covered by Medicare, which makes attendance at GP services affordable. However, wide variations have been reported in billing practices among GPs, with many not offering bulk-billing, particularly in rural areas. Study participants revealed that the billing practices resulted in increased out-of-pocket expenses for the patients. They claimed that many clients did not access services due to high costs and the lack of private insurance to
cover some of the associated fees of services not covered by Medicare. In contrast, one coordinator maintained that since Australia has a system of universal coverage, all patients have free access to CR programs and therefore they did not consider it as important:

“I don’t think people appreciate what they have got here as everything is free, including CR, and if there was a bit of cost they would probably make use of it and appreciate it better.”

Some coordinators considered their clients to be particularly disadvantaged by high pharmaceutical costs given their low socioeconomic status and the need for several medications for comorbid chronic problems. They identified financial difficulties and rising costs of prescriptions as a fundamental threat to adherence to medication regimes, as clients were becoming selective about the medications they purchased in order to reduce costs. This was evident in both older and younger clients. They also indicated that younger patients who are not supported by the Pharmaceutical Benefits Scheme often discontinue their medications, which is of concern as many need to continue their medications for at least a year to reduce the occurrence of another adverse event.

Geographic barriers identified by coordinators mainly related to rurality. Living in rural areas alone was a barrier to clients accessing health services, in terms of the limited health services provided for a small population spread over a large geographical area. This, in turn, forced clients to travel long distances to access basic health care from centralised services. One coordinator stated that although they referred clients to services:

“the distance from the city, it is one hour there and one hour back. Not everyone wants to go.”

The coordinators felt that many health providers not only did not understand the difficulties faced by people in rural areas, but also believed that failure to attend appointments or adhere to treatment was the client’s lack of interest, rather than recognising that it might be due to financial hardship. In addition, clients with multiple problems that necessitated multiple providers incurred additional transport costs. One coordinator stated that:
“they have to travel to bigger regional areas to obtain their medications, which costs more, particularly with petrol prices these days.”

**Pressure to return to work**

Indirect costs such as time off work were also identified by coordinators as a barrier to accessing CR services:

> “Some people don’t attend CR as they go back to work during the time we offer the program.”

They discussed how health promotion and screening activities in the workplace would be facilitators in health-related lifestyle modification. However, they expressed concern about management support to provide services in work time. The costs associated with purchasing healthy foods were another barrier identified, as they “do not come cheap”.

**Special factors to consider for the individual patient**

Individual barriers, including cultural issues, lack of social support and patients’ perceptions of health service providers, were other themes that emerged from the interviews in being important in achieving guideline adherence.

Cultural factors play an important role in CR program participation and guideline adherence. For example, coordinators noted that there was a low uptake of CR services among Aboriginal and Torres Strait Islander people. They talked about conducting a program at the Aboriginal centre to facilitate attendance from the Indigenous community. Another coordinator explained about her achievement in getting an Aboriginal woman in her mid-40s, who already had four infarcts, into the program.

An effective system of social support is important in facilitating effective health behaviours. There is also evidence that involvement of partners in the rehabilitation process is a critical factor in its effectiveness. Family involvement in CR programs was discussed by the majority of the coordinators, however they noted that often the family members did not actively engage in the risk modification behaviours:

> “I think it is very hard to give up if the family is still smoking.”
Some coordinators discussed the patients’ views regarding health service providers. They talked about patients not spending enough time informing the GP about their condition, believing that the GPs were “too busy to listen” to their problems. In contrast, others reported that patients hardly had any time to discuss their problems with the GPs. Another coordinator indicated that some patients declined to see other specialists “out of loyalty” to their GP. These situations created barriers to effective management.

5.10.15 Strategies employed to overcome barriers to implementation of the guidelines

The major themes identified under strategies employed to overcome the barriers to implementing evidence based guidelines included commitment to best practice and striving to overcome the odds. Each of these is discussed below.

Commitment to best practice

Another major theme that emerged from the interviews with coordinators was their commitment to best practice, despite the various barriers to implementing the guidelines. Incorporated within this major theme are the following sub-themes: doing the best we can, championing to provide evidence-based care, and providing practical knowledge.

Doing the best we can

Although most of the coordinators expressed frustration with the lack of staff, they all indicated that providing CR services on the best available evidence was vital and it was important for them to keep up-to-date with the recent developments in CR:

“I try to keep my practice up to speed with most things that is within my ability or within the budget and the service can provide.”

Participants discussed how despite the lack of resources, they provided innovative ways to deliver patient education and other services. While some developed their own information packages, others used the limited available resources sparingly. Some participants discussed how they used “the scare tactic” to encourage attendance at CR programs. They indicated that the scare tactic involved pointing out to patients the worst case scenario or associating their offending behaviour with the
worst possible outcome. They indicated that in some cases it was in the “best interest” of the patients, failing which many would have extensive complications resulting from heart disease. They also mentioned that “most cardiologists and some of the GPs do the same”.

To overcome the lack of referral, some coordinators indicated that they took additional measures to identify the patients who would be suitable for CR. They discussed how they “look at the emergency department presentations” and identify patients suitable for CR and then “follow them up with a phone call”. Others, particularly those in moderately and less accessible areas reported that they asked the family to contact them and felt that it was possible as it was a small community. They reported promoting the service by contacting the GPs and informing them of the CR programs. Some coordinators stated that despite their efforts they did not get any direct referrals from GPs.

Championing to provide evidence-based care
Providing feedback to members of the health care team has been reported to increase communication and enhance patient care. Most of the participants provided feedback to the GPs about the patients’ progress through the CR program. They also contacted the patients’ GP or cardiologist if they felt that the patients were not receiving optimal care. However, they reported that feedback from GPs to them was difficult to obtain. One CR coordinator said that:

“If we find someone without statin we follow that through with the GP or cardiologist.”

Identified in the major theme above, gate keeping was a major obstacle by some coordinators. However three participants stated that they circumvented the problem as they also worked as practice nurses in the GP’s surgery. They took the opportunity to discuss the patients’ problems with the GP during that role. Referring patients to services in order to receive evidence-based care was also mentioned by the coordinators. They mentioned that they personally organised the referral and made appointments for the patients:

“If we find somebody suffer [sic] from depression we would refer them to psychologists or ring the GP.”
Providing practical strategies to adhere to recommendations

CR coordinators discussed strategies they used to provide practical knowledge to promote a healthy lifestyle. Maintaining contact with patients following completion of the program to monitor their progress was one strategy reported. Activities such as “morning tea and cooking sessions” provided opportunities for coordinators to monitor patient progress and revise the content learned during the group program. They reported feeling encouraged because “people loved it”.

Striving to overcome the odds

Another major theme that emerged from the data was them striving to overcome the odds. They discussed the various approaches that they used to provide evidence-based care given the limited resources. These included education on the go, providing alternate methods of CR services, and community engagement.

Education on the go

Lack of time and staff did not prevent some coordinators from giving advice and education in other locations. They discussed how they provided education when they saw the patient “in the hospital for something else”. Others mentioned that living and working in a “small community” meant that they frequently saw “them at the supermarket” and they took the opportunity to provide education and shopping skills.

Providing alternate methods of secondary prevention

To overcome travel difficulties to services, coordinators provided home-based cardiac rehabilitation services to some patients, particularly the elderly. They felt that offering this service in the person’s own home could cut down on some of the travel costs as well as empower the patient to modify risk-related behaviour. Others scheduled the patient to consult more than one service during a visit to the centre to reduce travel.

Partnering and engaging with local communities

The success of health-related programs is largely dependent on partnership with, and leadership provided by, the local community. Participants described how they involved the local community in reducing risk factors for heart disease. This involvement ranged from providing education as well as spending time with other cardiac patients. They used community support and donations to organise activities.
such as walking groups that are mainly led by an ex-program participant. Support obtained from local restaurants regarding healthy cooking was also reported:

“our local restaurant runs a heart healthy day where all the food cooked is low fat.”

Engaging the “ambulance service to talk to them” was another community engagement strategy frequently mentioned. The use of the media to promote healthy behaviour was also discussed by the coordinators. Contributing articles to local publications as a method of community education about CHD was reported by five coordinators.

Some indicated that they had personally “been to the local gyms” to see “what they could offer for heart patients”. Another indicated that to facilitate implementation of the recommendations they encouraged patients to use the local sports centre.

Figure 5.3 presents a summary of the themes that were identified by participants relating to barriers and strategies employed to implement evidence based guidelines.
Figure 5.3  Summary of themes relating to barriers to implementing evidence-based guidelines

5.10.16 Facilitators to delivering evidence-based CR services

As discussed above facilitators and barriers to the implementation of the guidelines that were opposite poles of the same construct. Emerging from the data were factors assisting them in providing effective risk reduction services to the program participants as shown in Figure 5.2.

Adequate CR personnel and resources

Some coordinators from metropolitan regions indicated that they were adequately staffed compared to their colleagues in regional and rural areas, and having sufficient
staff was a major facilitator in the implementation of the recommendations. They mentioned that they maintained a database with people’s general details, diagnosis and risk factor profiles. Adequate staffing enabled them to undertake thorough assessments, provide education and teaching material as well as doing regular follow-ups at 6 months and 12 months and providing support thus empowering the patient. One coordinator stated that:

“we actually have a program, yeah, a real program.”

One coordinator discussed how she was able to better cater for the patients’ needs because they had adequate resources. For example, coordinators with sufficient resources reported telephoning the patients every week to monitor progress:

“people were more encouraged rather than a phone call 6 months down the track.”

Continuous professional development
All coordinators indicated the importance of continuous professional development opportunities to maintain and increase skills to enable effective practice. Some mentioned their education network that facilitated learning. Others spoke about the existence of clinical pathways as an educational tool for CR program staff. Attendance and presentations at seminars and conferences to facilitate knowledge expansion were also reported by some coordinators.

Collaboration and communication between health service providers
Effective collaboration between different health services was identified as a facilitator to improve CR services. Particular emphasis was laid on collaboration and communication between coordinators, cardiologists and some GPs. Coordinators indicated that they had extremely good access and working relationships with the cardiologists as well as the GPs, which they found valuable to provide comprehensive patient care. Positive comments were made by some coordinators about their telephone communication with GPs in the management of patients with CHD, particularly in areas where the waiting time to see a GP was long:

“Sometimes I ring the specialist and say, ‘you know this man because I know you see him and ask for advice’.”
One coordinator indicated that they are part of a referral network established to assess patient referral to CR services post-discharge. Almost all the coordinators acknowledged that patients, particularly those discharged from tertiary hospitals, were receiving evidence-based medication management. Those who felt that patients were not receiving optimal treatment made every effort to contact the GP or specialist to seek advice on the treatment regime.

Collaborating with other allied health services for the management of risk factors was seen as effective in providing strategies to reduce cardiovascular risk. Coordinators outlined strategies for promoting continuity of care and providing support following the program. Some coordinators said that they telephoned the patients to monitor progress, while others sent discharge letters to the patient’s GP. Some who worked as practice nurses in GPs’ surgeries indicated that continuity was maintained in that role. Others who also worked at the local hospital reported that they often saw the patients for other comorbid conditions. In the interviews, coordinators emphasised that promoting and maintaining continuity of care were priorities in reducing the risk of subsequent coronary events.

**Establishing a professional relationship with the patient and family**

Establishing good communication and creating rapport with the patient and the family was believed to facilitate management of CHD. Coordinators mentioned that they used different approaches to communicate with patients. Some indicated that they were receptive to people as they undertook patient assessments informally while developing a relationship with the patient and family. Another coordinator discussed how sharing her personal experience with weight loss enabled her to establish a relationship with the patients. A few others in the rural setting noted that the coordinator–patient relationship extended beyond the clinical setting and they were often asked for advice in the shopping centres. They felt that patients had begun to trust them and it was important to nurture that trust and maintain continuity of care.

**Supporting patients to adopt healthy lifestyles**

Coordinators reported a range of strategies that facilitated in supporting patients to adopt healthy lifestyles. Some participants described providing motivational
counselling, while the rest indicated that would like to learn motivational counselling skills. They perceived that teaching patients “hands-on skills” rather than providing posters or lectures would enable adoption of a healthy lifestyle. All of them indicated that where appropriate and when services were available they referred patients for lifestyle modification. They also mentioned that in some instances to support the patient they would “sometimes buy the medications for the patients”.

**Tailoring the model and vehicle of CR programs**

Some coordinators mentioned the different methods of service provision of their CR programs to cater for the needs of the patients. One coordinator referred to the “fast track” program developed for post-PCI patients who generally commenced work soon after the procedure. A few remarked that they conduct early morning or evening classes to enable the attendance of working patients. All coordinators indicated that they encouraged the patients to bring their family to the programs.

**Local community support**

Support from the local community was identified by some coordinators as an extremely valuable facilitator for implementing CR services. They mentioned that some community groups provided transport assistance to patients required to travel to appointments. In addition to transport assistance, the local community also raised funds to purchase much-needed exercise equipment. They discussed how members from the local community who previously had CABG or MI also participated in CR programs as mentors to other participants. The coordinators spoke about how many of the maintenance-stage CR programs were possible because of the commitment of the local community towards risk factor reduction.

In summary, although CR coordinators face a range of issues they appeared to negotiate and accommodate solutions. They also advocated for extensive information strategies to educate the GPs and the community about the importance and the benefits of CR. CR coordinators stated that they would welcome additional resources to improve the services that they provided. It was clear that they had plans for the use of additional resources. The majority of them indicated that they would “do a lot of preventative stuff like education, information” if they could see the patients before
they had the event. Others stated that they would include motivational interviews, personal trainers, and provide encouragement through supportive phone calls.

5.11 Discussion
Implementation of evidence-based guidelines is the second of three stages in guideline use, following the first stage, adoption of the guidelines, and prior to the last, institutionalisation of the guidelines. Clearly, considerable resources are invested for the development and implementation of evidence-based guidelines, yet despite these efforts the guidelines are not consistently successful in improving patient care and, in many instances, barriers to implementation have been reported.

The barriers reported by the coordinators – such as lack of health service and professional support, lack of access to guidelines, and consumer-related barriers – have also been identified by other researchers as barriers to guideline implementation, which adds further credibility to the results. Due to lack of resources it was not possible in this study to validate the data by asking participants to review the transcripts, however the credibility of the data was ensured by audio recording the interviews and using an independent person to perform transcription.

5.11.1 Compliance with guidelines
Evaluating compliance with guidelines can be complex because the percentage change required indicating a difference in guideline adherence remains variable. In this study, all CR coordinators indicated that they strive to provide maximum services within the limited resources, however they felt that the services provided were not optimal and would be improved with additional resources. A number of potential reasons for poor adherence to the guidelines were identified. The barriers included the complexity of the guidelines, lack of support from health professionals and the health care system, lack of resources and patient-related barriers.

The results indicated that the barriers and facilitators to implementing the guidelines were opposite poles of the same constructs. The main constructs were related to health services, programs, health professionals and the patient and family. These barriers closely parallel themes in the literature on adherence to guidelines by health professionals.
5.11.2 Issues relating to guideline implementation

Problems identified by CR coordinators relating to health service capacity included the limited access to, and in some areas the absence of, a dedicated CR program. It is therefore not surprising that given the inadequacy of services in Australia, participation in CR programs range between 6-20%. The lack of services for health care can result in a fragmented journey for patients in their struggle to obtain optimal health care.

The lack of dedicated funding leading to limited resources has contributed to the problem of inadequate CR services to ensure optimal care. The limited resources resulted in many services being provided during working hours, which was not beneficial to patients who returned to work following the acute event. Participants indicated that they used other models such as home-based CR to reach patients who would not attend traditional programs due to disability. This finding is congruent with barriers to guideline implementation reported in the literature.

The findings relating to CR coordinators striving to overcome the odds despite the lack of resources demonstrate their enthusiasm, dedication and commitment to provide evidence-based care. Poor coordination and referral to CR services was also identified as a problem by coordinators. This indicates that health care providers need to have a clearly defined role in the referral of eligible patients to CR. The use of pre-printed hospital discharge orders that specify CR referral, automatic inpatient consultation with a CR specialist, and routine patient education could be strategies to enable referral.

It is not unusual to have communication difficulties across health care disciplines and facilities, therefore it is essential to employ a clear and formal system of communication to improve the consistency and flow of information. Such formalisation will be important for those providing and referring to CR services, with the large amount of information that will be transferred with the development of various models for the delivery of CR services. The use of care plans and pathways will ensure that patients receive care according to the guidelines. These barriers need to be addressed at the level of the health care system. Although Australia has a universal system of access to CR, not all patients are aware and receive the services.
The development of a centralised referral system for CR could overcome problems associated with referral and thus provide optimal care.

Themes identified from the interviews also reflect frustration due to a perceived lack of support from colleagues and the health care system for their efforts to provide evidence-based cardiac rehabilitation services. Despite this, the coordinators maintained a positive attitude towards providing CR services. The lack of support perceived by the coordinators in this study could be due to the fact that the health care system focuses on acute illness rather than investing resources for the management of chronic illness.

Geographic location, resulting in lack of access to physical resources, GPs, allied health professionals, specialists and education, was identified as another significant barrier to participation in CR programs and therefore the implementation of the guidelines. This finding exemplifies the inability of services to provide the individualised evidence-based patient care that has been widely recommended. These inequalities in access to services among individuals in non-metropolitan areas are of particular concern for the state-funded health care systems that endeavour to provide equal access to all citizens.

The findings from the open-ended interviews revealed that the majority of the CR coordinators lacked the skills and knowledge to implement some of the recommendations. For example, assessment of the patients’ stages of change to successfully target behaviour change strategies for lifestyle modification is recommended in the guidelines, however coordinators reported lack of resources, knowledge, and skills in undertaking this assessment. This was confirmed in the survey where the question relating to assessment of the patients’ stage of change was incomplete. This information is important because guidelines are unlikely to be adopted in the absence of a strategy, therefore effective educational programs to update providers’ knowledge and strategies to address barriers to implementation need to be incorporated.

In general, educating health professionals to make the shift from an illness- to a patient-focussed model of care has an important role to play in promoting referral to CR. In particular, GPs need to be targeted in educational interventions since they provide the majority of care for patients, particularly those in non-metropolitan areas.
Another important aspect was how CR coordinators perceived that patients themselves viewed their condition. They felt that patients did not consider the seriousness of lifestyle modification following the acute event, which could explain some of the reasons for the frustrations felt by the coordinators. In addition, some of the patients – particularly those who had PCI – erroneously believed that they no longer had heart disease and did not need to attend CR programs. Other patient-related barriers were work commitments, time factors and costs associated with participating in CR programs such as parking, travel, and fees associated with specialist appointments. These findings are congruent with other international studies and should be considered when designing models for CR program delivery. Generalisability of these findings to other CR coordinators is likely given the recurrent themes from the literature and the diversity, including the geographic locations, of the participants.

5.11.3 Advantages of the methods used
This mixed-methods study was undertaken to identify adherence to and the barriers and facilitators faced by CR coordinators in applying evidence-based guidelines. The quantitative results, although limited, strengthened and supported the qualitative findings. Interviews with coordinators provided valuable insights into their views about factors that affect and improve the implementation of the guidelines. The major strength of this study was the random selection of coordinators from all geographical regions of NSW. This method provided a broad view of the barriers and facilitators faced by coordinators in all areas for the implementation of the guidelines. The findings reported above are based on 20 interviews and questionnaires. Data saturation was obtained following interviews with 20 CR coordinators.

5.11.4 Limitations of the study
Although the study methods were undertaken rigorously and the findings have implications for practice including guideline developers and health services, the limitations associated with the study should be taken into consideration. Firstly, although 90% of those invited to participate accepted, only 54% were available for the interview. This has been reported to be a common problem in research studies using the interview method. What is encouraging, though, is that the majority of
the CR coordinators scheduled the interviews outside normal working hours, i.e. before 8am or after 5pm, which indicates that despite their busy schedules they were keen to participate in research. In contrast, it could be postulated that those who were interviewed during the working hours had good support and resources.

Secondly, interpretation of the results is also limited by the small sample of coordinators within each geographic area and the findings may not be generalisable to other CR coordinators, particularly those in metropolitan areas. Thirdly, approximately half the surveys were not returned, which could be due to the fact that some coordinators did not maintain or have access to information about patient participation in CR programs. Another limitation was the omission of GPs and hospital doctors in the study. This was due to time constraints and limited budget.

Nevertheless, the information obtained from this study adds strength to the findings of previous research and may inform the design and evaluation of interventions to develop strategies for implementing guidelines and addressing barriers to participation in CR programs.

### 5.12 Recommendations for research

The persistent concern about nonparticipation in CR programs and the implementation of evidence-based guidelines requires further research, including evaluating:

1. the effectiveness of various models of CR delivery in increasing participation rates in CR
2. the effectiveness of strategies for automatic referral to CR and patient education as part of inpatient or outpatient cardiac care
3. the effect of patients’ beliefs, particularly those who have been discharged following PCI and their awareness of risk factor modification

### 5.13 Conclusion

The challenges associated with the traditional delivery of CR services have been well established. The findings from the study indicate that limited service capacity due to a lack of investment and planning is a major barrier to providing evidence-based cardiac care. Other barriers identified included rurality, lack of knowledge, and
communication difficulties, which reflect the range of issues that CR coordinators need to overcome to provide CR services. Low participation rates in CR programs have been reported, therefore extensive efforts towards developing alternate models for the delivery of CR to reduce the risk of heart disease are urgently needed. The following chapter presents findings from the follow-up of patients after coronary treatment which informed the development of the HeLM intervention. Based upon the literature described in Chapter 1, the SR and the data generated from the ICEBERG it appears that an intervention, that is based on evidence based guidelines, theoretically informed and targets both system, provider and patient factors may be useful. Practice change in the pressured context of healthcare may be brought about with the inclusion of the patient as a mediator for driving practice change.

5.14 Implications for the development of the HeLM intervention

CR coordinators face numerous obstacles to delivering evidence based services therefore there is a need for innovative solutions to address barriers e.g. distance. The HeLM intervention

1) would therefore be delivered through the mail and by telephone. Patients will be able to access the intervention in their own time.

2) is designed to be independent of local resources (When implemented in clinical practice the HeLM intervention will involve initial set up costs).

3) will provide an avenue for communication between the coordinator and the GP.
Chapter 6

Follow-up (12-24) of patients after coronary treatment (FACT) Study
6.1 Introduction

As reported in the previous chapter, evidence-based interventions are best developed when data is obtained from systematic review of the research literature, clinician expertise and patient preferences. This chapter presents the data obtained from patient information that contributed to the development of the HeLM intervention. The data that was obtained included: (1) the presence of cardiac risk factors in patients in the long term; (2) health-related quality of life status; (3) adherence to medications; (4) knowledge of CHD and the modifiable risk factors; (5) barriers to participation in CR programs; and (6) patient preferences for CR programs. In addition, this chapter also presents the development of a Cardiac Rehabilitation Enrolment Obstacles (CREO) scale that can be used in clinical practice. A description of the method and results of this study is described below.

Prior to developing interventions for health-related behaviour modification for the reduction of coronary risk factors, it is essential to identify the existing status of the problem, i.e. the number of individuals who continue to have coronary risk factors. As health-related behavioural change takes place over a period of time, the resulting outcome of reduction in coronary risk factors is not achieved until 12-24 months later. Therefore, identifying the coronary risk factor status 12-24 months following the acute event is a better indicator of the coronary risk factor status. The findings of this study also informed development of the HeLM intervention in terms of health-related behaviours that needed to be targeted.

The assessment of HRQoL as an adjunct to traditional hard outcomes has been reported to be increasingly beneficial in providing an indication of the impact of the disease, prediction of the course of the disease, the recovery process, developing tailored strategies for specific populations, and assessing the effectiveness of therapeutic interventions. These findings were therefore important for the development of the HeLM intervention.

Following an acute coronary event, the majority of patients receive several pharmacological therapies that have been demonstrated in RCTs to be effective in the secondary prevention of coronary artery disease.
as well as to prevent restenosis of the treated vessel.\textsuperscript{57,58} Adherence to medication regimes, described as the extent to which patients take medications as prescribed,\textsuperscript{169} is imperative to prevent coronary artery disease progression. For example, adherence to lipid-lowering treatment is associated with lower risk of recurrent coronary events,\textsuperscript{170} while poor compliance with hypertension medications is associated with adverse health outcomes such as stroke and left ventricular hypertrophy.\textsuperscript{171}

Knowledge of coronary risk factors is essential to increase health-promoting behaviours,\textsuperscript{64} and significant correlations between knowledge of risk factors and behaviour change have been reported.\textsuperscript{186,187} Although it is well known that knowledge alone does not result in behaviour change, it empowers individuals to self-manage their illness.

As reported in the previous chapter, CR is an intervention that is recommended for all patients with CHD including those who have had a PCI.\textsuperscript{34} Participation in CR has been associated with increased health-related behaviour changes; however, participation rates among this group of patients remain low.\textsuperscript{36,39,322,447}

Therefore, it was important to identify rates of adherence to medications, the knowledge level of patients relating to coronary risk factors and the obstacles to participation in traditional CR programs among this group of patients, because it informed the development and mode of delivery of the HeLM intervention.

The components of a lifestyle modification program are important to ensure participation and adherence to the program. Therefore it is essential to determine preferences of patients in relation to CR programs. To achieve this, preferences of PCI patients in relation to CR were determined using the revised Cardiac Rehabilitation Preference Form (CRPF-R).\textsuperscript{448}

### 6.2 Rationale for the study

The participants in this study were patients who underwent successful PCI at the Liverpool Health Service between April 2003 and March 2004. These participants were selected because the use of PCI as the treatment of choice for patients with CHD has increased steadily in the past decade.\textsuperscript{449} In 2001-2002, 23,949 PCI procedures were performed throughout Australia,\textsuperscript{449} representing a 12% increase from the previous year.\textsuperscript{17} The second reason for selection of this sample is that this
group represents the demographic and clinical characteristics of those most likely to suit a tailored, brief intervention.

Due to the rapid procedural technique and immediate potential success of PCI without requiring open-heart surgery, patients experience less pain, and have a short hospital stay. These patients underestimate the severity of their cardiovascular disease and may not consider the coronary event as an important warning for them to engage in lifestyle changes. Failure to adopt recommended lifestyle and behavioural changes as well as the technical aspects of PCI the could lead to restenosis of the treated vessel, progression of coronary atherosclerosis and diminished quality of life among these patients.

Liverpool Hospital was chosen as the preferred site for recruitment of patients because a large number of PCI procedures are conducted at this hospital. Local data for 2003 indicates that 437 PCI procedures were performed in Liverpool Hospital alone. In addition, patients receiving treatment there come mainly from the SSWAHS (Western Zone), which has a diverse socioeconomic background, and this provided a comprehensive view of the outcomes of interest from this perspective.

6.3 Aims of the study

Given that the rationale for this study was to identify patient information, the aims of this research study were to survey patients 12-24 months following PCI in order to: (1) profile their cardiac risk factor status, HRQoL, adherence to medications and knowledge relating to CHD and its risk factors; (2) determine the preferences of PCI patients in relation to CR; and (3) identify obstacles to CR participation following PCI and develop and evaluate the psychometric properties of a scale to assess these obstacles.

6.4 Research questions

1. What is the cardiac risk factor status in patients 12-24 months following PCI?
2. What is the HRQoL status in patients 12-24 months following PCI?
3. What is the long-term medication adherence rate in patients following PCI?
4. What is the knowledge level of CHD and its risk factors in patients 12-24 months following PCI?
5. What are the obstacles identified by patients for nonparticipation in CR programs?

6. What are the preferences of PCI patients in relation to CR?

6.5 Research design

This study was undertaken to investigate the research questions in a naturalistic setting using a cross-sectional survey design and a retrospective audit of the medical records. The study was undertaken in a naturalistic setting as participants could complete the questionnaire within their own natural environment free of external influence. The cross-sectional study method was used because the aim of the research was to profile the health-related status of a cross-section of the CHD population at one specified moment in time. A self-administered survey design was considered appropriate for this study due to the widespread geographic distribution of PCI patients across SSWAHS (Western Zone) who underwent PCI at Liverpool Hospital between March 2003 and April 2004.

6.5.1 Surveys as a research method

Postal surveys were sent to all patients 12 months after the index PCI because this method has been reported to have numerous advantages as described in Chapter 5 Section 5.7.2. A draw back of this method is the low response rates, which was overcome using strategies to maximise questionnaire return as described in section 6.6.3.

6.6 Method

6.6.1 Consultation with key stakeholders

Prior to commencing the study extensive consultation regarding the project was undertaken with the Cardiology staff specialist and the Director of Cardiology at Liverpool Hospital. Both demonstrated strong support for the research. A one-page letter describing the project was sent to all cardiologists within the SSWAHS and their approval for the study to proceed was sought. An in-depth description of the project was provided at the Liverpool Cardiology meeting.

6.6.2 Selection of participants for the study

Non-probability purposive sampling was used to recruit a sample of patients who had undergone successful elective, primary or rescue PCI at the Liverpool Health Service
between April 2003 and March 2004 and were aged between 18-80 years. The eligibility of these patients was confirmed by a review of the information on the Clinical Information Service (CIS) database which maintains records of all patients admitted to Liverpool Hospital. Secondly, as the data was collected using a self-administered questionnaire only those participants who were able to complete it with or without assistance were recruited. Completing the questionnaire with assistance enabled the inclusion of non-English speaking participants who are generally excluded from trials.\textsuperscript{45,61,265,299} Finally, as the completion of the questionnaire required good cognitive function only those patients who had a telephone Mini Mental State Examination (MMSE) score of more than 30 (which indicates good cognitive function) were included in the study.

The presence of significant comorbidities, such as cerebrovascular accident with significant neurological deficit and patients with malignant disease undergoing active therapy among patients, can result in severe inaccuracies in the findings, such as patients who had a stroke leading to hemiparesis following PCI who were not able to engage in the recommended level of physical activity. Patients who had a hospital stay of more than 30 days following the PCI were also excluded as it was determined that these patients would have significant comorbidities. As patients were contacted by mail and telephone, it was essential for them to have a postal address and a telephone number. Those patients who did not have a postal address and/or telephone number listed on the cardiology or CIS database were also excluded from the study. In addition, patients who were cognitively impaired or had any condition of sufficient severity to impair cooperation in the study, such as chronic alcoholism, were excluded. Patients who were transferred to a nursing home following the PCI were also excluded as there was no mechanism to identify the names of the nursing homes to which they were discharged. In addition, transfer to a nursing home also denotes that individuals require assistance with activities of daily living, and inclusion of these patients will result in flaws in the data. A flow diagram of the selection process is presented in Figure 6.1

\textbf{6.6.3 Recruitment of patients}
All patients who underwent PCI at Liverpool Hospital between April 1 2003 and March 31 2004 were eligible to participate in the study. Liverpool Hospital is the
tertiary referral hospital for southwestern Sydney and the major trauma centre for NSW. It is the only hospital in southwestern Sydney that provides a comprehensive range of high-level clinical services for cardiac patients including coronary angiography, PCI and CABG. In 2004 southwest Sydney had higher hospital separation rates for CHD, left heart cardiac catheterisation and coronary angioplasty (male) procedures than any other hospital in NSW. Southwest Sydney is the most ethnically diverse health area in Australia and also has some of the poorest communities in the state.

Patients were identified from the cardiology database and a list was compiled. It was important that patients who were deceased were not sent a copy of the questionnaire, therefore all attempts were made to identify these patients. This was accomplished by contacting the CIS department at Liverpool Hospital which maintains information for patients who have deceased within the SSWAHS. The revised list was then assessed against the selection criteria and those patients who did not meet the criteria were excluded. An invitation to participate in the study along with a subject information sheet was then sent to the remaining patients. Patients were asked to contact the researcher if they did not wish to participate in the study. If the patients had not contacted the researcher within three weeks, they were telephoned to seek their participation. Three attempts were made to contact each patient, after which they were declared non-contactable. Those who agreed to participate were assessed for their cognitive status using the Telephone Interview for Cognitive Status (TICS) Questionnaire. Patients who were determined to not be cognitively impaired according to the TICS scale were then asked if they preferred to receive the questionnaire in the mail or if they preferred to complete the survey via the telephone. For those patients who chose to complete a telephone survey a date and time was organised. In the event that the scheduled appointment could not be adhered to, two other attempts were made to contact the patient, following which the patient was declared lost to follow-up. Those patients who opted to complete the survey themselves were mailed a questionnaire, consent form and a reply paid envelope.
Methods to increase response rates
Given the evidence that response rates to postal questionnaires are generally poor, response aiding strategies were used. Non-responders were sent a reminder letter prompt on Day 15 and a telephone prompt at Day 30 in accordance with the evidence on methods to increase response to postal questionnaires. All participants who took part in the study were sent a thank-you letter. In order to obtain a representative sample, participants from a non-English speaking background were encouraged to complete the questionnaire with assistance.

6.6.4 Data collection
Data were obtained using two methods. Information about the PCI procedure was collected from the cardiology database and data from patients were collected using a self-administered questionnaire. The self-administered questionnaire was piloted using five participants prior to use. Based on their comments two questions were rephrased and the font size was increased. The questionnaire comprised of participant demographics including age, gender, country of birth, level of education, marital and income status and the following data items and validated scales for assessment of the outcome variables (Appendix 14). It should be noted that the self-administered questionnaire presented in Appendix 14 was used for a larger study and only data relevant to this thesis has been reported.

Assessment of cognitive status
Since impaired cognitive status was an exclusion criterion, participants who consented to be a part of the study participated in a telephone interview to assess their cognitive status to determine their eligibility for the study. The Telephone Interview of Cognitive Status (TICS) questionnaire was adapted for this purpose. The TICS is a 11-item screening test modelled on the Mini Mental State Examination (MMSE) and assesses areas such as orientation, registration, immediate verbal memory, and attention. The maximum score obtainable is 41 points and participants with a score of less than 30 are considered to be cognitively impaired. The TICS correlates very highly ($r = 0.94$) with the MMSE. Test-retest reliability of the TICS has also been estimated to be high ($r = 0.97$). Participants with a score <30 were excluded from the present study. However, in this study all patients assessed had a TICS score more than 30.
Assessment of cardiac risk factors
The cardiac risk factors assessed included smoking, physical activity, obesity status, blood pressure, cholesterol, depression, anxiety and stress levels.

Smoking status
This outcome was assessed by self-reports. Self-reporting of smoking habits is widely used to estimate the prevalence of cigarette smoking. Assuming urinary cotinine-creatinine is the ‘gold standard’, the sensitivity, specificity and positive predictive values for self-reports of smoking status have been reported to be 97%, 95% and 85%. Participants were asked whether they smoked before and/or after the PCI, and if yes, the number of cigarettes smoked per day was determined. Participants were considered to be non-smokers if they had never smoked. Former smokers were defined as subjects who had not smoked in the last 6 months at the time of survey.

Physical activity
This outcome was assessed using three items from the Active Australia Survey (AAS) questionnaire, which has been widely used in the Australian population. The questions assessed the number of sessions and the total time spent doing activities during the previous week. The questions covered all types of activity including light, moderate, and vigorous exercise. Test-retest reliability for assessing activity status of the instrument has been established at 0.54 in an older population. The AAS also has good criterion validity for Australian adults. Participants were classified as inactive if they reported less than 150 minutes of moderate and/or vigorous activity per week.

Obesity
BMI was used as an indicator of obesity. Participants were asked to provide details regarding their height and weight which were converted to metres and kilograms respectively. BMI was calculated for all participants who provided a valid height and weight measurement using the following formula: weight (kg) divided by height squared (m$^2$). All patients were classified according to predefined categories of BMI for patients 18 years and over developed by WHO, which have been adopted as
According to this classification, participants were considered to be overweight if their BMI $> 25$ kg/m$^2$.

**Blood pressure and Cholesterol levels**

Participants were asked if they had a history of high blood pressure and/or high cholesterol and if they were receiving lipid-lowering medications. Self-reports are commonly used to assess blood pressure values. Responses to these questions provided a general incidence of the problem. To obtain the persistence of these risk factors, participants were asked to report the numerical value of their most recent blood pressure and cholesterol tests. Researchers have reported that less than 50% of patients with coronary artery disease have knowledge about their total cholesterol values, therefore participants were asked if the levels of their most recent blood pressure and cholesterol values were high, low or normal. Participants who were 65 years or older were determined to be hypertensive if they reported a blood pressure value greater than or equal to 140/90 mmHg, in accordance with the RRIHD guidelines described in the previous chapter. Presence of hypertension in participants less than 65 years of age was determined if they reported a blood pressure value of greater than 130/85 mmHg. Participants who could not provide a numerical value but indicated that their blood pressure level was high were also considered to be hypertensive. Hypercholesterolaemia was considered if participants reported the value of their most recent total cholesterol level to be greater than 4.0 mmol/L or self-reported their cholesterol level to be high.

**Depression, anxiety and stress levels**

There is extensive evidence to support that depression, anxiety and stress are negative emotions related to adverse cardiac outcomes. Therefore, the presence of these emotions was assessed using the 21-item Depression Anxiety and Stress Scale (DASS). The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress. Each of the three scales contains seven items. The depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty
relaxing, nervous arousal, and being easily upset/agitated, irritable/overreactive and impatient. Participants were asked to respond to each item using a four-point scale to indicate the extent to which each item applied to them in the last 2 weeks. The scale ranged from 0 “did not apply to me at all” to 4 “applied to me very much, or most of the time”. The maximum score obtainable for each subscale is 28. Construct validity of the DASS has been undertaken against the Beck Depression Inventory (BDI) and the Beck Anxiety Inventory (BAI). The DASS Anxiety scale correlated 0.81 with the BAI and the DASS Depression scale correlated 0.74 with the BDI. Concurrent validity of the DASS 21 with DASS 42 has been reported to be high ($r = 0.84$). Internal consistencies of the DASS subscales are 0.94 for depression, 0.87 for anxiety and 0.91 for stress. In order to determine the severity of these states, the sum of the scores for the seven questions in each subscale is calculated and doubled. This value is assessed against the severity rating index (Table 6.1).

<table>
<thead>
<tr>
<th>Depression</th>
<th>Anxiety</th>
<th>Stress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0 – 9</td>
<td>0 - 7</td>
</tr>
<tr>
<td>Mild</td>
<td>10 – 13</td>
<td>8 – 9</td>
</tr>
<tr>
<td>Moderate</td>
<td>14 – 20</td>
<td>10 – 14</td>
</tr>
<tr>
<td>Severe</td>
<td>21 – 27</td>
<td>15 – 19</td>
</tr>
<tr>
<td>Extremely Severe</td>
<td>28+</td>
<td>20+</td>
</tr>
</tbody>
</table>

**Health related quality of life**

Health related quality of life was assessed using a self administered 27 item disease specific, valid and reliable instrument; The MacNew Heart Disease HRQoL Questionnaire (MacNew) developed in Australia. The MacNew is modified from the original Quality of Life after Myocardial Infarction Questionnaire (QLMI) and consists of three subscales that measures the Emotional, Physical, Social and Global HRQoL life domains. The instrument comprises of a 13 item physical limitation domain, 14 item emotional function domain, and 13 item social function domains. In addition to the studies that provide psychometric data, the MacNew has been successfully administered in numerous other studies.

Participants were asked to respond to each item using a seven-point scale to indicate the extent to which each item applied to them in the previous two weeks. The
minimum score obtainable for any item is one which indicates poor HRQoL and the maximum possible score for any domain is 7 (high HRQoL). Internal consistencies of the English version of the MacNew subscales are 0.93 for physical, 0.95 for emotional and social functioning. Test-retest correlations of the English version of the MacNew in patients with myocardial infarction and angina ranges from $r_{tt} = .83 – .87$. In general the MacNew is reliable and meets the reproducibility standard of 0.70 for group comparison.

**Medication adherence**

**Current medications**
Participants were asked if they were taking medications for controlling high blood pressure, high cholesterol, depression, high blood glucose, body weight, breathing difficulties, and pain. In addition participants were also asked if they were receiving medications for quitting smoking and preventing blood clots and if they found it bothersome to take their medications.

**Adherence to medications**
Adherence to medication was assessed by self report using the Haynes validated questions and the Morisky Medication Adherence Scale (MAS). Pooled data from methodologically strong studies demonstrates that when compared to pill counts, self reports have a sensitivity of 55%, specificity averaging 87% and a likelihood ratio for a positive test of 4.4.

The Haynes instrument consists of two items. The first item was a previously validated question "Do you regularly miss taking any of your medications?" As the method of questioning has been reported to affect the accuracy of responses, non threatening, non judgemental approaches as described in the literature were used. The question was therefore prefaced with the following statement "People often have difficulty taking their pills for one reason or another". We are trying to learn more about that experience. If the response was affirmative participants were asked to report the numbers of pills missed in the previous day and week. When compared to pill counts, these questions have been reported have a correlation coefficient of 0.74 ($p < 0.0001$), sensitivity of 96%, specificity 50% and a positive predictive value of 70%.
The MMAS\textsuperscript{482} comprises a 4-item self-report scale which includes: “Do you ever forget to take your medicine? Are you careless at times about taking your medicine? When you feel better do you sometimes stop taking your medicine? Sometimes if you feel worse when you take the medicine do you stop taking it?” Each of these questions is answered using a yes/no option. Reliability of these items (item to total correlation coefficients of .48 to .56) and the total scale has been reported and is modest (alpha=0.64). \textsuperscript{482}

**Knowledge of CHD and modifiable risk factors**

Knowledge of CHD was assessed using 12 multiple-choice questions adapted from the Indiana Cardiac Rehabilitation Knowledge Questionnaire. \textsuperscript{484} Knowledge of cardiac risk factors that could be modified was assessed using a 10-item list of risk factors that was also derived from the Indiana Cardiac Rehabilitation Knowledge Questionnaire. \textsuperscript{484} Participants were asked to tick all the risk factors that they thought were modifiable from the predetermined list. The reliability and validity of the questionnaire have not been reported, yet the questionnaire has been used previously in studies that have been subjected to peer review. \textsuperscript{484}

**Identification of the important elements of a CR program**

Participants’ preferences for the important elements of a CR program were assessed using the CRPF-R Scale.\textsuperscript{448} This scale is modified from the original 17-item CRPF scale for use in the Australian setting. The CRPF-R consists of two factors, namely CR program features (10 items) and Convenience features (5 items). Cronbach’s alpha coefficients for the total CRPF-R have been reported to be 0.87 and 0.85 for Factor 1, CR program features, and 0.81 for Factor 2, Convenience features. The 15 items are ranked by the participant on an ordered categorical scale with 3 levels ranging from 1 (little importance) to 3 (very important).\textsuperscript{448} Higher scores on the 15-item in the CRPF-R scale reflect higher priority ranking on CR features. The potential range of scores of the 15-item CRPF-R scale (with a 3-point Likert scale) is 15 to 45.

**Obstacles to participating in CR programs**

Barriers to participating in CR programs were assessed using the CREO scale. A
detailed description of the development of the CREO scale has been presented in section 6.10.

6.7 **Data analysis**

Preliminary assessment of the data set was conducted prior to analysis to ensure accurate entry and coding of the data. Frequencies were computed to detect incorrect entries. In the presence of incorrect entries, the original questionnaires were examined and the data verified. Likewise, missing responses were also checked against the original questionnaires. Data were computed, coded and analysed using SPSS version 13. Descriptive analyses (frequencies and percentages, means and standard deviations [SD] as appropriate) were undertaken to assess the characteristics of the patients. A description of the method of analysis of the various outcomes is presented below.

6.7.1 **Assessment of cardiac risk factors**

Categorical data have been presented as percentages and continuous data as means (SD). Differences between continuous variables were assessed using independent *t*-tests and the chi-square test was used for categorical variables. Unadjusted multiple comparisons were considered to be significant at *p* < 0.05. Patients were asked about their smoking status prior to the PCI, therefore data relating to smoking status before and after PCI have been compared. Data relating to hypertension, cholesterol, physical activity, BMI, depression, anxiety and stress prior to the PCI were not collected, therefore only follow-up results have been reported.

6.7.2 **Health related quality of life**

The maximum possible score in any domain is 7 and the minimum is 1. The scores in each domain are calculated as an average of the responses in that domain. Missing responses do not contribute to the score. For example, if only 10 of the 14 emotional items are answered, the emotional score is the average of 10 responses. If more than 50% of the items in a scale were missing, that scale score was set to missing. The global HRQoL score is calculated as the average of all scored items. The participants in the study were a homogenous cohort, i.e. they all had PCI at the same facility, therefore they were stratified into four time periods according to their date of
the initial PCI and a HRQoL trajectory was mapped. The four time periods were 12-14 months, 15-17 months, 18-20 months and 21-24 months following the initial PCI.

6.7.3 Medication adherence
Categorical data have been presented as percentages and continuous data are presented as means (SD).

6.7.4 Knowledge of CHD and risk factors
Responses on the cardiac risk factor checklist were classified as “correct” or “incorrect” identification of modifiable risk factors. Comparison between correct identification of modifiable risk factors and the self-report of personal risk factor of the participant was computed using chi-square test. The percentage of correct identification of each modifiable risk factor was calculated.

6.7.5 Participation in cardiac rehabilitation
Categorical data have been presented as percentages. Prediction of the outcome of CR participation (yes/no) was undertaken using multivariate logistic regression. Binary variables entered were gender (male/female), marital status (living with partner/living alone), and income (less than $50,000 per year/$50,000 or more per year). The only continuous variable included in the model was age ($\geq 65$ years versus those $\leq 64$ years). Odds ratio for each variable along with a 95% CI were computed. The Hosmer-Lemeshow test was used to assess the fit of the model with a P-value of greater than 0.05 used as the cut-off value to indicate no difference between the observed and model-predicted values, indicating acceptable fit of the data to the model.\textsuperscript{485}

6.8 Ethical considerations
Approval was obtained from the SSWAHS Human Research Ethics Committee (Appendix 15) and the University of Western Sydney Ethics Committee (Appendix 16). Numerical unique identifiers and password-protected files were used to maintain patient privacy and confidentiality. The master list for these unique identifiers was stored in a locked filing cabinet accessible only to the Chief Investigator and destroyed at the end of data collection. All questionnaires received were stored in locked filing cabinets at CANR. No individuals were identified in reports or
publications. Ethical issues described in the previous chapter were also applicable to this study.

6.9 Results
A total of five hundred and forty one patients underwent PCI during the study period (April 2003- March 2004). In this study as patients were identified retrospectively the selection criteria was applied in two stages. Following the first stage of the exclusion criteria 518 patients were determined to be potentially eligible for the study and were sent the subject information sheet. Change of address which is a well established disadvantage of postal surveys was responsible for the return of one hundred and forty four subject information sheets. Attempts were made to contact these patients using telephone numbers listed on the cardiology database, however none of these patients were able to be contacted. Of those who were able to be contacted 270 agreed to participate. These patients were then assessed for their cognitive functional status using the TICS scale. The TICS scores for the 202 patients ranged from 31-39. As none of the 270 patients had scores below 30 they were all considered to have normal cognitive function and were mailed a questionnaire for completion. A total of 202 patients returned a completed survey for a response rate of 74%. Figure 6.1 presents a flow chart of patients through the study.
Figure 6.1 Flow chart of participants through the study
6.9.1 Characteristics of participants

One hundred and forty-eight males and 54 females returned a completed questionnaire. The age of the participants ranged between 35-87 years with a mean age of 64 years (SD 11.7). Female patients were significantly older (68.8 years; SD 10.5) than their male counterparts (62.2 years; SD 11.6) ($p < 0.0001$). The majority (80%) of the patients were aged between 51 and 80 years.

Nearly three quarters (72%) of the participants were married or living with a partner, and approximately 57% had completed secondary schooling. More than half the patients (60%) were retired and approximately 8% of the patients were unemployed. Reasons for unemployment included redundancy (n=6), poor health (n=19), unable to find work (n=1), and workers’ compensation (n=3). Table 6.2 presents demographic data of the participants.

Table 6.2 Demographic characteristics of participants

<table>
<thead>
<tr>
<th>Marital status</th>
<th>Frequency n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married/De-facto</td>
<td>146 (72.3)</td>
</tr>
<tr>
<td>Single/Divorced</td>
<td>25 (12.4)</td>
</tr>
<tr>
<td>Widowed</td>
<td>31 (15.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Educational level</th>
<th>Frequency n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not complete primary school</td>
<td>7 (3.5)</td>
</tr>
<tr>
<td>Completed primary school</td>
<td>16 (8)</td>
</tr>
<tr>
<td>Left high school before intermediate or school certificate</td>
<td>55 (27.2)</td>
</tr>
<tr>
<td>Intermediate or School Certificate (Year 10)</td>
<td>45 (22.2)</td>
</tr>
<tr>
<td>Leaving or High School Certificate (Year 11/12)</td>
<td>15 (7.4)</td>
</tr>
<tr>
<td>Apprenticeship/Trade qualification</td>
<td>38 (18.8)</td>
</tr>
<tr>
<td>University degree</td>
<td>10 (4.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occupation (n=193)</th>
<th>Frequency n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retired</td>
<td>115 (59.5)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>17 (8.8)</td>
</tr>
<tr>
<td>Working</td>
<td>60 (31)</td>
</tr>
<tr>
<td>Student</td>
<td>1 (0.5)</td>
</tr>
</tbody>
</table>
6.9.2 Details of the PCI procedure

The majority of the participants (79%) in this study had no previous history of PCI, 17% had either CABG or PCI and 5% had both CABG and PCI. Percutaneous insertion of a single transluminal stent into a single coronary artery was the most commonly performed procedure in 70% of the participants.

Most of the patients (42.1%) had the PCI procedure a few days following an acute MI. In 26.7% of the cases the procedure was pre-planned, i.e. the patients were admitted to hospital on the day of the procedure. Approximately 25% of the patients had a PCI after being admitted to hospital with chest pain and were not diagnosed with a MI. In 13 patients PCI was performed as a rescue following failed thrombolytic therapy.

6.9.3 Presence of cardiovascular risk factors

Approximately one-third of the patients – nearly half the women (46%) and a quarter of the men – had at least two modifiable risk factors. Twenty-six patients had four and two patients had five modifiable risk factors. A third of the participants (n=64) indicated that they had no heart problems. Table 6.3 presents the number of patients with modifiable risk factors.

<table>
<thead>
<tr>
<th>No. of risk factors</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>27 (13.4%)</td>
</tr>
<tr>
<td>1</td>
<td>56 (27.7%)</td>
</tr>
<tr>
<td>2</td>
<td>62 (30.7%)</td>
</tr>
<tr>
<td>3</td>
<td>29 (14.4%)</td>
</tr>
<tr>
<td>4</td>
<td>26 (12.9%)</td>
</tr>
<tr>
<td>5</td>
<td>2 (1%)</td>
</tr>
</tbody>
</table>

Cigarette Smoking Status

One in three respondents (35%) indicated that they had never smoked. There was a modest decrease in the number of participants who smoked cigarettes from 48 (18%) before the PCI to 30 (11%) at the one year follow-up. Nearly half (n=15) of the
participants who smoked more than 10 cigarettes per day before the PCI had reduced their cigarette intake (Table 6.4). The remaining continued to smoke despite advice from their health professionals to quit. The majority of the participants who quit had a previous history of PCI or CABG. Recommendations from the NHFA indicate that participants smoking more than 10 cigarettes/day should receive pharmacotherapy, however only one of the 15 participants who met this criterion reported receiving nicotine replacement therapy to quit smoking.

<table>
<thead>
<tr>
<th>Table 6.4</th>
<th>Comparison between smoking status before and after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before PCI</td>
</tr>
<tr>
<td>Never smoked</td>
<td>70</td>
</tr>
<tr>
<td>Ex smoker</td>
<td>79</td>
</tr>
<tr>
<td>Do not smoke everyday</td>
<td>1</td>
</tr>
<tr>
<td>Smoke from 1 to 10 cigarettes a day</td>
<td>11</td>
</tr>
<tr>
<td>Smoke more than 10 cigarettes a day</td>
<td>31</td>
</tr>
</tbody>
</table>

All patients participating in the study were asked if they had been advised to stop smoking by their doctor, cardiologist, nurse or health educator. The majority of the patients (92.6%) of the patients reported that they had been asked whether they smoked. Of those patients who smoked all patients indicated that they were advised by their health professional to quit.

**Hypertension**

Ninety-six participants (48%) indicated that they had a medical history of hypertension, however a large proportion (n=139; 70%) reported receiving medications for the control of hypertension. The majority of the participants (n=184; 91%) reported that their blood pressure was last measured in the three months prior to the study, however exact systolic and diastolic blood pressure readings were provided by only 36% of the participants. In accordance with the recommendations from the NHFA, a third of the participants older than 65 years of age had a systolic blood pressure greater than 140 mmHg and nearly a quarter who were less than 65 years of age reported a systolic blood pressure of greater than 130 mmHg (Table
One hundred and eighty-eight participants reported the level (high, low, appropriate) of their last BP value. Seventy percent (n=142) of the patients reported that their blood pressure level was right for their age, 11% (n=24) indicated that their blood pressure was high, 6% (n=12) had low blood pressure and 5% (n=10) could not remember their blood pressure status. Of the 24 participants who indicated that they had high BP, four were not receiving antihypertensive treatment (Table 6.5).

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>At follow-up</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension (n=200)</td>
<td>Number of participants who stated they had high BP</td>
<td>24 (12%)</td>
</tr>
<tr>
<td></td>
<td>For participants ≥ 65 years who provided exact values</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Systolic BP &gt; 140 (n=35)</td>
<td>11 (31%)</td>
</tr>
<tr>
<td></td>
<td>Diastolic BP &gt; 90 (n=33)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>For participants &lt; 65 years who provided exact values</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Systolic BP &gt; 130 (n=37)</td>
<td>8 (22%)</td>
</tr>
<tr>
<td></td>
<td>Diastolic BP &gt; 85 (n=36)</td>
<td>3 (8%)</td>
</tr>
</tbody>
</table>

Hypercholesterolaemia

Ninety-six participants (49%) reported having a history of hypercholesterolaemia, however the majority of the participants (n=166; 82%) were receiving cholesterol-lowering medications. A large proportion (n=171; 85%) reported that their cholesterol levels were last checked within the last six months prior to the survey, however only 78 could provide an exact cholesterol value. The mean cholesterol value for these participants was 4.4 mmol/L (SD 0.9) with a range from 2.9 mmol/L to 7 mmol/L. Analysis undertaken according to recommendations from the NHFA indicated that more than half the participants who provided this information had hypercholesterolaemia (> 4mmol/L) (Table 6.6).
Table 6.6  Number of participants with high cholesterol at 12-24 month follow-up

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>At follow-up</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypercholesterolaemia (n=200)</td>
<td>Number of participants who stated they had high cholesterol</td>
<td>36 (18%)</td>
</tr>
<tr>
<td>For participants who provided exact values (n=78)</td>
<td>Total cholesterol &gt; 4 mmol/L (155 mg/dL)</td>
<td>45 (58%)</td>
</tr>
</tbody>
</table>

One hundred and forty participants reported the level (high, low, right) of their last cholesterol value. Of these, 36 (18%) had high cholesterol and 24 could not remember the level of the last reading.

**Physical activity status**

Data regarding physical activity status was obtained from 178 participants. Twenty-four were unable to recall the number of times they had walked and 22 indicated that they had not walked during the previous week. The NHFA guidelines\(^{34}\) recommend 30 minutes of moderate intensity physical activity on five or more days per week (150 minutes per week minimum). Of those participants who reported to have walked (n=154), only 93 (52%) indicated that they walked for a total time of 150 minutes or more (Table 6.7). The total time spent walking for these participants ranged from 150 to 3360 minutes (median=300; SD 431.6). When asked how active they were prior to the PCI, 45% (n=91) of the participants reported that their activity level was about the same, 24% (n=49) were less active and 30% (n=60) were more active compared to before they had the PCI.

Table 6.7  Participation in physical activity

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>At follow-up</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity</td>
<td>Never walked</td>
<td>22 (12%)</td>
</tr>
<tr>
<td>(n=178)</td>
<td>Walked for at least 150</td>
<td>93 (52%)</td>
</tr>
<tr>
<td></td>
<td>minutes/week</td>
<td></td>
</tr>
</tbody>
</table>
**Obesity**

BMI was calculated as an indicator of obesity, however it could be calculated for only 193 participants as data relating to either height or weight was not provided by the remaining participants. The mean BMI for all participants was 28.7 kg/m\(^2\) (SD 5.3). Only 43 (22%) out of 193 participants were in the healthy weight range with the majority (50%) classified as pre-obese. Table 6.8 presents the number of participants classified by BMI category.

**Table 6.8 BMI Classification**

<table>
<thead>
<tr>
<th>BMI</th>
<th>Classification</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 18.5</td>
<td>Underweight</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>18.5–24.9</td>
<td>Healthy weight range</td>
<td>43 (22.2%)</td>
</tr>
<tr>
<td>≥ 25</td>
<td>Overweight</td>
<td></td>
</tr>
<tr>
<td>25.0–29.9</td>
<td>Preobese</td>
<td>83 (43%)</td>
</tr>
<tr>
<td>≥ 30</td>
<td>Obese</td>
<td></td>
</tr>
<tr>
<td>30.0–34.9</td>
<td>Class I obesity</td>
<td>46 (23.8%)</td>
</tr>
<tr>
<td>35.0–39.9</td>
<td>Class II obesity</td>
<td>11 (5.7%)</td>
</tr>
<tr>
<td>≥ 40</td>
<td>Class III obesity</td>
<td>9 (4.7%)</td>
</tr>
</tbody>
</table>

**Psychological Status**

Depression, anxiety and stress scores could be calculated for 183, 184, and 182 participants respectively. The majority of the participants did not have any of these risk factors. However, some form of depression, anxiety or stress was reported in nearly a quarter of the participants (Table 6.9).

**Table 6.9 Psychosocial status**

<table>
<thead>
<tr>
<th></th>
<th>Depression (n=183)</th>
<th>Anxiety (n=184)</th>
<th>Stress (n=182)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>12 (7%)</td>
<td>8 (4%)</td>
<td>13 (7%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>19 (10%)</td>
<td>22 (12%)</td>
<td>10 (5%)</td>
</tr>
<tr>
<td>Severe</td>
<td>7 (4%)</td>
<td>5 (3%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Extremely severe</td>
<td>8 (4%)</td>
<td>11 (6%)</td>
<td>5 (3%)</td>
</tr>
</tbody>
</table>
6.9.4 Health-related quality of life

Data relating to emotional and social domains were obtained from 200 participants and 201 participants provided data on physical and global domains.

**Emotional score**

In patients whose follow up was between 12-14 months following the index PCI the mean emotional score was 5.24 (SD 1.2) with this score greater (mean score 5.86 SD .98) in patients who were followed up 15-17 months. A decline in scores was observed in participants who were followed up at 18-20 (mean score 5.69 SD 1.2) and 21-24 months (mean score 5.41 SD 1.3) after the PCI. These differences in scores were not statistically significant. (Figure 6.2)

![Box plot of emotional score over time periods](image)

Figure 6.2  HRQoL Emotional Domain scores
**Physical Score**

In patients whose follow up was between 12-14 months following the index PCI the mean physical score was 5.05 (SD 1.3) with this score gradually increasing until 20 months after the procedure. A decline in scores was observed in participants who were followed up at 21-24 months (mean score 5.26 SD 1.3). (Figure 6.3)

![Figure 6.3 HRQoL Physical Domain scores](image-url)
Social score
In patients whose follow up was between 12 -14 months following the index PCI the mean social score was 5.43(SD 1.4) with this score greater (mean score 5.97 SD 1.2) in patients who were followed up 15-17 months. A decline in scores was observed in participants who were followed up at 18-20 (mean score 5.9 SD 1.3) and 21-24 months (mean score 5.6 SD 1.5) after the PCI. These differences in scores were not statistically significant (Figure 6.4).

![Figure 6.4 HRQoL Social Domain scores](image-url)
Global score

The mean emotional score in the first trajectory period was 5.17 (SD 1.2) with this score reaching the maximum (5.62 SD 1.2) at 18-20 month follow up followed by a decline in the scores in the last follow-up period (Figure 6.5). These differences in scores were not statistically significant.

Figure 6.5  HRQoL Global Domain scores

Scores in the physical domain were the lowest when compared to the other domains in all time periods of the HRQoL trajectory. Overall HRQoL scores for all domains increased in patients at 15-17 following the index PCI and declined thereafter, however the scores were still higher than those at 12 months (Figure 6.6).
6.9.5 Medication adherence

Use of Medications
All except three patients reported taking medications. Medications were most commonly to control high cholesterol and high blood pressure and to prevent blood clots (Table 6.10). Approximately 50% of the patients were taking 3-4 types of medications per day. The use of nitroglycerine medication for the relief of angina was minimal, with the majority (84%) reporting not taking it in the previous four weeks.
Table 6.10  Medications taken by participants

<table>
<thead>
<tr>
<th>Medications taken for</th>
<th>No. of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>41 (20.3%)</td>
</tr>
<tr>
<td>Heart conditions</td>
<td>119 (58.9%)</td>
</tr>
<tr>
<td>Breathing difficulties</td>
<td>26 (12.9%)</td>
</tr>
<tr>
<td>Depression/anxiety</td>
<td>18 (8.9%)</td>
</tr>
<tr>
<td>Pain relief</td>
<td>48 (23.8%)</td>
</tr>
<tr>
<td>Body weight</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>166 (82.2%)</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>139 (68.8%)</td>
</tr>
<tr>
<td>Prevention of blood clots</td>
<td>161 (79.7%)</td>
</tr>
<tr>
<td>Quitting smoking</td>
<td>4 (2.0%)</td>
</tr>
</tbody>
</table>

**Medication adherence**

Overall, patients were highly adherent with their medications. A large proportion of the participants (94.6%) reported that they did not regularly miss taking their medications, however approximately 11% indicated that they had missed some of their medications in the previous week. Of those participants who reported that they missed taking some of their medication, four had missed more than three tablets. A small proportion of the participants reported that they intentionally missed tablets if they felt better, worse or were going out (Table 6.11).
Table 6.11 Medication adherence rates of participants

<table>
<thead>
<tr>
<th>Adherence Category</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regularly miss taking medications</td>
<td>7/198 (3.5%)</td>
</tr>
<tr>
<td>Missed tablets in the last week</td>
<td>22/198 (10.9)</td>
</tr>
<tr>
<td>Number of tablets usually missed in a week</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>183/202 (90.6%)</td>
</tr>
<tr>
<td>1-3 tablets</td>
<td>15/202 (7.5%)</td>
</tr>
<tr>
<td>4 or more</td>
<td>4/202 (2%)</td>
</tr>
<tr>
<td>Could not remember</td>
<td>8/202 (4%)</td>
</tr>
<tr>
<td>Stops taking medications if feeling better</td>
<td>4/196 (2%)</td>
</tr>
<tr>
<td>Stops taking medications if feeling worse</td>
<td>9/195 (4.5%)</td>
</tr>
<tr>
<td>Stops taking medications if going out</td>
<td>10/197 (5%)</td>
</tr>
</tbody>
</table>

"Missing data

Approximately half the patients stated that it was not bothersome to take medications. Participants had excellent knowledge of recommended actions when they felt side effects of the medications, with the majority (87.8%) reporting that they would notify their doctor before making any changes to the medications. The remaining participants indicated that they would stop taking their medications until the next time they visited their doctor (10.2%) and did not know what to do (2%).

6.9.6 Knowledge of CHD and modifiable risk factors

Knowledge of CHD

Responses relating to patients’ understanding of CHD and its management were varied. Of the 12 questions that were used to assess this outcome, only 12 participants (5.9%) were able to identify all the correct responses. One hundred and seventy-one participants correctly identified seven or more responses. Table 6.12 presents the number of correctly identified responses by the participants.
Knowledge relating to the causes, consequences and areas where anginal pain could be felt was poor with less than 60% of the participants identifying the correct response. The majority of the participants identified correct responses for the effect of smoking and the risk of heart disease (78.2%), management of chest pain during exercise (84.7%), management of the side effects of medication (85.6%), healthy eating habits impact and hypertension (82.7%), and foods that were the highest source of cholesterol (94.1%). Table 6.13 presents the number of participants who demonstrated knowledge of CHD.

<table>
<thead>
<tr>
<th>Number of correct responses</th>
<th>Frequency (%)</th>
<th>Number of correct responses</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1 (0.5%)</td>
<td>7</td>
<td>23 (11.4%)</td>
</tr>
<tr>
<td>1</td>
<td>1 (0.5%)</td>
<td>8</td>
<td>36 (17.8%)</td>
</tr>
<tr>
<td>2</td>
<td>4 (2.0%)</td>
<td>9</td>
<td>31 (15.3%)</td>
</tr>
<tr>
<td>3</td>
<td>4 (2.0%)</td>
<td>10</td>
<td>37 (18.3%)</td>
</tr>
<tr>
<td>4</td>
<td>5 (2.5%)</td>
<td>11</td>
<td>32 (15.8%)</td>
</tr>
<tr>
<td>5</td>
<td>5 (2.5%)</td>
<td>12</td>
<td>12 (5.9%)</td>
</tr>
<tr>
<td>6</td>
<td>11 (5.4%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 6.13  Correct responses to questions relating to knowledge of CHD

<table>
<thead>
<tr>
<th>Knowledge relating to:</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cause of anginal pain</td>
<td>109 (54%)</td>
</tr>
<tr>
<td>consequences of CHD</td>
<td>121 (59.9%)</td>
</tr>
<tr>
<td>areas where anginal pain could be felt</td>
<td>90 (44.6%)</td>
</tr>
<tr>
<td>effect of smoking and the risk of heart disease</td>
<td>158 (78.2%)</td>
</tr>
<tr>
<td>management of chest pain during exercise</td>
<td>171 (84.7%)</td>
</tr>
<tr>
<td>management of chest pain not relieved with nitroglycerine tablets/sprays</td>
<td>126 (62.4%)</td>
</tr>
<tr>
<td>management of occurrence of chest pain while driving</td>
<td>151 (74.8%)</td>
</tr>
<tr>
<td>sexual relations after CHD</td>
<td>140 (69.3%)</td>
</tr>
<tr>
<td>management of the side effects of medication</td>
<td>173 (85.6%)</td>
</tr>
<tr>
<td>storage of nitroglycerine tablets</td>
<td>130 (64.4%)</td>
</tr>
<tr>
<td>healthy eating habits impact and hypertension</td>
<td>167 (82.7%)</td>
</tr>
<tr>
<td>foods that were the highest source of cholesterol</td>
<td>190 (94.1%)</td>
</tr>
</tbody>
</table>

**Knowledge of modifiable risk factors**

Most participants were able to identify high cholesterol (87%), smoking (83%), hypertension (82%), physical inactivity (72%) and obesity (72%) as the modifiable risk factors for coronary artery disease. However, less than half (46%) the respondents identified diabetes as a modifiable risk factor (Figure 6.7). Although a large proportion of participants identified individual risk factors for CHD, only 30% recognised all six modifiable risk factors. Five risk factors were identified by 9%. Nine participants identified only one modifiable risk factor and 13 indicated that none of the pre-identified risk factors were modifiable.
Figure 6.7 Correct identification of modifiable risk factors

The majority of the participants who were smokers, overweight, had hypertension, high cholesterol and did not participate in physical activity were aware that these were risk factors that could be changed. However, only 65% of participants with diabetes correctly identified this risk factor as amenable to change or improvement (Table 6.14). With the exception of diabetes, there was no statistically significant difference in the knowledge of risk factors amenable to change among participants with and without the particular risk factor. In the case of diabetes, participants with this risk factor were more likely to identify it as modifiable.
**Table 6.14** Correct identification of modifiable risk factors in participants with that specific risk factor

<table>
<thead>
<tr>
<th>Modifiable risk factors</th>
<th>Correct identification %</th>
<th>Chi-square</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overweight &amp; obesity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants without this risk factor</td>
<td>81</td>
<td>1.925</td>
<td>0.165</td>
</tr>
<tr>
<td>Participants with this risk factor</td>
<td>70</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants without this risk factor</td>
<td>40</td>
<td>9.295</td>
<td>0.002</td>
</tr>
<tr>
<td>Participants with this risk factor</td>
<td>65</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants without this risk factor</td>
<td>83</td>
<td>0.169</td>
<td>0.681</td>
</tr>
<tr>
<td>Participants with this risk factor</td>
<td>79</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>High cholesterol</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants without this risk factor</td>
<td>85</td>
<td>3.063</td>
<td>0.80</td>
</tr>
<tr>
<td>Participants with this risk factor</td>
<td>97</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants without this risk factor</td>
<td>83</td>
<td>0.209</td>
<td>0.648</td>
</tr>
<tr>
<td>Participants with this risk factor</td>
<td>87</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Physical inactivity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants without this risk factor</td>
<td>69</td>
<td>1.650</td>
<td>0.199</td>
</tr>
<tr>
<td>Participants with this risk factor</td>
<td>78</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Elements of CR program that were considered important by participants who attended**

The following elements of the CR program were considered to be very important by those who attended: setting goals (51.6%), receiving advice regarding exercise (60.9%), nutrition (56.5%) and stress management (48.4%), having no pain during the exercise program (61.7%), seeing progress (45.9%), and receiving encouragement (53.2%). Elements that were considered to be of little importance
included: exercising with someone (40.6%), interference with daily living (42.6%) and support from other participants (39.3%).

**Comparison of CRPF-R scores among demographic groups**

There were no demographic (age, gender, and employment status) differences in the CR program preference importance priority rankings, as reflected by total CRPF-R scores and the ‘CR program features’ subscale scores (Table 6.15). However, women were more likely to place greater importance ($p=0.02$) in the convenience features of a cardiac rehabilitation program than males (Table 6.15).

**Table 6.15  CRPF-R scores comparisons: demographic characteristics**

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>Total CRPF-R</th>
<th>Factor 1: CR program features</th>
<th>Factor 2: Convenience features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 64 years</td>
<td>31.4 (6.2)</td>
<td>21.6 (4.2)</td>
<td>9.8 (3.0)</td>
</tr>
<tr>
<td>More than 64 years</td>
<td>32.5 (6.8)</td>
<td>33.1 (4.8)</td>
<td>10.4 (2.0)</td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>0.31</td>
<td>0.56</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>33.5 (6.6)</td>
<td>22.4 (5.0)</td>
<td>11.0 (2.5)</td>
</tr>
<tr>
<td>Male</td>
<td>31.3 (6.3)</td>
<td>21.6 (4.2)</td>
<td>9.7 (3.0)</td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>0.09</td>
<td>0.33</td>
<td>0.02*</td>
</tr>
<tr>
<td><strong>In paid employment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>31.7 (6.2)</td>
<td>21.7 (4.3)</td>
<td>10.0 (2.9)</td>
</tr>
<tr>
<td>Yes</td>
<td>32.0 (6.8)</td>
<td>22.1 (4.6)</td>
<td>9.9 (3.1)</td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>0.78</td>
<td>0.61</td>
<td>0.89</td>
</tr>
</tbody>
</table>

* $p < 0.05$

Test of significance: Independent $t$-test

**Participation in cardiac rehabilitation programs**

Of the seventy respondents (35%) who stated that they participated in a CR program, less than a quarter (20.4%) were women. Of those who participated, 41.2% indicated that the reason they participated in a CR program was because it was recommended to them by their specialist or general practitioner, 22.1% stated that they were informed of a CR program by a nurse on the ward and 26.5% by other health
professionals. A minority indicated that they received a reminder from the program coordinator (6%), 26.5% personally felt the need to attend a CR program and 8.8% stated that they saw the benefits in others who had participated in a CR program.

**Reasons why participants did not enrol in a CR program**

More than half the participants did not respond to the reasons for not enrolling in a CR program. Therefore, as the data in each section of the Likert scale were too few, the comparators were collapsed to provide a stronger picture of the reasons for nonattendance at CR programs.

A large proportion of participants (>60%) reported that they were either not informed (36.5%) or were unsure if they were informed (28.2%) of a CR program. Similarly, 44.3% indicated that they were not contacted by staff to attend a CR program. Approximately 45% (n=35) of the participants thought it was unnecessary to attend, while others were unsure whether they should attend (25%). Other reasons stated by participants as to why they did not attend CR programs were that they had previously attended CR either for themselves or for their partner, were happy to organise their own program, or their doctor had organised swimming and walking programs for them.

**6.10 Development of the cardiac rehabilitation enrolment obstacle (CREO) scale**

The CREO scale and its scoring system were developed in three stages. Stage one involved item generation and content validation, which comprised of a comprehensive literature review and interviews with experts (CR program coordinators), stage two included an exploratory factor analysis, and stage three involved instrument testing: assessing the reliability and validity of the rating scales.

**6.10.1 Item generation and content validation for the CREO scale**

**Comprehensive literature review**

A comprehensive search of the Ovid databases MEDLINE (1966-2004), CINAHL (1966-2004) and EMBASE (1980-2004) and the Cochrane Library (Issue 4 2004) was undertaken to identify the reported barriers to participation in cardiac rehabilitation. The Medical Subject Headings terms used to identify the items
included cardiac rehabilitation, predictors, attendance and barriers. The search located eight comprehensive reviews and numerous publications that identified predictors of and barriers to CR attendance.

**Interview with CR program coordinators**
Telephone interviews were conducted with CR program coordinators from metropolitan, rural and remote NSW in order to identify the barriers to patients’ participation in CR programs. A detailed description of the interview methods and the results have been described in Chapter 5. The emergent themes were used to generate items for the development of the instrument. Based on the findings, 15 multinomial questions requiring estimates were developed.

### 6.10.2 Instrument Testing

**Validity and reliability were determined by the following steps:**

**Validity** Content validity refers to the extent to which a measurement reflects the specific intended domain of content. For this study, a reference group was established, consisting of experts in cardiac rehabilitation, clinical cardiology, questionnaire development and psychometrics. The group provided structured comments relating to face and content validity, comprehensibility and comprehensiveness of the items. Based on their feedback, a number of the items in the questionnaire was reworded to correct ambiguity. The formatting of the questionnaire was reorganised so that items relating to personal, practice and organisational barriers were grouped together to minimise confusion and assist the responder. A panel of CR coordinators who did not participate in the telephone interviews reassessed the refined questionnaire.

**Comprehensibility** ensures that the participants understand the text in the questionnaire. Therefore, importance was given to the wording of the items. Simple unambiguous wording was used. The Flesch Reading Ease score and the Flesch-Kincaid Grade Level score were calculated for each component of the questionnaire. This score rates text on a USA school grade level. A score of 8.0 indicates that an 8th grader can understand the document. Both scores were calculated using Microsoft Word for Windows. Based on recent Australian research, ‘standard’ readability Flesch scores between 60 and 70 requiring eight to nine years of education were considered appropriate for the questionnaire.
Five patients who had an ACS were then asked to comment on the questionnaire for its comprehensibility. The feedback relating to the comprehensibility was positive and no amendments were required.

**6.10.3 The final CREO scale**

The final scale (CREO) consisted of 15 items (Appendix 17) with two broad themes. The first section related to the patients’ personal obstacles and the second to their organisational obstacles. Responses to each item were based on a five-point Likert scale ranging from “strongly agree (1)” to “strongly disagree (5)”. Responses to each item on the questionnaire were developed so that a higher item score indicated a more favourable attitude.

**6.10.4 Factor analysis of CREO scale**

Factor analysis is a statistical procedure that explores relationships among variables and establishes a group of items that are interrelated. Principal component analysis with iteration, oblique rotation, and pairwise deletion of missing data were used to test the dimensionality of the CREO scale. Pairwise deletion was selected to limit the loss of data and to preserve as many observations as possible. The correlations ranged from 0.01 to 0.63 with a Kaiser-Meyer-Olkin measure of sampling adequacy of 0.63, indicating that despite the relatively small sample size (n=114) these values met the requirements for adequate factor analysis. A sample of 120 meets the adequate sample size of five subjects per item criterion. Using the scree test criterion by Cattell, two factors were extracted. The popular criterion of unrotated eigenvalues greater than one rule was not used because some of the items of this instrument had low correlations. Using this rule when correlation between variables is fairly low will result in too many factors being extracted. Interfactor correlation exceeded 0.32, indicating that the two factors are correlated, hence direct oblimin (oblique) rotation was used. A factor loading of 0.30 or greater indicating at least a 10% overlap in variance between the item and factor was accepted as a significant loading.

The 15 items in the CREO scale were reverse scored to reflect a higher score representing more self-reported obstacles in cardiac rehabilitation enrolment. Seventy-six of the participants (n=76) completed all 15 items of the CREO scale. The potential range of scores of the 15-item CREO scale (with a 5-point Likert scale)
is 15 to 75. The distribution of scores for participants who completed all items on the scale ranged from 15 to 59 with a mean of 36.7 (SD 8.3).

The two-factor solution coincides with the theoretically postulated number of factors of the CREO scale. The percentage of variance accounted for by the unrotated two-factor matrix was 45.5%. All 15 items of the scale loaded significantly on one of the two factors. The first factor accounted for 29% of the variance and reflected self-statement related personal obstacles for non-cardiac rehabilitation enrolment (e.g. do not have time, too far from home, and lack of motivation). This factor was labelled as ‘patient-related obstacles’. The second factor accounted for 16.5% of the variance and consisted of items related to organisational-related factors (e.g. long waiting list, not informed about program) for non-enrolment in cardiac rehabilitation, and the second factor was labelled ‘health service-related obstacles’. Aside from being the most parsimonious and consistent with the theoretically postulated number of factors, the two-factor analysis offered the most meaningful and interpretable solution (Table 6.16).

The internal consistency of the scale and subscales was high (Cronbach’s alpha coefficients of 0.80 for the total CREO scale, 0.82 for Factor 1: Patient-related obstacles and 0.70 for Factor 2: Health service-related obstacles).
Table 6.16  Factor Loadings for Principal Component Analysis with Oblique Rotation (n=104)

<table>
<thead>
<tr>
<th>Factor 1: Patient-related obstacles</th>
<th>Factor 2: Health service-related obstacles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not have time</td>
<td>0.794</td>
</tr>
<tr>
<td>Unsuitable class time</td>
<td>0.747</td>
</tr>
<tr>
<td>Conflict with work</td>
<td>0.688</td>
</tr>
<tr>
<td>Too far from home</td>
<td>0.673</td>
</tr>
<tr>
<td>Lack of family support</td>
<td>0.664</td>
</tr>
<tr>
<td>Fear of further pain</td>
<td>0.641</td>
</tr>
<tr>
<td>Do not like group activities</td>
<td>0.627</td>
</tr>
<tr>
<td>Language difficulties</td>
<td>0.556</td>
</tr>
<tr>
<td>Lack of motivation</td>
<td>0.485</td>
</tr>
<tr>
<td>Thought unnecessary</td>
<td>0.310</td>
</tr>
<tr>
<td>Not contacted by cardiac rehabilitation staff</td>
<td>0.798</td>
</tr>
<tr>
<td>Long waiting list</td>
<td>0.745</td>
</tr>
<tr>
<td>Lack of support/referral from doctor</td>
<td>0.689</td>
</tr>
<tr>
<td>Not informed about program</td>
<td>0.671</td>
</tr>
<tr>
<td>Doctor said unnecessary</td>
<td>0.501</td>
</tr>
</tbody>
</table>
Comparison of cardiac rehabilitation enrolment and CREO scale and subscales

Comparisons by independent $t$-tests were performed to determine differences for each factor between participants who enrolled in a cardiac rehabilitation program and those who did not. Although all patients were required to complete this section of the questionnaire, responses to this item were received from only 114 participants, 13 of whom participated in CR.

Participants who enrolled in a cardiac rehabilitation program had lower scores on the CREO scale (M 31.0, SD 9.0) than those who did not enrol (M 36.9, SD 8.3), $t(72)=2.16, p < 0.03$. Similarly, enrollees had lower scores on the health service-related obstacle factor (M 10.8, SD 3.4) than non-enrollees (M 14.0, SD 4.8), $t(88)=2.47, p < 0.02$. Although this trend of lower scores was also observed on the patient-related obstacle factor, the difference was not statistically significant between enrollees and non-enrollees (Table 6.17).

### Table 6.17 Mean and Standard Deviation Total and Factor Scores

<table>
<thead>
<tr>
<th></th>
<th>Enrollees in Cardiac Rehabilitation</th>
<th>Non-enrollees in Cardiac Rehabilitation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$M$</td>
<td>$SD$</td>
</tr>
<tr>
<td>Total 15 items: CREO scale</td>
<td>31.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Patient-related obstacles</td>
<td>20.9</td>
<td>6.6</td>
</tr>
<tr>
<td>Health service-related obstacles</td>
<td>10.8</td>
<td>3.4</td>
</tr>
</tbody>
</table>

### 6.11 Discussion

Percutaneous coronary intervention remains a safe and effective revascularisation technique, resulting in an increased number of procedures performed each year.

Although the culprit lesion is technically repaired, the underlying risk factors continue to persist.

#### 6.11.1 Cardiovascular risk factors status

In this chapter the general trends of the presence of risk factors in the long-term following PCI are presented. The results support findings from other researchers.
that 80% participants with CHD have at least one risk factor, which remains of concern as it could contribute towards the progression of CHD and further cardiovascular events.

Self-reported hypertension was identified as a common risk factor; however, long-term blood pressure control was near optimal with only 18% of the participants having this risk factor at the 12-24 month follow-up. The high prevalence of hypertension in women identified in this study remains of major concern and strategies to address this must be implemented. Tighter blood pressure control is vital given the evidence of the prognostic significance of this risk factor. Numerical values for blood pressure and cholesterol were provided by only a small number of participants which could indicate a lack of knowledge of their risk factor status, thereby precluding them from making lifestyle changes.

Self-reported inadequate management of long-term cholesterol control was also identified. Secondary prevention guidelines from the NHFA recommend a total cholesterol level of less than four mmol/L, however more than half of the participants who reported their value had a total cholesterol level greater than the recommendations. This finding is consistent with other studies that indicated that despite medical management almost three-quarters of the participants did not achieve the target cholesterol level. None of the participants reported on the LDL or HDL values, which could be due to the lack of knowledge of these results or simply because the participants could not remember. Another interesting finding was that a large proportion of these participants with high cholesterol levels believed that their level was normal. This finding can be ascribed to denial by participants to accept risk factor status and/or inaccurate information provided by health professionals due to the lack of awareness of the new guidelines. Although the majority of the participants were receiving lipid-lowering therapy, a large proportion had not achieved an optimal level. Possible reasons for these findings could include inadequate reassessment of lipid level and adjustments made to lipid therapy by health professionals, despite clear evidence of the risk of coronary events associated with hypercholesterolaemia.

These outcomes have major implications for interventions targeting lifestyle modification. Educating participants about their blood pressure and cholesterol and
informing and stressing the importance of knowing the numerical values could assist in risk factor modification. In addition, monitoring participants following their discharge from hospital, and providing strategies for adherence to medications and health-related behaviour changes are also vital aspects in the continuum of cardiac care.

Published data indicate that cigarette smoking is the most common risk factor encountered, however in this study only 15% continued to smoke, despite advice to quit. This finding is consistent with recent research that approximately 20% of patients continue to smoke after a cardiac event. Despite the reduction in the rate of smoking following the coronary event, a significant proportion of participants continued to smoke, which, in combination with other risk factors, is a strong predictor of future mortality and morbidity. The low prevalence of cigarette smoking could be underestimated as the results were based solely on self-reports rather than objective markers.

In this study, although a large proportion of participants reported to have walked, only half of the participants reported to walk for 150 minutes or more each week as per the NHFA recommendation. This finding has significant clinical implications as it demonstrates the lack of knowledge among participants about the amount of physical activity required to obtain cardio-protective benefits. For some participants, it could also be possible that they chose to make poor lifestyle decisions despite knowing the consequences of physical inactivity. As could be expected in a population that seldom exercises, the mean BMI for all participants was above the recommended guidelines at 28.7kg/m² with the majority of the participants in the pre-obese stage. This finding is particularly concerning given that the people in this study are representative of a much larger group in the Australian community, and it does support the obesity epidemic in Australia.

Some level of depression, anxiety and stress was reported by approximately a quarter of the participants, eight of whom had a history of depression and anxiety and were receiving treatment. There is mounting evidence that depression is associated with up to a 5-fold increase in relative risk of mortality in participants suffering an AMI; however there evidence of no benefit relating to event-free survival among patients who receive a psychosocial intervention compared to those who do not. Unlike
other studies\textsuperscript{498} that reported stress to be a commonly reported risk factor, in this study extremely severe stress was reported by only a small number of participants. Nevertheless, this risk factor should not be ignored and stress management strategies need to be incorporated in patient education and risk factor modification programs for those who require it.

6.11.2 Functional status and health-related quality of life

In this study, there were no statistically significant differences in any of the HRQoL domains during 12-20 months post PCI trajectory period. However, it is worth noting that the emotional and social domain scores increased at 18 months, which reflects improved mental and social stability, and began to decrease thereafter. This finding relating to emotional scores supports other studies that have reported significantly lower emotional scores at the one and eight year follow-up compared to baseline.\textsuperscript{499}

Other studies report significant improvements on the dimensions of mobility in participants 12 months following PCI. This finding was evident up to 20 months, following which the scores started to decline. Reasons for reduced scores in the later period could be due to the fact that the majority of the participants were elderly and the decline could have been due to the ageing process and comorbid conditions rather than CHD.

Of interest, patients’ perceptions of HRQoL following the procedure was greatest at 20 months for physical and global scores and at 18 months for emotional and social scores. The impact of improved social and emotional well-being may have potentially impacted on the individual’s self-efficacy for exercise and other positive health behaviours.

The HRQoL in participants in the later window of the follow-up period had declined for all domains, however the scores were still higher than those at 12 months, supporting the improved quality of life two years following PCI.

6.11.3 Medication Adherence

A large proportion of the participants reported taking medications for lowering cholesterol and blood pressure and preventing blood clots, which is consistent with the general literature.\textsuperscript{177,178} However, due to the method of data collection it is
difficult to differentiate between patient non-adherence and physician non-prescription for the remaining participants. In spite of the lower perception of risk attributed to people undergoing PCI, very few participants in this study reported that they missed taking their medications. However, the study highlights the fact that few participants reported the correct method for the storage of nitroglycerine medications, which is of concern because improper storage of these medications can render them ineffective, leading to increased morbidity and hospitalisations.

6.11.4 Knowledge of CHD and risk factors
Overall the knowledge level of the participants relating to CHD and its management was poor. A greater proportion of participants demonstrated knowledge of foods that were high in cholesterol, management of chest pain and management of medications, which is encouraging.

A large proportion of the participants were able to identify at least one of the seven modifiable risk factors. What is concerning, though, is that nearly half the participants were unable to identify at least four of the modifiable risk factors. Among the six modifiable risk factors investigated, knowledge for high cholesterol (87%), smoking (83%) and hypertension (82%) was the highest. This is comparable with other studies that have reported similar findings. Identification of diabetes as a risk factor for CHD was extremely low, which is of major concern given the strong association of diabetes with adverse health outcomes. A striking finding of this study is that more than a third of the participants with diabetes did not identify diabetes as a risk factor for CHD. This pattern of knowledge may be due to relatively aggressive advertising campaigns as well as educational programs discouraging the use of saturated fats and tobacco, compared with a relative absence of the same for diabetes. Given the fact that medical complications arising from diabetes have considerable impact on mortality and morbidity, particularly in participants with CHD, knowledge of this risk factor and early intervention may prevent progression of the disease. This finding highlights a potential area of emphasis for future educational programs.

6.11.5 Important elements of a CR program
Women were more likely to place greater importance in the “convenience features” of a CR program. This could be due to the fact that female participants in this study
were significantly older and more likely to be widowed. This is an important finding for the development of alternate strategies of CR, in particular for older women. The study also shows that those who were recommended by a health professional to attend CR were more likely to place greater importance on specific features of the program.

6.11.6 Participation in CR programs

Participation in CR programs was 35.6%, which, although not optimal, is well above other reported participation rates among participants following PCI in the Australian setting. The main reason for participation in the CR program was a recommendation from the GP or specialist, which demonstrates that the strength of a physicians’ advice greatly influences participation rates. It is interesting to note that only a small number of participants indicated that CR was recommended to them by the nurse. This could be due to the fact that nurses on the ward have a busy workload and these participants are often missed due to their short hospital stay. However, this is of major concern and strategies need to be developed to inform these participants of CR participation. A few participants also stated that they personally felt the need to attend the CR program, which is indicative of a strong intention for risk factor modification. However, it could be assumed that the remainder do not consider PCI as a warning sign and see no need to modify risk factors. It could be postulated that poor participation in the CR program could be due to poor referral practices.

Of note, only a quarter of the women – compared to 37% of the men – participated in CR programs. This could be due to the fact that the women were considerably older than men, although this was not significant in the multivariate model. Inferior outcomes among women with heart disease underscore the importance of attention to these lower participation rates.

Many factors may contribute to an under use of CR services, including individual social and economic situations, overall health knowledge, access to health care, health care-seeking behaviours, as well as providers’ practice patterns and communication of health messages. These observations have major implications for clinical practice in terms of development of models for CR participation.

Findings from the logistic regression analyses indicate that factors related to family circumstance have a significant effect on participation in CR programs, with marital
status identified as the strongest predictor in this cohort of participants. This suggests that support or the lack of it from other members of the household may play a crucial role in participation in CR programs, although there may be other reasons, such as the distance to a CR program, waiting times and strength of referral, that could influence participation. This finding is consistent with studies undertaken in participants following MI or CABG where marital status was the strongest predictor of participation. Of note, the higher number of men in this study infers that female partners may be a driver for participation.

The second barrier to nonparticipation in this study was age. Younger age was associated with a higher probability of participation in CR programs. Decreased participation among older people is consistent with other literature, and could be due to challenges in transportation and the presence of comorbid conditions and greater levels of functional impairment.

Although the cost of CR is not a factor, because programs are free of charge, in this study the participants who had a mean income exceeding $50,000 were more likely to participate in CR programs. Factors related to socioeconomic status are complex and are related to issues such as level of education and financial status. It could be that these participants possessed higher levels of self-efficacy and found it easier to direct themselves towards a long-term goal, such as reduction of risk factors, compared with those in lower socioeconomic strata, who may be oriented towards more immediate needs. Participants in higher income categories could also have greater access to transport and more disposable income to spend on services required to participate in cardiac rehabilitation. Increasingly, the link between socioeconomic status and adverse cardiovascular outcome is being demonstrated.  

### 6.11.7 Development of the CREO scale

Although barriers to CR participation have been identified, without valid and reliable measurement instruments it is not feasible to recognise these participants during their hospital stay. The 15-item CREO scale was designed to assess the barriers to participation in CR programs among participants following PCI, and was based on the evidence identified in the published literature and interviews with expert CR program coordinators. The comprehensive approach to development and assessment of the CREO scale ensures excellent content validity.
A two-factor solution, namely organisational and personal barriers, was found to best fit the data, which indicates that these are the main reasons for nonparticipation. The CREO scale was able to differentiate between cardiac rehabilitation enrollees and non-enrollees, with the former having a lower score on the CREO score. A comparison was available between people who did attend CR and those who did not, and this was facilitated by the prospective study design. By doing so, the representativeness and the discriminative ability of the scale has been demonstrated. However, subsequent testing of the validity and discriminative ability of the CREO scale with larger populations is needed. Further studies to confirm its responsiveness and validity are necessary, and this may make the instrument beneficial in identifying nonparticipants and providing them with alternate strategies.

6.11.8 Limitations of the study
Although this study has provided valuable data, the limitations that preclude generalisability of the findings should be recognised. An important limitation of this study was the recruitment method which prevented the collection of complete baseline data from the participants. Although the medical records of participants were audited vital data relating to risk factors were often missing. Collection of data prior to the PCI procedure would assist in undertaking comparisons before and after the PCI. Secondly evaluation of all outcome variables were based solely on participants self reports which the researchers acknowledge is subject to recall and social desirability bias resulting in underreporting of actual values. However it was beyond the scope of this study to obtain blood pressure, cholesterol and blood glucose values from GPs or cardiologists. The method of questionnaire administration also precluded assessment of waist measurement which has been reported a robust indicator for obesity status. In addition other known coronary risk factors such as diabetes, were not assessed at follow up as it would be inappropriate to evaluate this outcome due to the lack of baseline data. Furthermore, information on dietary habits was not collected and mortality rate due to CHD could not be ascertained as it was beyond the scope of this study. Finally only 70 % of the total number of patients who underwent PCI were able to be contacted and only 75 % of those who agreed to participate returned a completed questionnaire. The length of the questionnaire could also be a factor in the non-response rate. This non response error is a threat to the external validity and therefore inhibits generalisation of the findings.
Never the less, this study brings to the attention of clinicians the need to focus on an overlooked component of holistic patient care namely the need for extensive risk factor educational programs for participants who have undergone PCI.

6.12 Conclusions
In this chapter, the results of a self-reported survey undertaken in 202 patients, 12-24 months following PCI have been presented. This group of patients were studied because PCI treatment for CHD is becoming increasingly common. Although these patients have the same risk factors as those who receive other methods of treatments, namely CABG, patients who have had PCI are less likely to attend CR and believe that they no longer have heart disease. The findings related to their cardiac risk factor status, HRQoL, adherence to medications and knowledge relating to CHD and its risk factors have been presented. In addition, the development and evaluation of a scale to assess obstacles to cardiac rehabilitation enrolment in patients following PCI has been described. The preferences of PCI patients in relation to CR have also been reported. This information has contributed to the development of the HeLM intervention described in Chapter 7.

6.13 Implications for the development of the HeLM intervention
1) The findings from this study indicated the presence of at least two modifiable risk factors in approximately 70% of participants with the majority of the participants classified as overweight and physically inactive. Therefore the HeLM intervention was designed to include physical activity and diet. In addition as smoking causes restenosis of the treated vessel, smoking cessation was also included.

2) Participants reported insufficient knowledge relating to CHD and modifiable risk factors or they could be in denial therefore the HeLM intervention included information about CHD and modifiable risk factors

3) As convenience features of a CR program were important the HeLM intervention was delivered using the mail and telephone.
Chapter 7

Feasibility of the Health-related Lifestyle self-Management (HeLM) intervention
7.1 Introduction

This chapter presents the components of the HeLM intervention. In addition, the methods and the feasibility of implementing the HeLM intervention are described. Chapters 4, 5 and 6 have reported on the evidence obtained from a systematic review of the literature, a qualitative interview of CR coordinators, and a survey of patients following PCI. The findings from these three studies that were used in the development of the HeLM intervention are summarised in Table 7.1.

Table 7.1 Findings from Chapters 4, 5 and 6

<table>
<thead>
<tr>
<th>Findings from the systematic review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• there was evidence of a benefit of brief structured interventions for risk factor reduction. However further investigations are warranted to support the evidence</td>
</tr>
<tr>
<td>• three to six telephone support calls over a six month period, each lasting 15-30 minutes, could be effective in risk factor reduction</td>
</tr>
<tr>
<td>• brief motivational support can be delivered by persons trained in motivational interviewing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Findings from the interviews with CR coordinators</th>
</tr>
</thead>
<tbody>
<tr>
<td>• CR coordinators face numerous obstacles, including health service, professional and patient related barriers to delivering services</td>
</tr>
<tr>
<td>• CR coordinators were committed to providing evidence-based care through alternate methods of service delivery and community engagement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Findings from the survey of patients post-PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 70% of participants had at least two modifiable risk factors</td>
</tr>
<tr>
<td>• hypertension and hypercholesterolaemia were the most common biophysiological risk factors</td>
</tr>
<tr>
<td>• approximately 80% of participants were classified as overweight</td>
</tr>
<tr>
<td>• a quarter of the participants had some form of depression, anxiety or stress</td>
</tr>
<tr>
<td>• improvements in HRQoL scores were observed at 18 months following the index PCI, after which a decline was observed</td>
</tr>
<tr>
<td>• there were high rates of self-reported medication adherence</td>
</tr>
<tr>
<td>• participants had limited knowledge relating to CHD</td>
</tr>
<tr>
<td>• there was a lack of awareness regarding modifiable risk factors</td>
</tr>
<tr>
<td>• the accessibility of a CR program were important</td>
</tr>
<tr>
<td>• there were less than optimal participation rates in CR programs</td>
</tr>
</tbody>
</table>
7.2 The HeLM intervention

The HeLM intervention was developed based on the above findings and was embedded within the framework of chronic disease management, the TTM of behaviour change\(^\text{203,204}\) and motivational support\(^\text{207,377}\).

The intervention consisted of the following components: goal-setting, the HeLM Booklet (Appendix 24), personalised risk factor card (Appendix 25) and patient feedback form (Appendix 26), team building and communication with GPs (Appendix 27), three supportive telephone calls (Appendix 28), a fridge magnet, and a health diary (Appendix 29). Each of these is described below.

7.2.1 Goal-setting

Goal-setting is an established strategy used both explicitly and implicitly in behaviour modification programs where the patients set optimistic yet realistic goals that facilitate health behaviour change and maintenance\(^\text{506}\). This strategy is often used to assess the effectiveness of a program on behaviour modification. In this study, patients were asked to set a goal that they would like to achieve by the six week follow-up. This was done during the initial data collection prior to discharge from the hospital.

Goal-setting was undertaken according to the SMART principles, which have been demonstrated to enable individuals to stay motivated and achieve their goals\(^\text{507}\). The acronym SMART stands for Specific, Measurable, Achievable, Realistic and Time.

**Specific:** Patients were asked to write down specific goals they would like to achieve. To set the specific goal they had to identify: who would be involved, what they would like to accomplish, when they would like their goal achieved, as well as a location and any requirements and constraints\(^\text{507}\). For example, losing weight was considered as a general goal and a specific goal would be a target weight of 65 kg in one month.

**Measurable:** In order to identify if the goal has been met it should be measurable. Weight, physical activity, smoking status, and fruit, vegetable and fat intake are all measurable outcomes. Patients were asked to record their current smoking, physical activity and diet for a week so that they could measure the difference at follow-up.
Achievable: Goals that are important should be achievable. Patients were instructed to set goals that were flexible in order to accommodate any unexpected challenges. For example, losing 50 kg in 10 weeks is unachievable if the individual is injured and exercise was the main factor in weight reduction. Patients were asked to visualise themselves reaching the goals. This method has shown that patients identify strategies and develop attitudes, abilities and skills to reach their goals.

Realistic: Setting realistic goals is the key to goal attainment. Patients were instructed to set a goal that they believed they could accomplish. They were also asked to identify any conditions that would have to exist to enable them accomplish the goal. For example, walking 10 minutes each day would be a realistic goal for an individual who is sedentary and morbidly obese.

Time: Setting a deadline for the achievement of a goal demonstrates a sense of urgency. The absence of a timeline generally results in procrastination and boredom. Patients were encouraged to set realistic timelines to achieve the goal. For example, a time-based goal would be losing 10kg by 16 September 2007.

7.2.2 The HeLM booklet
The HeLM booklet was based on the TTM of behaviour change. The evidence is supportive of the effect of information booklets on knowledge and self-management. The 50 page colour booklet was developed as a self-help resource to provide skills training for modification of health risk-related behaviour relating to smoking, physical activity and saturated fat intake. The booklet was designed to have a colour-coded section corresponding to each of the five stages of change for each of the health risk-related behaviours. Specific strategies that the patients could activate in order to progress to the next stage were listed in each stage of change section. This method ensured that the information in the booklet was tailored to the patient.

Content of the booklet
The first section of the booklet was intended to provide information, as knowledge has been shown to be necessary, but in itself not sufficient motivation for, behaviour change. Therefore, this section covered the meaning of coronary artery disease and the risk factors. As the booklet was designed to be interactive, patients were asked to identify the risk factors that applied to them.
The second section of the booklet was a short quiz about how the patients felt about their current smoking, physical activity and diet habits. Responses to the quiz enabled the patients to identify their stage of change. Provision was made in the booklet for participants to write down their stage of change and then go to the appropriate colour-coded section to identify strategies for behaviour modification.

The third section of the booklet was related to information and strategies corresponding to the stage of change for each of the health risk factors, namely smoking, physical activity and fat intake. This section was designed to enable the individual to weigh the positive and negative aspects of a risk-related behaviour (decisional balance). It also included experiential and behavioural activities (processes for change) that individuals could use to progress through the various stages of change. The following elements were included in each stage of change for each of the risk factors.

Pre-contemplation Stage The information in this section included reasons why people in general continued the particular offending behaviour, the need to change to healthy habits, and facts about the effects of their offending behaviour on their health. Participants were also asked to list their own personal reasons for continuing the offending behaviour as well as the need to change.

Contemplation Stage The contents of this section were targeted at people who were thinking about changing to a healthy behaviour. This section included information on what they could do and how they could start to adopt healthy habits. Participants were also provided with space to list the strategies that they have identified to make progress. In addition, this section incorporated a journal where participants could record their offending health habits (e.g. number of cigarettes smoked per day). The benefits of modifying risk factors were emphasised, information about the effect of a delay in modifying risk factors was provided and the importance of setting a goal was stressed.

Preparation Stage In this section, four principles were targeted: (a) reversal of the decisional balance (more cons than pros of health-related risk habits); (b) more extensive use of behavioural processes of change; (c) the reinforcement of self-efficacy; and (d) the acquisition of relapse-prevention skills. Information in this section included strategies for preparation, identification of a date to commence
healthy habits, and contract negotiation with oneself. In addition, a list of high-risk situations was identified and management strategies for each risk situation planned. Participants could also list some situations that they considered to be high-risk and plan a course of action. A crisis management plan was included in case the participant relapsed to the offending habits.

**Action Stage**  
This section included information and tips for preventing relapse, and encouragement to pursue the goal. The action stage focussed on increasing the use of behavioural processes, reinforcing self-efficacy, providing relapse-prevention skills, and reinforcing attempts towards healthy behaviours by congratulating the individual for adopting healthy behaviours.

**Maintenance Stage**  
In this section, the barriers that the individuals would have to overcome and strategies for continuing to maintain the healthy behaviours were provided. Encouragement, relapse prevention and incorporation of new behaviour into lifestyle were emphasised.

**Validity and reliability assessment of the HeLM booklet**  
The importance of assessing the validity and reliability of patient information has been well established.510,511

**Validity and reliability were determined by the following steps:**  
**Validity**  
Content validity refers to the extent to which a measurement reflects the specific intended domain of content.489 For this study, a reference group consisting of consumers, experts in CR, smoking cessation, physiotherapy, dietetics and clinical cardiology was developed. The group provided structured comments relating to the factual content of the information that was presented, along with additional evidence-based information. Contentious issues were discussed and decisions made depending on the quality and strength of the scientific evidence that was available.512 The group also commented on the visual aspects, comprehensibility and comprehensiveness of the content. Based on their feedback, a number of the changes was made and the content reworded to correct ambiguity. Two CR coordinators who did not participate in the initial validation process assessed the refined booklet.

**Comprehensibility** ensures that the participants understand the text in the HeLM Booklet.489 Therefore, importance was given to the wording of the items. Simple
unambiguous wording was used. The Flesch Reading Ease score \(^{490}\) was calculated for each component of the HeLM Booklet. This formula is widely used and is calculated based on the average sentence length (the number of words divided by the number of sentences) and the average number of syllables per word (the number of syllables divided by the number of words). It provides a readability score ranging from 0 (extremely difficult) to 100 (extremely easy), which is used to predict ease of readability.

The Flesch-Kincaid Grade Level score was also calculated for every component of the booklet. This score rates text on a USA school grade level. A score of 8.0 indicates that an 8\(^{th}\) grader can understand the document. The formula used for this calculation was also based on the average sentence length (the number of words divided by the number of sentences) and the average number of syllables per word (the number of syllables divided by the number of words).

Both scores were calculated using Microsoft Word. Based on recent Australian research, \(^{491}\) 'standard' readability (Flesch scores between 60 and 70) requiring eight to nine years of education was considered appropriate for the booklet. Findings from the FACT study (Chapter 6) demonstrated that the majority of the patients had left school before secondary education and 47.8\% had neither completed secondary school nor attained any subsequent qualifications. Therefore, it was decided to target the readability of the HeLM booklet at a Year Six level. The HeLM booklet was subsequently given to a Year Six student and three patients for assessment of readability. Their recommendations were incorporated into the booklet.

**Visual aspects of the booklet**

With the assistance of a graphic designer, the visual aspects of the HeLM booklet including the length, format and layout were refined. \(^{513}\) Graphics were added to improve the visual quality. The formatting of the booklet was reorganised so that the headings for each of the risk-related behaviours were consistent.
7.2.3 Feedback of personal risk

Risk factor card
Biomedical risk assessment is the process of giving individuals feedback on the physical effects of their health-related behaviours by physiological measurements. Based on the responses to the questionnaire, including BMI, smoking status, participation in physical activity and the patient’s laboratory data, individual risk factor cards were generated. The risk factor card included the patients’ values for all cardiovascular risk factors along with the normal values for comparison. In addition, any of the patients’ abnormal values were highlighted. A five year mortality risk score and the risk of developing CHD or having a recurrent CHD event was calculated and presented from the results obtained using the cardio risk calculator provided by Merck, Sharpe & Dohme. The risk factor calculator is based on the Framingham Heart Study in the USA and requires inputting data relating to gender, age, cholesterol level, HDL, systolic blood pressure, smoking status and the presence of left ventricular hypertrophy and diabetes. The total score was calculated by adding together the points for each risk factor. For people with pre-existing CHD, the risk of developing CHD or having a recurrent CHD event within the next 10 years is more than 20% (high risk).

All information about risk factors was presented on an A5 laminated risk factor card (Appendix 25). However, it is recognised that calculating risk using the Framingham score has limitation as it does not provide reliable risk estimates in type 2 diabetes.

Personalised letter
The evidence is supportive of a reduction in unhealthy behaviour relative to controls when the intervention and personalised feedback were conducted through the mail and not face-to-face. Using the responses provided in the baseline questionnaire, participants were mailed a personalised letter providing feedback about their existing habits relating to smoking, exercise and diet and how they felt about modifying these risk-related behaviours. This feedback was provided to enable them to read the appropriate section of the HeLM booklet for strategies for risk modification.
7.2.4  Team building and communication with GPs

Communication with the GP included a letter describing the patient’s participation in the study. GPs were requested to provide support for these patients and enforce lifestyle changes. GPs were also encouraged to provide patients with risk factor education.

7.2.5  Three supportive telephone calls

Three supportive phone calls were made during the six-week intervention period. The first telephone call was made one week following the mailing of the intervention package to ensure that the participant had received the intervention package and to answer any queries. The second telephone call was made three weeks following the mailing of the intervention and focussed on providing motivational support targeted at the participants’ stage of change. The third telephone call was made five weeks following the mailing of the intervention. During this phone conversation, progress of the participant was monitored, encouragement and support provided and a date was scheduled for the follow-up visit at the research centre. Each telephone call was designed to last no more than 30 minutes and strictly focused on the purpose for which they were made. The main purpose of the telephone calls was to enforce responsibility and provide advice and support. The phone conversations were based on the elements tested under the terms “BI” and “motivational interviewing”, which included feedback, responsibility, advice, menu, empathy, self-efficacy. The motivational phone calls were made to facilitate the progress along the different stages of change.

Feedback  Feedback of personal risk was emphasised during the telephone interviews.

Responsibility  Emphasis was placed on personal responsibility for change. Patients were advised that smoking, physical inactivity and increased weight were their own responsibility and choice. Miller has reported that “perceived control” is an important aspect of motivation for behaviour change and maintenance. The information booklet also included a log for patients to record their cholesterol and blood pressure levels as well as physical activity level and smoking habits.

Advice  The provision of advice is fundamental to brief intervention strategies. Participants were provided simple comprehensible advice to modify cardiac risk. This advice was reinforced from the HeLM booklet that covered the risk factors for
coronary artery disease, the benefits of lifestyle modification, and tips for smoking cessation, increasing physical activity and maintaining a low-fat diet.

**Menu** The HeLM booklet provided a menu of evidence-based self-help resources to prevent relapse and maintain lifestyle management. Patients were also given information about a CR centre nearest to their place of work or home.

**Empathy** Patients were treated in an empathetic and understanding manner. Feedback and telephone support were not aggressive, confrontational, dictatorial or intimidating.

**Self-efficacy** Patients were assisted to identify barriers and facilitate the integration of lifestyle change. Feedback was also provided through praise, positive encouragement, and guidance with problem-solving. Rather than emphasising helplessness or powerlessness, self-efficacy was encouraged.

**Training of the interviewer**
All telephone support calls were made by the research assistant (RA), who had previous experience in motivational interviewing. Each stage was linked to a motivational script and stage-relevant clinical content to enable the delivery of consistent information\(^{380,517}\) (Appendix 28). The RA also undertook a one-day comprehensive course in motivational interviewing at the Alcohol and Drug Service, NSW Health. The course involved a workshop, presentation and practical experience with a counsellor from the Quit line.

### 7.2.6 Fridge magnet

Visual cues have been reported to be an effective method to remind individuals and reinforce the information that is being learnt.\(^{518}\) In this study, participants in the intervention group were given a fridge magnet that provided information on what to do in an emergency.

### 7.2.7 Health diary for self-monitoring

Patients were given a health diary where they could self-monitor their results, e.g. blood pressure, cholesterol, weight, and physical activity, with room to document subsequent values. Self-monitoring is defined as “the systematic observation and recording of target behaviour”\(^{519}\) and has been reported to be an effective behavioural treatment to improve self-management in patients with chronic disease.\(^{520}\) Self-monitoring enables patients to recognise signs and symptoms and
triggers, all of which assist in self-management. Among patients with a chronic illness, increased awareness of their condition facilitates effective planning of self-management. In addition, self-monitoring and recording enables better communication between the patient and the health care professionals. Various methods for self-monitoring including paper and electronic diaries have been reported to be valuable tools for monitoring behaviour change. A health diary assists people to keep track of tests, examinations and results that are important for their health.

7.3 Feasibility of the HeLM intervention

A feasibility study is undertaken to provide information, which may include operational and financial impact data, to assist researchers with deciding whether a research study under consideration should proceed. It is usually a small scale version done in preparation for a larger study. This chapter is a report of the feasibility study of the HeLM intervention.

7.4 Aim of the study

The aim of this study was to investigate the feasibility of conducting a structured brief HeLM intervention in patients with ACS to reduce Major Acute Coronary Events (MACE) which includes mortality, hospitalisation for MI, cardiac arrest, and revascularisation. The specific objectives were to: (1) assess the feasibility of the intervention in terms of: (a) recruiting patients with ACS to participate in a study on risk factor modification, (b) treatment program attrition, adherence and completion rates, (c) suitability of data collection methods and questionnaire completion, and (d) acceptability of the intervention by the participants; (2) identify the rate of CR attendance among participants; and (3) assess the effect of the HeLM intervention on the behavioural changes related to cardiac risk factors, namely smoking status, participation in physical activity, obesity, and saturated fat, fruit and vegetable intake.

7.5 Design of the study

The RCT design was used to investigate the feasibility of the HeLM intervention in preparation for a large RCT. This research design is the most rigorous way of
determining whether a cause-effect relation exists between two or more clinical interventions.\textsuperscript{524} Although other study designs, including non-RCTs, have the ability to detect associations between an intervention and an outcome, they cannot exclude the possibility that the association was caused by a third factor linked to both intervention and outcome.\textsuperscript{524,525} Allocating participants randomly ensures comparability between intervention groups in known and unknown factors that may influence outcomes.\textsuperscript{524,525} Other advantages of RCTs include identical treatment for all groups except for the experimental intervention, blinded assessment and analysis based on intention to treat.\textsuperscript{524,525} As a RCT design will be used for a larger study for the reasons mentioned above, this feasibility study was also conducted using the same design.

\textbf{7.6 Research methods}

\textbf{7.6.1 Recruitment of participants}

All patients admitted to the acute and subacute coronary care unit of a metropolitan hospital in SSWAHS (Western Zone) and who met the inclusion criteria were invited to participate in the study using a predeveloped recruitment script (Appendix 18). The criteria for inclusion in the study were patients aged 18 years or older who were admitted to the coronary care unit (CCU) or coronary care unit subacute (CCU-S) with a diagnosis of an ACS,\textsuperscript{526} and had one or more of the following modifiable risk factors: (a) smoking (more than 1 cigarette per day\textsuperscript{34} or a breath Carbon monoxide (CO) level of 6 or 8 ppm\textsuperscript{527} ) (b) overweight and obesity as determined by BMI > 25 kg/m\textsuperscript{2}\textsuperscript{34} and increased waist-hip ratio (>0.9 for males and >0.8 for females)\textsuperscript{528} (c) high saturated fat intake (more than 21 points) as measured by the 17-item Short Fat questionnaire\textsuperscript{529}; (d) low physical activity (less than 30 minutes of moderate intensity physical activity per day for most days of the week (150 minutes per week minimum)\textsuperscript{34}; (e) documented history of high total cholesterol (> 4 mmol/L)\textsuperscript{34}; and (f) documented history of hypertension (BP>140/90 mm Hg if the patient is \textgeq 65 years; BP>130 mmHg if the patient is \textleq 130/85 mm Hg and BP > 125/75 mm Hg if the patient has proteinuria.\textsuperscript{34}

Patients were excluded if: (1) they had major comorbidities, such as cerebrovascular accident and cancer, that would complicate their convalescence; (2) their physician did not want them to participate in the trial; (3) they were unavailable for long-term
follow-up; or (4) they were unable to understand English and personally give informed consent. These patients were excluded because the components of the HeLM intervention including the Take the HeLM booklet, telephone support and advice was conducted only in English.

This feasibility study was undertaken using 20 participants in each group. Participants were provided with a subject information sheet (Appendix 19) and written consent (Appendix 20) was obtained.

7.6.2 Data collection and management

All patients who consented to participate in the study had their anthropometric measurements performed by the RA. Data were collected using a questionnaire (Appendix 21) and an audit of the patient’s medical records (Appendix 22). The type of data collected and the instruments used to measure the outcomes are presented below.

Participant demographics

The demographics that were collected included age, gender, level of education, marital status and employment status.

Feasibility of the study

The feasibility of the study was evaluated from four different perspectives, namely recruitment, treatment program attrition, adherence and completion rates, suitability of data collection methods and questionnaire completion by participants, and acceptability of the intervention.

Recruitment of patients with ACS was determined by the length of time it took to enrol the sample (20 patients), the number of patients who met the study criteria and the number who consented to participate in the study.

Treatment program attrition, adherence and completion was determined by calculating the attrition rate and the ability to complete the program in the six weeks.

Suitability of data collection methods and questionnaire completion by participants was determined by the completion rate of the questionnaires.

Acceptability was defined as the way participants perceived the proposed treatment and whether they believed it was appropriate and suitable for them. This outcome
was assessed by asking the participants to rate the different components of the intervention on a Likert scale. Acceptance from 80% of the participants indicated that the intervention was acceptable. In addition, participants were asked to provide personal comments about the intervention.

**Participation in CR**

Attendance at outpatient CR programs, including number of sessions attended, was determined from self-reports.

**Health-related behavioural outcomes**

*Smoking status* was assessed using:

**Self-reports** Participants were asked to indicate their current smoking status. Those who stated that they smoked were asked a further two questions to identify: (a) the number of cigarettes that they smoked; and (b) their tobacco dependence level. The tobacco dependence level was assessed using a single reliable question, i.e. time to first cigarette.

*Carbon monoxide monitoring* A breath CO monitoring was performed using a pico Smokerlyser (Bedfont Instruments; Kent, UK), an inexpensive portable CO monitor. Participants were asked to exhale completely, inhale fully, and then hold their breath for 15 seconds. If the participants were unable to hold their breath for 15 seconds, they were asked to hold it for as long as possible. Participants were then asked to exhale slowly into the Smokerlyser and were encouraged to exhale fully in order to sample the alveolar air. A breath CO level of 6 or 8 ppm was taken as the cutoff between smokers and non-smokers.

*Exercise habits* The AAS was used to determine exercise habits. This survey reports on the frequency and duration of a range of activities performed within a broad class of physical activity intensity. The validity of this instrument is described in Chapter 6.

*Obesity* This outcome was measured by undertaking the following anthropometric measurements: height, weight, BMI, and waist-to-hip ratio as further described below.
**Height** was measured on an even and firm floor surface. Participants were asked to remove their footwear and stand erect with heels together, and with heels, buttocks and shoulders pressed against the wall. The arms hung freely with palms facing the thighs. The measurement was taken with participants taking a deep breath, standing tall and looking straight ahead with the head upright. Standing height was recorded to the nearest cm. Height was defined as the vertical distance from the floor to the top of the head and was rounded to 0.5 cm.

**Body Weight** was recorded at baseline using a digital scale with an accuracy of 0.1 kg. At follow-up, body weight was measured using stand-on scales. The reliability of the two scales was measured prior to commencing the study using five people.

**BMI** was calculated from the patients’ height and weight that were measured at baseline and at follow-up using the standardised scales. Patients were classified as being overweight or obese if their BMI > 25 kg/m$^2$.  

**Waist-Hip ratio** (WTHR) is a reliable indicator of cardiovascular risk and was measured at baseline and follow-up. When compared with the odds ratio for MI for the highest BMI quintile, the WTHR quintile is significantly more predictive of MI, with an odds ratio of 2.52 compared with 1.44. Waist and hip circumferences have also been reported to be more predictive of MI risk than BMI, although not as predictive as WTHR. Waist circumference was taken with a tape measure at the point midway between the costal margin and iliac crest in the mid-axillary line, with the participant standing and breathing normally. Hip circumference was measured at the widest point around the greater trochanter. The WTHR was calculated as the waist measurement divided by the hip measurement.

**Dietary saturated fat intake** This outcome was determined by using a 17-item Short Fat questionnaire, a valid fat intake self-reported questionnaire. When compared with the food frequency questionnaire, the Short Fat questionnaire demonstrated a correlation of 0.55 for total fat as a percentage of total energy, r=0.67 for saturated fat as a percentage of total energy, and r=0.44 for polyunsaturated to saturated fat ratio. Reproducibility was 0.85, assessed using 25 subjects after seven to nine months.

**Dietary fruit and vegetable intake** Two questions from a valid fruit and vegetable intake questionnaire were used to determine the fruit and vegetable intake.
Validity data indicates that the correlation of the fruit and vegetable servings from the 2-item and 17-item measure with three 24-hour telephone recalls was 0.28 and 0.31, respectively. Although these results appear small to moderate in magnitude, these correlations are in the range of validity coefficients for other self-report dietary measures.

7.6.3 Clinical outcomes
Serum lipid, blood pressure and blood glucose levels, quality of life, psychosocial risk factors and medication adherence were the clinical outcomes assessed. Serum lipid, blood pressure and blood glucose levels were assessed to determine the feasibility of the methods used for obtaining the data. Quality of life, psychosocial risk factors and medication adherence were assessed to determine understanding and completion of the questionnaires. These findings are important for the conduct of a larger study.

Serum lipid level
Baseline lipid levels were obtained from the patients’ records. Recommendations from the guidelines were used as indicators.

Blood pressure level
Baseline blood pressure levels were obtained from patients’ notes. In order to prevent unnecessary measurements which could result in complications such as bruising, as the majority of these participants were receiving antiplatelet and/or anticoagulant treatment, it was decided by the research team to note the last BP measurement that was recorded in the medical charts. These had usually been recorded earlier on the day of recruitment by the nursing staff in the CCU-S beds, or were being read by automatic instrumentation if the participant was in a CCU bed. For the follow-up data collection, the RA took the blood pressure manually according to the guidelines developed by the National Blood Pressure Advisory Committee of the National Heart Foundation of Australia using a sphygmomanometer and stethoscope. The accuracy of the sphygmomanometer was checked by calibrating it against a reading of the blood pressure of two patients (nonparticipants in the study) taken by automatic instruments on the ward. The hand-held sphygmomanometer was found to be accurate and consistent with the blood pressures taken by the bedside instruments on the ward. A difference of 2-3 mm was accepted as normal. Based on this fact
there was 100% concordance between the sphygmomanometer and the automatic readings. This task was feasible as there were only four portable sphygmomanometers in the unit. However there were 8 monitors in the CCU and 4 in the CCU-S and it was not possible to calibrate all. Information obtained from the Nursing Unit Manager (NUM), however, indicated that all 12 monitors measured the same readings.

**Blood glucose level**
Baseline blood glucose levels were obtained from patients’ notes. Self-reports were used to identify follow-up blood glucose levels

### 7.6.4 Quality of life
This outcome was measured using the MacNew Quality of Life Instrument, which has been specifically designed as a measure of health-related quality of life for patients following MI. A detailed description of the MacNew is presented in Chapter 6.

### 7.6.5 Psychosocial risk factors
The DASS, which is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress, was used to measure this outcome. A detailed description of the DASS is presented in Chapter 6.

### 7.6.6 Medication adherence
Adherence to medications was undertaken using validated questionnaires. A detailed description of the medication adherence questions is presented in Chapter 6.

### 7.6.7 Readiness of change for the following risk factors: smoking, physical activity and fat intake
These outcomes were assessed using the Stage of Change questionnaire. The reliability results using a test-retest analysis with a 2-week time interval for the measure of stages of change relating to quitting smoking were $k = 0.72$, and doing more exercise $k=0.52$.

### 7.6.8 Medical Records Audit
A chart audit of all participants was undertaken to obtain the medical and cardiac history including classification of acute coronary syndrome, medications prescribed,
risk factors, serum lipid profile and blood pressure values. The length of hospital stay was also obtained from the patients’ medical records.

**7.6.9 Incidence of Major Acute Coronary Event (MACE)**

This was assessed through self-reports.

**7.7 Recruitment Process**

A one-page letter describing the project was sent to all cardiologists and the CR coordinators in the participating hospital and their approval for the project sought. A brief 15-minute information session at the Cardiology and CR coordinator meetings was also provided. While the NUM and the staff in the participating wards were also informed of the study, no details of the intervention were given to ensure blinding. The NUM was requested to identify a person in the ward (preferably a RN) who had knowledge of the patients’ diagnoses and treatments to act as a liaison between the RA and the ward staff. The liaison person was given a copy of the inclusion/exclusion criteria for the study.

Each day the RA visited the CCU and CCU-S and met the liaison person to identify patients from their list who potentially met the study criteria. The clinical notes of these patients were reviewed to confirm eligibility. All patients were screened and those who fulfilled the study criteria were approached and invited to participate in the study. Patients were informed that study participation would involve retrieving data from their medical records, three telephone follow-up calls and a visit to the hospital clinic six weeks following discharge for reassessment and completion of a follow-up questionnaire. Patients were also given the name and contact details of the CR centre closest to their home. A written consent to participate in the study was obtained prior to their discharge from the hospital. At the time of recruitment, a baseline questionnaire was completed for all patients who consented to participate in the study. The patients’ personal details, which included both mail address and telephone number, were obtained at this stage.

**7.8 Randomisation**

Upon receipt of a completed baseline questionnaire from the RA, a statistician, who was blind to the trial details and baseline assessment and who had no connection with the study, randomised patients to either the intervention or control group using a
random numbers table. Following randomisation, the HeLM intervention (see HeLM intervention section) commenced with those patients randomised to the intervention group.

### 7.9 Implementation of the HeLM intervention

The HeLM intervention was conducted using postal and telephone communication. Using the information obtained from the baseline data collection, the RA identified the risk factors and calculated the risk scores for each patient using a risk factor calculator. Personal risk factors and the result of risk factor calculation were provided for patients in the intervention group in the form of a laminated risk factor card (Appendix 25). A personalised letter providing feedback on their current health-risk behaviour was also sent to all patients in the intervention group. The package that was posted to patients in the intervention group included: (i) the Take the HeLM booklet; (ii) the risk factor card; (iii) a personalised letter; (iv) fridge magnet; and (v) the patient diary. The participant’s GP was informed of their in the study. Two weeks following the mail-out of the intervention package, participants were contacted by telephone to confirm receipt of the booklet. They were also provided with telephone advice and encouraged to ask questions that they might have. Further phone calls were made to the participants at weeks three and five. These phone calls were limited to 15-30 minutes each and were strictly focussed on providing motivational support and encouragement and monitoring progress. The telephone support was conducted by an RA who had previous experience in motivational interviewing. In addition, predeveloped questions based on stages of change and motivational support were used as a guide during the interview (Appendix 28). During the telephone call at week five, a date and time was also set for a clinical assessment.

**The control group** received usual care, which included the provision of information relating to heart disease by health professionals in the clinical area. Participants in both groups were informed of CR services available in their area. All participants were informed that they would receive parking vouchers when they attended the 6-week follow-up assessment.
7.10 **Outcome assessment and follow-up data collection**

Participants in both groups were contacted at week five of the intervention to organise a date and time for the 6-week clinic visit for data collection. Three attempts were made to contact the participants, after which they were declared lost to follow-up. Participants were also sent a pre-notification letter informing them of the 6-week clinic visit for follow-up data collection. The same survey instrument was used for both the baseline and 6-week follow-up. In addition, at the 6-week follow-up patients in the intervention group were also asked to rate the different components of the intervention on a Likert scale. These components included satisfaction with the Take the HeLM booklet, personalised risk factor card, telephone support and patient diary. They were also asked to provide any personal feedback relating to the intervention. All patients were given a thank-you letter, pens, a recipe book from the NHFA, a pedometer, and relevant health-related risk reduction literature following completion of the 6-week assessment.

7.11 **Management of the data**

All responses received were coded to ensure confidentiality. The data were collated and analysed using SPSS 13.0. All data entry was undertaken by the RA who was not blinded to the group allocation. Descriptive statistics were used to analyse all variables. Blinded outcome analysis was planned for all primary and secondary outcome measures, however with limited resources available for the feasibility study, analysis was done by the researcher who also collected baseline data. An intention to treat analysis was undertaken for all clinical endpoints. Where relevant, the results from the quantitative analysis and the comments from the participants have been presented together.

7.12 **Ethical considerations**

Approval was obtained from the SSWAHS Human Research Ethics Committee (Appendix 30) and the University of Western Sydney Ethics Committee (Appendix 31). Numerical unique identifiers and password-protected files were used to maintain patient privacy and confidentiality. The master list for these unique identifiers was stored in a locked filing cabinet, accessible only to the Chief Investigator and
destroyed at the end of data collection. All questionnaires received were stored in locked filing cabinets at CANR. No individuals were identified in reports or publications.

7.13 Results
The results of this feasibility study have been presented according to the objectives reported in Section 7.4 of the study.

7.13.1 Incidence of Major Coronary Events (MACE)
None of the 44 patients who were contacted for the 6-week follow-up had died, required re-hospitalisation for myocardial infarction or an unplanned revascularisation, or had a cardiac arrest. Three patients were readmitted to hospital, of whom one was admitted for non-cardiac reasons and the remaining two for revascularisation of the coronary arteries that could not be performed at the initial admission.

7.13.2 Feasibility of participant recruitment
Recruitment to the study was from July 29–October 10 2006. Participants were recruited from a population of 547 potential subjects who were discharged from the CCU and CCU-S during this period. Of these patients, 125 (22.9%) met the inclusion criteria and were eligible for participation in the study. The remaining patients were excluded as they were non-English speaking or admitted with conditions that did not meet the inclusion criteria such as atrial fibrillation, heart failure, non-cardiac chest pain and other non-cardiac related problems (Table 7.2).
Table 7.2 Reasons for patients excluded from the study

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Frequency (n=)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-English speaking</td>
<td>21</td>
<td>5.0</td>
</tr>
<tr>
<td>Cardiac problems other than ACS</td>
<td>158</td>
<td>37.4</td>
</tr>
<tr>
<td>Respiratory</td>
<td>20</td>
<td>4.7</td>
</tr>
<tr>
<td>Renal</td>
<td>6</td>
<td>1.4</td>
</tr>
<tr>
<td>Haematology, oncology</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Neurology</td>
<td>4</td>
<td>0.9</td>
</tr>
<tr>
<td>Vascular</td>
<td>9</td>
<td>2.1</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>General medical problems</td>
<td>17</td>
<td>4.0</td>
</tr>
<tr>
<td>Scheduled for CABG</td>
<td>14</td>
<td>3.3</td>
</tr>
<tr>
<td>No modifiable risk factors</td>
<td>14</td>
<td>3.3</td>
</tr>
<tr>
<td>Multiple comorbidities</td>
<td>147</td>
<td>34.8</td>
</tr>
<tr>
<td>Transferred to another hospital</td>
<td>4</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Very few patients were eligible according to the original inclusion criteria, as many were admitted with non-ACS for elective PCI. Therefore, two weeks following commencement of the study the criteria were amended to include patients who were admitted to CCU or CCU-S following elective PCI. This decision was based on the fact that these patients also had CHD and modifiable risk factors and were suitable for inclusion in the study.

**Number of patients recruited to the study**

Although 125 patients were eligible for participation in the study, only 51 (40.8%) agreed to participate and completed a baseline questionnaire. Reasons for nonparticipation included could not return for second interview, discharged early or after hours and refusal to participate. Table 7.3 and Figure 7.1 present the reasons for nonparticipation in the study. One participant denied having had an AMI, despite clear evidence from his presentation, physical findings and biochemical reports, and did not consider himself to be in the category of people with an existing heart condition.
Table 7.3  Reasons for nonparticipation in the study

<table>
<thead>
<tr>
<th>Reason for nonparticipation</th>
<th>Frequency (n=)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could not return for 2nd interview due to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>work commitments</td>
<td>48</td>
<td>27.4</td>
</tr>
<tr>
<td>distance</td>
<td>29</td>
<td>16.5</td>
</tr>
<tr>
<td>Refused to participate</td>
<td>11</td>
<td>0.3</td>
</tr>
<tr>
<td>Discharged early</td>
<td>6</td>
<td>1.0</td>
</tr>
<tr>
<td>Discharged out of hours</td>
<td>31</td>
<td>5.2</td>
</tr>
</tbody>
</table>

Figure 7.1  Flow chart of participants through the study

Participant demographics
Seventy-eight percent (n=40) of the participants in the study were male and 22% (n=11) were female. The majority of the participants (67%) were married or living with a partner and approximately 50% of the patients had either an Intermediate or
School Certificate (10 years education) or below. The mean age of the participants was 57 years (+/-8.78 SD) and there was no significant difference in the ages between participants in the intervention and control groups. Half the participants were in some form of employment and approximately a third were retired. The findings indicated no statistically significant difference between the intervention and control groups in demographic characteristics at baseline. Table 7.4 presents the demographic characteristics of the participants at baseline.

**Table 7.4 Demographic data of the participants**

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=29)</th>
<th>Control (n=22)</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (Mean, SD)</strong></td>
<td>57.14, SD 8.96</td>
<td>56.41, SD 8.73</td>
<td>p=0.772</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td>p=0.230</td>
</tr>
<tr>
<td>Male</td>
<td>21</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td>p=0.382</td>
</tr>
<tr>
<td>Did not complete primary school</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Completed primary school</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Left school before Year 10</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Intermediate or School Certificate (Year 10)</td>
<td>5</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Leaving or Higher School Certificate (Year 11/12)</td>
<td>8</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Apprentice/Trade qualifications</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>University degree</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td>p=0.246</td>
</tr>
<tr>
<td>Living with a partner</td>
<td>18</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Not living with a partner</td>
<td>11</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
<td>p=0.582</td>
</tr>
<tr>
<td>Employed full-time</td>
<td>9</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Employed part-time or casual</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Unemployed (not retired or on pension)</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>9</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Permanently unable to work</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Home duties</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
7.13.3 Treatment program attrition, adherence and completion rates

Number of participants who completed the HeLM intervention
Of the 51 patients who agreed to participate in the study, 29 were randomised to the intervention group and were sent the HeLM intervention package in the mail. All 29 patients were contacted one week following the mailing of the HeLM intervention package and all reported that they had received the package. Only 24 (83%) participants could be contacted for the 3 and 5-week telephone follow-up for motivational support.

Reasons for inability to complete the HeLM intervention
Participants who were working found it difficult to arrange suitable appointment times, despite having earlier committed themselves to undertaking the second interview. In addition, those who were working proved more difficult to contact for the phone intervention. In some cases no contact at all could be made during office hours and these people were lost to follow-up.

Number of patients completing final data collection
The final data collection was undertaken one week following completion of the intervention. All 51 participants were eligible to participate in the final data collection; however, only 44 could be contacted, of whom 34 presented for the 6-week follow-up data collection. Reasons for not presenting to the research centre for the 6-week data collection included: being unwell (n=2), declined to attend (n=2), did not turn up (n=4) and away on holidays (n=2).

There were no statistically significant differences between the dropouts and the responders on gender, employment status and marital status. However, responders were significantly older (p=0.005) and had more years of schooling (p=0.040) compared to the non-responders (Table 7.5).
Table 7.5  Comparison between dropouts and participants completing the study

<table>
<thead>
<tr>
<th></th>
<th>Responders</th>
<th>Dropouts</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean)</td>
<td>59.24</td>
<td>52.06</td>
<td>p=0.005</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>27</td>
<td>13</td>
<td>p=0.810</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not complete primary school</td>
<td>2</td>
<td>0</td>
<td>p=0.040</td>
</tr>
<tr>
<td>Completed primary school</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Left school before Year 10</td>
<td>8</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Intermediate or School Certificate (Year 10)</td>
<td>7</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Leaving or Higher School Certificate (Year 11/12)</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Apprentice/Trade qualifications</td>
<td>10</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>University degree</td>
<td>1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with a partner</td>
<td>25</td>
<td>10</td>
<td>p=0.286</td>
</tr>
<tr>
<td>Not living with a partner</td>
<td>9</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed full-time</td>
<td>11</td>
<td>9</td>
<td>p=0.422</td>
</tr>
<tr>
<td>Employed part-time or casual</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Unemployed (not retired or on pension)</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>12</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Permanently unable to work</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Home duties</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

7.13.4  Suitability of data collection methods and questionnaire completion

Measuring blood pressure

Extensive precautions as described in the data collection section were taken to obtain consistent blood pressure readings. Blood pressure readings were available for all participants.
Obtaining serum lipid levels
None of the patients recruited to the study had their serum lipid level measured. Data for the serum lipid levels were obtained from self-reports of patients who could remember the values.

Obtaining blood glucose levels
None of the patients recruited to the study had their blood glucose level measured. Data for the blood glucose levels were obtained from self-reports of patients who could remember the values.

Smoking status
To determine the participants’ smoking status, their CO level was measured using a smokelyser. At baseline assessment the CO level registered for the participants who smoked was consistently false negative. This result could be due to the timing of the assessment of CO levels rather than the smokelyser, as many of these patients had not smoked for at least 24 hours prior to participating in the study, thus allowing for CO dissipation. Therefore, the usefulness of the assessment of the CO level in this study at baseline remains questionable.

Completion of the questionnaire
The majority of the data were collected by means of a self-report questionnaire that included various validated measurement scales. Most of the participants completed the entire questionnaire without assistance, while some (n=5) required assistance with some sections and a few (n=3) preferred the questionnaire to be read to them. A small proportion of participants who spoke English as a second language had difficulties understanding some terminology used in the validated scales within the questionnaire, and required assistance from the researcher for completing the questionnaire. For example, the question in the DASS that asked to rate the statement “I feel downhearted and blue” was not understood by some. Participants completed the sections of the questionnaire relating to health-related risk reduction behaviours with ease, namely eating, exercise and smoking habits.

The time taken to complete the questionnaire varied depending on the participant’s age and cultural background. Those over 65 and those for whom English was not a first language required more time to complete the questionnaire. The time varied
from 30-45 minutes. Although a few (n=2) indicated that the questionnaire was too long, all participants completed the survey.

7.13.5 Acceptability of the HeLM intervention

All 19 participants in the intervention group who attended the 6-week follow-up reported that the HeLM intervention was acceptable and that it provided them with information and strategies for risk factor modification in a non-confrontational manner. The mean score for the overall acceptability of the HeLM intervention was 8.7 (SD 1.15) (10=excellent – 0=poor).

Take the HeLM Booklet

Nine out of the 10 patients stated that the timing for receiving the intervention was appropriate. Only one patient indicated that the intervention was delivered too soon after discharge. The majority of the patients (n=7) had read the Take the HeLM booklet completely, while one had not read any of it due to family issues and two had read only the sections relevant to them. Participants rated the Take the HeLM booklet between 8 and 10 (10=excellent – 0=poor) for each of the components relating to usefulness, relevance, and ease of reading. Overall the patients were satisfied with the information in the Take the HeLM booklet. Patients also commented that their partners and other members of their family found the Take the HeLM booklet useful and referred to it frequently. The responses to each component of the Take the HeLM booklet are presented in Table 7.6. Participants were impressed with the professional content and simplicity of the HeLM booklet. They were grateful for the information and indicated that they could read through the sections that applied to them in their own time without disrupting their routine. Completion of the tasks within the booklet was reported to be useful as participants were able to set goals. Most participants said that the HeLM booklet encouraged and supported them to adopt healthy lifestyle habits.

Only one participant had negative comments, saying that “it was all about quitting smoking” and thus irrelevant for him as he had quit 20 years ago. He also declined to come back for a second interview (although he had agreed to do so at the first interview) saying that he “wouldn’t gain anything from it”.
**Risk factor card**

All patients indicated that they were pleased to receive the risk factor card. Seven of the 10 participants who completed this section of the questionnaire knew of only some of their personal risk factors prior to receiving the card. Two patients indicated that they were not aware of any of their risk factors prior to receiving the card.

The majority knew about the prominent risk factors such as smoking or eating fatty foods. However, a large proportion were not aware of the full range of risk factors that affected their chance of having a further cardiac event. None of them were aware that once having had a cardiac event, the risk of another was approximately $20%$. Patients indicated that they were pleased to obtain that information from the risk factor card. Participants also indicated that the risk factor card made them think about the health-related behaviour that they could change (Table 7.6).

**Table 7.6  Satisfaction with the HeLM intervention**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Satisfaction with the HeLM booklet</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The information provided was easy to read</td>
<td>8.8</td>
<td>0.97</td>
</tr>
<tr>
<td>The information provided could be understood easily</td>
<td>8.8</td>
<td>0.97</td>
</tr>
<tr>
<td>The information provided was useful</td>
<td>8.7</td>
<td>1.0</td>
</tr>
<tr>
<td>After reading the booklet were you able to see the benefits of adopting healthy habits?</td>
<td>8.9</td>
<td>0.8</td>
</tr>
<tr>
<td>After reading the booklet were you able to increase your confidence in being healthy?</td>
<td>8.8</td>
<td>1.09</td>
</tr>
<tr>
<td>After reading the booklet were you able to learn to cope with difficult situations?</td>
<td>8.2</td>
<td>1.48</td>
</tr>
<tr>
<td><strong>Satisfaction with the risk factor card</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the risk factor card make you think about the health related behaviour that you could change?</td>
<td>8.0</td>
<td>1.49</td>
</tr>
<tr>
<td><strong>Satisfaction with the telephone support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the conversation with the nurse motivated you to make healthy changes to your lifestyle?</td>
<td>8.2</td>
<td>0.78</td>
</tr>
<tr>
<td>Was the information given in the telephone call useful?</td>
<td>7.9</td>
<td>1.37</td>
</tr>
</tbody>
</table>
Telephone support
All participants in the intervention group stated that they appreciated contact from
the health professional after discharge to follow-up on their health. The length of the
telephone call varied between 5 and 30 minutes (mean length of time 17 minutes).
All of them stated that they valued the follow-up phone support and felt free to talk
to the interviewer. They indicated that the telephone support motivated them to
commence health-related behaviour changes (Table 7.6).

Patient Diary
All participants indicated that the patient diary was useful (mean score 8.1, SD 1.10)
(10=excellent – 0=poor). Seven patients stated that they had not started entering any
records in their diary, however one of the seven also indicated that they were using a
diary obtained from the diabetic centre.

GP communication
Letters were sent to the GPs of all participants in the intervention group. However,
none of them made any verbal or written contact with the researchers. It could be
inferred that the GPs had no objection to the intervention.

In general, no major issues were identified with any specific aspects of the
intervention, suggesting that the content of the HeLM intervention was acceptable.

7.13.6 Effect of the HeLM intervention on participation in
CR programs
All 44 patients who were contacted at follow-up were asked if they participated in
CR. Only three participants randomised to the HeLM intervention and one to the
control group participated in CR. When asked if they were contacted by the CR
nurse, 28 participants indicated that they were not contacted by any health
professional other than the RA. One of the 28 participants who was not contacted by
the CR coordinator but participated in CR reported that he attended following advice
from the RA.
7.13.7 Effect of the HeLM intervention on behavioural risk factor status

At baseline there was no statistically significant difference between the intervention and control groups in the number of participants with individual behavioural risk factors.

Smoking
At the baseline assessment 16 participants – 10 in the intervention group and 6 in the control group – indicated that they smoked cigarettes. Two patients, one in each group, had given up smoking at the 6-week follow-up (Table 7.7).

Physical activity
A total of 18 participants – nine in each group – reported to have walked for 150 minutes or more at the baseline assessment. At the 6-week assessment a greater number of participants (n=14) in the intervention reported to be engaging in 150 minutes of walking each week compared to the control group, however this difference was not statistically significant (Table 7.7).

Body mass index
The mean BMI in the intervention group was lower than the control group at the 6-week follow-up. However, this difference was not statistically significant. The mean BMI of participants in both groups had reduced from baseline to follow-up, however this reduction was also not statistically significant (Table 7.7).

Waist-to-hip ratio
For females, the mean WTHR in the intervention group was lower than the control group at the 6-week follow-up. However, this difference was not statistically significant. For males, the mean WTHR in the intervention and control groups was the same at the 6-week follow-up. When compared to baseline values, men in the control group had greater reductions in the WTHR compared to those in the intervention group. However, this difference was not statistically significant. The WTHR of male and female participants in both groups had reduced from baseline to follow-up, however this reduction was also not statistically significant (Table 7.7).
Saturated fat intake
The mean fat intake score in the intervention group was lower than the control group at the 6-week follow-up. However, this difference was not statistically significant. The mean fat intake score of participants in both groups had reduced from baseline to follow-up, however this reduction was also not statistically significant (Table 7.7).

Fruit and vegetable intake
The mean number of servings of fruit and vegetable intake in the intervention group was higher than those in the control group at the 6-week follow-up. However, this difference was not statistically significant (Table 7.7).

Table 7.7 Risk factor status at 6-week follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=29)</th>
<th>Control (n=22)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>9</td>
<td>6</td>
<td>0.510</td>
</tr>
<tr>
<td>Walked for 150 minutes or more</td>
<td>14</td>
<td>10</td>
<td>0.842</td>
</tr>
<tr>
<td>Body mass index</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>29.5 (6.2)</td>
<td>31.25 (7.61)</td>
<td>0.375</td>
</tr>
<tr>
<td>Waist-to-hip ratio</td>
<td>Females</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.93 (0.02)</td>
<td>0.96 (0.05)</td>
<td>0.487</td>
</tr>
<tr>
<td></td>
<td>Males</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.98 (0.05)</td>
<td>0.98 (0.06)</td>
<td>0.947</td>
</tr>
<tr>
<td>Fat intake</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>15.96 (6.14)</td>
<td>17.18 (8.67)</td>
<td>0.564</td>
</tr>
<tr>
<td>Fruit intake</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.39 (1.49)</td>
<td>2.00 (1.11)</td>
<td>0.310</td>
</tr>
<tr>
<td>Vegetable intake</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.90 (1.67)</td>
<td>2.45 (1.59)</td>
<td>0.346</td>
</tr>
</tbody>
</table>

Stages of Change
At baseline there was no statistically significant difference between the intervention and control groups in the number of participants in each stage of change for any of the three health-related behaviours. At follow-up 8/9 smokers in the intervention group and 5/6 in the control group indicated that they were thinking of quitting smoking within the next 30 days (Table 7.8). Compared to baseline results, there were a greater number of participants in both the intervention and control group who indicated that they had been physically active for less than 6 months although these results were not statistically significant (Table 7.9).
in both groups indicated that they were avoiding fatty foods at baseline assessment. However, there was an increased number of participants in the intervention group who indicated that they avoided fat intake from time to time (Table 7.10).

Table 7.8  Smoking- Participants stage of change at 6-week follow-up

<table>
<thead>
<tr>
<th></th>
<th>No not thinking of quitting</th>
<th>Yes within the next 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Group</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Control Group</td>
<td>0</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 7.9  Physical activity - Participants stage of change at 6-week follow-up

<table>
<thead>
<tr>
<th></th>
<th>No and do not intend to be PA in the next 6 months</th>
<th>No but I intend to be PA in the next 6 months</th>
<th>No but I intend to be PA in the next 30 days</th>
<th>Yes I have been PA for &lt; than 6 months</th>
<th>Yes I have been PA for &gt; 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Group</td>
<td>1</td>
<td>3</td>
<td>9</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Control Group</td>
<td>2</td>
<td>1</td>
<td>5</td>
<td>6</td>
<td>8</td>
</tr>
</tbody>
</table>

PA- Physically active

Table 7.10  Fat intake - Participants stage of change at 6-week follow-up

<table>
<thead>
<tr>
<th></th>
<th>Not given any thought to fat intake</th>
<th>Mean to lessen the amount of fat</th>
<th>Avoid fat from time to time</th>
<th>Avoid fat for ≤ 6 months</th>
<th>Avoided fat for &gt; 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Group</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Control Group</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>11</td>
</tr>
</tbody>
</table>
7.14 Discussion

The study undertaken in a single centre was designed to investigate the feasibility of a structured brief HeLM intervention for patients with ACS. The specific objectives were to evaluate the (1) incidence of MACE; (2) feasibility of the study in terms of: (a) recruiting patients with ACS to participate in a study on risk factor modification, (b) treatment program completion and attrition rate from study at follow-up, (c) data collection methods and questionnaire completion, and (d) acceptability of the intervention by the participants; (3) rate of CR attendance among participants; and (4) effect of the HeLM intervention on the behavioural changes related to cardiac risk factors, namely smoking status, participation in physical activity, obesity, and fat, fruit and vegetable intake. Each of these objectives has been achieved and is discussed below.

7.14.1 Feasibility of recruiting patients with ACS

Fifty-one participants were recruited to the study over a two-month period. However, it should be noted that the initial criteria were modified to include all patients admitted to the CCU and CCU-S with documented CHD and modifiable risk factors.

Enrolling representative populations is essential to the generalisability of study findings. In this study, 78% of the participants were male and 22% were female. Although this ratio of male to female participation is unequal, it is consistent with other trials undertaken in the cardiac population. Baseline characteristics in the intervention and control groups were comparable, which demonstrates success of the randomisation methods.

A number of factors were identified that impeded the recruitment process. Firstly, limited time and resources were available for assessment of potential participants. As a result, some participants who may have been eligible in a larger study had to be excluded. For example, a thorough assessment of the level of independence in activities of daily living (ADLs) was not possible, without review by competent allied health staff such as occupational therapists (OTs) or the use of a validated tool such as the Barthel Index. In addition, the short length of stay did not allow for suitable allied health intervention or assessment by OTs. Inclusion of all these participants in the current study would have resulted in biased findings, for example
if participants who were not capable of increasing their exercise levels due to being frail and/or infirm were included.

It was important for the purposes of the trial that participants had good cognitive function. In a few instances, a brief assessment of participant’s cognitive status revealed considerable deficits. This might not have been apparent during the brief encounter of data collection. Screening for cognitive status was not part of the study, which resulted in further exclusion of people who could be potential participants in the study.

Incomplete documentation by health care professionals about participants’ level of independence in personal care and toileting as well as their cognitive status limited the ability of the researcher to include the patients in the study. Many participants who worked could not be included as they would not be able to return for a second interview. Needless to mention, many younger people who had more to gain from lifestyle changes were unable to participate, as the ability to return for the second interview was a criterion for admission to the study. Many participants who did shift work were often not able to be contacted for the telephone support.

Persons from a non-English speaking background who had limited proficiency in the English language were also excluded as they were unable to provide a valid informed consent to participate in the trial, or understand and complete the questionnaire. The relatively high percentage of non-English speaking people living in the area where this study was conducted meant that a significant number of participants were excluded on this basis alone. Providing an interpreter service for these participants would be suitable, however it was not within the study budget. In addition, the discharge of the participants may have been delayed due to the limited availability of interpreters at given times.

Prior to and during the research study the research team made extensive efforts to develop strong professional relationships, trust and explicit communication strategies with the staff in the participating wards. This was a major facilitator during the recruitment process. Education sessions about the study were provided by the researchers and were attended by all members of the staff. Commitment from the participating wards was obtained, which involved nomination of a designated member of staff to be the liaison between the participants and the researchers. A
major strength of the recruitment process was the involvement of the ward bed coordinator, an experienced nurse who provided a list of all patients who were potentially eligible for inclusion in the study. This method was advantageous as it saved the RA time by precluding the assessment of medical records of those patients who would be ineligible. In addition, the ward coordinator also provided a list of those patients who were likely to be discharged the following day, which was helpful particularly if the following day was a weekend. Advance planning of data collection times enabled the ward bed coordinator to plan their work and support the project.

7.14.2 Adherence to treatment program completion and attrition rate

Specific challenges associated with undertaking research in the clinical setting were identified, and these are clearly reflected in the reasons cited by patients for nonparticipation in the study and dropouts. For participants who commenced the study, various factors including illness, work commitments, and family priorities interfered with study completion. As a large number of participants had returned to work after their cardiac event, they were unable to be contacted to complete the intervention. To overcome the communication challenges, the researcher utilised other strategies such as voice messages with limited success. The use of text messaging in future studies should be investigated.

There is limited parking around Liverpool Hospital, therefore the researchers provided parking vouchers which encouraged some participants to attend the follow-up data collection. Despite this, other problems with parking were identified, as parking using these vouchers was restricted to the carparks about 300 metres distant from the research office where the follow-up data collection was undertaken.

Unusually hot days occurred in the months of October and November in 2006. The Australian Bureau of Meteorology reported that 2006 had the second hottest daytime temperatures ever recorded in NSW.550 The hot days may have been a factor in deterring some participants in returning for the second interview.

Despite the issues associated with recruitment and follow-up, this pilot study has demonstrated that a large multicentre trial would be feasible. Various lessons have been learned that will be valuable in planning such a trial. Difficulty in obtaining a return visit from the participants for the second data collection despite providing free
parking has demonstrated that alternate methods, such as the RA visiting the participants for data collection, need to be considered.

### 7.14.3 Data collection methods and questionnaire completion

The initial data collection was undertaken on the ward at the time of patient recruitment. On most occasions participants were in four-bed rooms, and therefore their responses could have been influenced by other participants in the room, particularly for those whom the RA had to explain the questions. The location of the follow-up data collection presented a challenge for some participants. The follow-up data collection was undertaken at the research office, with the interviewer and subject on their own. On one occasion, the second data collection was conducted in the outpatient dialysis unit at Liverpool because the participant was receiving treatment, and on another at the Cardiac Catheter laboratory at Liverpool Hospital as the participant was unable to locate the research department. Given the responder burden identified by two participants, the length of the questionnaire should be considered during the design of the larger study.

The measurement of blood pressure using the methods described previously was successful. However, the absence of monitoring blood glucose and lipid levels should be noted and taken into consideration during the design of a larger study. In addition, recent evidence suggests that girth measurement is adequate to determine overweight and obesity, which should also be considered when designing a larger trial.

A number of participants had been admitted for elective PCI procedures. The rapid recovery following an uncomplicated PCI procedure resulted in participants being discharged early the next morning to accommodate new patients. Patients were not willing to stay back and complete the study and could not be kept due to pressure on hospital beds.

### 7.14.4 Acceptance of the intervention

The majority of the participants reported that the intervention was useful and rated the different components of the intervention highly. It was clear from the participants that the HeLM intervention succeeded in providing them with risk factor education and motivation to change behaviour. It was not possible to calculate exact risk factor
scores for patients using the Framingham calculator because the majority of them did not have cholesterol levels monitored. This could be due to the fact that all patients were receiving statin therapy, which is now standard treatment for ACS, and that cholesterol monitoring in the acute phase would produce inaccurate results.

Response to the telephone intervention varied. Some people conversed for 5 minutes while others spoke at some length, usually pre-empting the set questions and often bringing up issues of their own. The employment of a RA with extensive skills in motivational interviewing was another facilitator for the HeLM intervention.

### 7.14.5 Effect of the HeLM intervention on CR participation rates

A greater number of patients randomised to the intervention group participated in CR. This could be due to the fact that they were motivated by the HeLM intervention, however the small size of the study does mean that cause and effect cannot be confidently established.

### 7.14.6 Effect of the HeLM intervention on risk factor modification and stages of change

The HeLM intervention demonstrated no statistically significant difference in the risk factor status and the progression through the stages of change between the two groups. This can be attributed to the small sample size of the study which resulted in few patients at each stage of change for each of the health-related behaviours.

### 7.14.7 Strengths of the HeLM study and the HeLM intervention

The HeLM study holds several strengths. Firstly, the methodological strengths which included the random assignment of participants to treatment groups that ensured no systematic differences between the treatment groups at baseline. Secondly delivery of the intervention by a single trained person ensured that the intervention was delivered uniformly to all participants in the intervention group. Finally this feasibility study will inform a power calculation for the primary outcome, which is a single composite score of modifiable risk factors. The HeLM intervention itself has numerous strengths. The intervention was developed based on the actual available evidence and embedded in a theoretical framework namely the TTM that has been demonstrated to be successful in behaviour change. Individuals may have more than
one risk factor and could be at different stages for each of these risk factors; the Take the HeLM booklet was therefore designed to incorporate the different stages of change for each of the behavioural risk factors. The HeLM intervention could be an alternate model for secondary prevention as it can be delivered to a large population in a short time and can be accessed remotely.

7.15 Implications for the conduct of a larger trial
Suggestions for improvement that will enable the success of a larger multicentre trial include:

(1) Longer term follow-up

(2) Exclusion of assessment of smoking status using breath CO monitoring at baseline, as participants were admitted to the ward for at least 24 hours during which they had not smoked a cigarette, leading to false negative results because the CO in the lungs dissipates after 5-6 hours\(^{545,546}\)

(3) Inclusion of a validated instrument to assess cognitive function and ADLs which will increase the proportion of eligible participants

(4) Use of other risk factor calculators which do not rely on cholesterol values for risk calculation and methods to convey the level of risk to lay people should be included.

(5) In order to improve follow-up data collection the use of home visits or telephone interviews could be considered. However, this would require self-reports for smoking, physical activity, blood pressure and blood sugar levels which would be a weakness of the method. The desirability of getting objective measurements would preclude the potential to include a large number of participants in the final data collection given the target audience.

(6) Given the fact that many of the participants were employed, providing after hours personnel to deliver the intervention may encourage participation in follow-up visits.

(7) Only a small percentage of the participants were smokers, therefore reformatting the booklet so that information relating to smoking cessation is presented as the last risk factor in the book.
7.16 Conclusions
In this chapter, the methods and results of the feasibility of conducting a randomised controlled trial of the HeLM intervention have been reported. The findings indicate the relevance of conducting a feasibility study prior to undertaking a large scale trial. The study demonstrates that the intervention and the process could be implemented in a larger RCT. The most important outcome in a larger study would be to assess the effectiveness of the HeLM intervention on optimal risk factor management and achievement of risk factor goals in participants with CHD, both in the short- and long-term. Further research is necessary to evaluate the cost-effectiveness of the intervention.
Chapter 8

Discussion and Conclusion
8.1 Introduction

The management of CHD remains a serious health concern in Australia. While the treatment for ACS, the acute phase of CHD, has received much attention, there has been less focus on management in the post-acute phase. Significant initiatives both at the local and government level are required so that patients can reach evidence-based treatment targets as determined in the RRIHD guidelines.

The aim of this project was to systematically develop and evaluate the feasibility of an evidence-based HeLM for risk factor modification in patients discharged from hospital following treatment for ACS. The HeLM intervention was developed on the principles of evidence-based practice, namely a systematic review of the literature, clinician expertise and patient information and preferences. Therefore the development of the intervention involved three discrete yet interrelated studies. The evidence obtained from each of these studies was considered in the development of the HeLM intervention.

The first study was a systematic review of the literature, titled Effectiveness of brief structured interventions on risk factor modification for patients with CHD, which was undertaken to investigate if brief interventions were effective in behaviour modification leading to risk factor reduction. This study was carried out because there is no consensus among clinicians and experts regarding the effectiveness of brief interventions for risk factor modification, as well as the evidence of poor participation rates in CR programs and the long duration of other lifestyle modification programs. This study also provided evidence for the number and duration of telephone calls for ongoing support for patients, which was part of the HeLM intervention. A detailed discussion of this study is presented in Chapter 4.

The second study was a telephone interview of CR coordinators undertaken to identify the barriers and facilitators to implementing the evidence-based RRIHD guidelines. Results obtained from this study were used to inform the mode of delivery of the HeLM intervention. A detailed discussion of this study is presented in Chapter 5.

The third study was a follow-up of patients 12-24 months post-PCI to investigate their coronary risk factor and quality of life status, knowledge of CHD and risk
factors and participation in CR. This particular group of patients was selected because of the increasing number of patients with ACS who are treated with PCI. The significance of this study is the identification of the patients’ risk factor status, knowledge of CHD and risk factors, their quality of life, adherence to medications and participation in CR. These findings were used in the development of the intervention. A detailed discussion of this study is presented in Chapter 6.

8.2 Key Findings

8.2.1 What is the effectiveness of brief structured interventions on risk factor modification for patients with CHD?

The findings from the systematic review of RCTs indicated that there was strong evidence to support the use of brief structured interventions for smoking cessation. Yet there was inconclusive evidence to demonstrate support or undermine the effectiveness of brief compared to extensive interventions for modification of other coronary risk factors related to diet. There was suggestive but inconclusive evidence that brief interventions targeted at multiple risk factors may lead to risk factor modification in patients with CHD, compared to extensive interventions. These findings are critical for the development of alternate brief lifestyle modification programs, given the poor participation in CR programs and other lifestyle modification programs of long duration. The aim of brief programs is generally to target the motivational status of the patients to make the necessary changes for lifestyle modification. Findings from this systematic review also indicated that three telephone calls, each lasting 15-30 minutes over a period of six weeks, as part of the brief intervention provided the support for patients to make the recommended lifestyle changes. The interventions in the individual studies were mainly delivered by nurses or allied health professionals who received training.

8.2.2 What are the barriers and facilitators identified by the CR coordinators to implementing the Reducing Risk in Heart Disease guidelines?

Barriers to participation in CR programs identified by the twenty CR coordinators mainly related to health services, professionals and the patient. The health service barriers included shortages of dedicated CR personnel, service inadequacies, lack of
dedicated funding and access to equipment, lack of access to GPs, specialists and risk reduction services, limited access to – and in some areas the absence of – a dedicated CR program, and referral procedures from tertiary and procedural centres. The barriers relating to professionals included gate keeping, inadequate communication between providers and CR coordinators, variations in clinical practice patterns, limited knowledge and skill level of clinicians, lack of awareness of locally available programs, lack of access to guidelines and education, and a lack of accountability among health professionals. The patient-related barriers included coming to terms with a diagnosis of heart disease, challenges in changing behaviour, having heart disease is costly and other personal barriers. Overcoming these barriers requires a joint effort at the local, State and Federal levels, consequently researchers are investigating newer methods for risk factor reduction.

8.2.3 What are the cardiac risk factors, HRQoL status, long-term medication adherence rate, and knowledge level of CHD and its risk factors in patients 12-24 months following PCI?

The findings from the post-PCI patient survey supported other research regarding the presence of at least two modifiable risk factors in approximately 70% of participants. Hypertension and hypercholesterolaemia were the most common biophysiological risk factors, particularly among females. Approximately 80% of participants were overweight and a quarter of the participants had some form of depression, anxiety or stress. The mean BMI for all participants was above the recommended guidelines at 28.7kg/m², with the majority of the participants in the pre-obese stage. This finding is particularly concerning given that the people in this study are representative of a much larger group in the Australian community, and it does support the obesity epidemic in Australia. Some level of depression, anxiety and stress was reported by approximately a quarter of the participants. These results are of major concern, as it could lead to the recurrence and or progression of CHD.

What was encouraging in this study is the high rate of medication adherence, which could be a reason why a second episode of ACS had not occurred in these patients. However, it should be noted that this finding was based on self-reports. It has been well established that adherence to medications declines over a period of time, particularly among those who have no symptoms. Therefore, it is vital that these
patients are supported to continue with their medication regime. The study highlighted the fact that participants were not aware of the correct method for the storage of nitroglycerine medications, which is of concern because improper storage of these medications can render them ineffective, leading to increased morbidity and hospitalisations.

Exploration of the knowledge level regarding CHD and its risk factors highlighted the fact that these patients had limited knowledge of CHD and the majority were unaware of the risk factors for CHD. Of particular concern is that patients who had diabetes were not aware that this was a risk factor. This finding indicates that patients are not informed of risk factors and the need for lifestyle modification prior to discharge. Knowledge of the risk factors is important as it provides a rationale for behaviour modification leading to risk factor reduction. An enquiry into blood pressure and cholesterol values indicated that the majority of the patients did not know the exact numerical values, and in many instances when the numerical value was high, patients believed that it was normal or appropriate for their age. This finding suggests that there may be a tendency that providing patients with a diary to record their blood pressure and cholesterol values could be beneficial in increasing their knowledge and self-management skills.

8.2.4 What are the obstacles identified by patients for nonparticipation in CR programs and what are their preferences?

Findings from the survey demonstrated that less than a third of participants had attended CR. The main reason for participation in the CR program was a recommendation from the GP or specialist, which demonstrates that the strength of a physician’s advice greatly influences participation rates. The fact that only a few patients felt the need to attend a CR program indicates that patients do not consider PCI a warning sign nor do they appreciate the benefits of modifying risk factors. Reasons for nonattendance included timing, distance, length of program, work commitments, lack of family support, transportation and lack of motivation to attend the programs. These findings could be anticipated particularly given the short hospital stay and early return to work following PCI. Therefore these patients require alternate strategies for risk factor modification. The HeLM intervention was developed taking into consideration all these barriers identified by the patients.
Accessibility and convenience features of a CR program were important to women. Participants indicated that they preferred to be contacted by a health care professional following their discharge. A large proportion stated that they did not like group activity and preferred programs that were flexible and individually tailored. These results are important and were included in the HeLM intervention.

This project highlights the importance of involving patients and health care providers in the development of evidence-based interventions for risk factor modification.

8.2.5 Development of the CREO scale

There has been extensive research on the barriers to participation in CR programs,\textsuperscript{38,68,69,156} however there is no valid and reliable measurement instrument that can be used in the clinical setting to identify patients who may not attend CR programs. The development of such a scale is useful as it would identify patients who could not attend CR so that clinicians could provide them with alternate strategies for secondary prevention. The two-factor 15-item CREO scale was designed to assess the barriers to participation in CR programs among patients following PCI, and was based on the evidence identified in the published literature as well as interviews with expert CR program coordinators. The comprehensive approach to the development and assessment of the CREO scale ensures excellent content validity. The representativeness and the discriminative ability of the scale were demonstrated.

8.2.6 Characteristics of the HeLM intervention

Several key factors identified from the findings of the three studies were used for the development of the HeLM intervention. In addition, since the underlying cause of ACS is a chronic disease, namely CHD, the intervention was designed to promote self-management, which is an important element for the management of chronic disease.\textsuperscript{228,232,238} Reviews of the effectiveness of chronic disease management interventions indicate that interventions based on behaviour change models are more likely to be effective than those that are not.\textsuperscript{238} The guidelines developed by the NHFA and the CSANZ\textsuperscript{34} support this finding and clearly indicate that patients should be assessed for their stage of change prior to implementing any secondary prevention programs. Therefore, in the HeLM intervention patients were provided with a HeLM booklet which enabled them to self-assess their stage of change. The
HeLM booklet consisted of strategies to promote behaviour modification according to the stage of change for each risk factor. Goal-setting is another important element of chronic disease management, therefore the HeLM intervention involved setting both short- and long-term goals collaboratively with the patient. Other effective features of chronic disease management, such as team building and communication with GPs, providing a written action plan (in the form of a fridge magnet) and the use of health diaries, were also included in the HeLM intervention.

Findings from the systematic review, although inconclusive, suggest beneficial effects of brief interventions in modifying risk factors. The HeLM intervention was therefore based on the principles of brief intervention and consisted of: Feedback of personal risk of further coronary events using the Framingham calculator, individual responsibility where the patients were given a diary to record biomedical values which was reinforced by the RA, advice provided in the HeLM booklet and telephone support calls, a menu of strategies for risk factor modification in the HeLM booklet, empathy used by the RA during the telephone support, and self-efficacy which was provided in the HeLM booklet and encouraged by the RA.

### 8.2.7 Feasibility of the HeLM

The feasibility of the HeLM intervention for patients with ACS was undertaken in a single centre. The study indicated that the HeLM intervention could be applied to all patients with CHD and not necessarily those who have had ACS. The HeLM intervention was acceptable to patients, providing them with information and strategies for risk factor modification in a non-confrontational manner. The study did not demonstrate a difference in the risk factor status among those randomised to the HeLM intervention and those who were not. This is mainly because the study was not powered to detect differences, however the HeLM intervention succeeded in providing participants with risk factor education. A detailed discussion of the feasibility of the HeLM is presented in Chapter 7.

One of the greatest challenges of cardiac care is to integrate comprehensive risk factor modification strategies into clinical practice. Although various strategies for risk factor modification have been demonstrated to be effective in clinical trials, these may not prove equally effective in clinical practice due to a paucity of resources, particularly personnel. The HeLM intervention is a postal-
delivered intervention combined with telephone support by a trained health professional. This intervention can be easily delivered by nurses, GPs or other health professionals who have received appropriate training. Although the HeLM intervention was determined to be useful and acceptable, its effectiveness needs to be investigated in a larger RCT. Nevertheless, it is crucial that a united front among health care workers is maintained to combat this global epidemic of CHD.

8.3 Implications for practice

Aggressive risk factor modification is the most important aspect of managing the patient with ACS. Currently, there is a failure to integrate comprehensive lifestyle modification into clinical care provided to patients after ACS events, which reflects the lack of importance given to risk factor reduction and adherence to treatment in the post-acute phase. Increased resources have been injected into health services for the management of the acute phase to reduce mortality, however there is a deficiency in resource allocation for rehabilitative aspects of care, which indicates that the Australian health care system is orientated predominately to the management of acute illness.

Management of patients with ACS has advanced rapidly, beginning with sophisticated biomarkers\(^23\) for early and quick detection to treatment with PCI. In the past, treatment with PCI was reserved for patients who had a myocardial infarction. However, with the evolving definition of ACS, treatment with PCI has also been recommended as the first line therapy for patients with unstable angina,\(^20\) who might not have suffered an AMI and therefore do not consider themselves to have heart disease. Although they are classified as having ACS, these patients have not had a MI and are informed by their physician that they have not had a heart attack, which gives them a false sense of security. The rapid procedural technique of PCI combined with minimal pain, short hospital stay and early return to work also indicates to patients that they no longer have heart disease. Consequently, ACS patients might not consider risk factor reduction either due to lack of knowledge or denial.

It is well known that although PCI is effective for revascularisation of the culprit lesion causing the ACS, it does not stop the process of atherosclerosis, the underlying cause of CHD, which can be slowed only through risk factor modification.
Therefore, ACS patients require alternate strategies for secondary prevention and risk factor modification.

This burden on health resources will intensify as patients continue to be treated with PCI without comprehensive risk factor management. Therefore, integrated services for risk factor reduction thus preventing further ACS events requiring acute coronary treatment are also warranted. This is of particular relevance in addressing the ‘revolving door’ syndrome, i.e. people developing ACS due to smoking, physical inactivity and improper diet, who are treated in hospital, then continue to smoke, not participate in physical activity and continue to eat unhealthy foods, and finally develop ACS again. The evidence from the literature indicates that although the cost of the initial management of ACS is high, 10 year costs relating to subsequent admissions for ACS are also comparable.\(^{28}\) Therefore, patients who have had ACS should be provided with interventions for risk factor modification to reduce the occurrence of further ACS events and reduce treatment costs including re-hospitalisations.

### 8.4 Limitations of the project

This thesis has clearly described the development and feasibility of the HeLM intervention for lifestyle modification and adherence to protective cardiotherapy to reduce risk factors for CHD. The chapters in this thesis have identified discrete limitations in terms of study design, data analysis and results relating to each of the three studies undertaken. However, it is important to identify the limitations of the overall project.

The multi-method design of the project included the conduct of three distinct yet interrelated studies which facilitated the development of the HeLM intervention by building on, integrating and synthesising the findings of each study. However, limitations relating to the use of a single health service for the survey of patients post-PCI and assessing the feasibility of the intervention potentially inhibit widespread generalisation of the data. Yet it should be noted that although only patients who had PCI at one hospital were surveyed, it was the only hospital in the area health service that undertook PCI at the time the study was conducted. Nevertheless, similarities between the data collected in these studies and those in the published literature support the integrity of the findings.
Since the commencement of this project, a number of strategies have been published for lifestyle modification and adherence to cardioprotective therapy in patients with CHD. However, these strategies may not be suitable in every clinical setting. Therefore, having a range of interventions will give clinicians a menu of strategies to choose from in order to provide optimal care for risk factor modification.

8.5 Conclusion
The HeLM intervention was developed on the actual available evidence from a systematic review of the literature, clinician expertise and patient information and preferences. Therefore, the content and method of delivery of the HeLM intervention was identified by conducting three separate yet interrelated studies as described previously. Based on the findings of these three studies, it was determined that the intervention would be brief, motivational and delivered in a non-confrontational manner, would provide education and support, use limited resources and be able to be used by patients in their own time. The HeLM intervention consisted of the HeLM booklet, goal-setting, personalised risk factor card and telephone support as vital features to enable patients to change behaviour. In particular, empowering patients about their risk factor status using personalised risk factor cards based on scientific evidence has not been previously reported and is a promising area for future research. A key strength of this study is the empirically derived conceptually congruent intervention. The HeLM intervention if demonstrated to be effective in a large randomised controlled trial may be a strategy that could reach CHD patients who have thus far eluded traditional CR programs and support them to make the necessary lifestyle changes. The HeLM intervention may also be an adjunct to traditional CR and have a synergistic effect in facilitating health-promoting behaviours in CHD patients. Findings from this study will help inform future research on the impact of individualised support using the HeLM techniques in promoting lifestyle changes and adherence to cardioprotective pharmacotherapy in CHD patients.
References


43. Redfern J, Ellis E, Briffa T, Freedman SB. Modular prevention of heart disease following acute coronary syndrome (ACS). *BMC Cardiovascular Disorders* 2006;6(26).


45. Parthan A, Vincze G, Morisky DE, Khan ZM. Strategies to improve adherence with medications in chronic, 'silent' diseases representing high cardiovascular


97. Brunner E, White I, Thorogood M, Bristow A, Curle D, Marmot M. Can dietary interventions change diet and cardiovascular risk factors? A meta-


244. Vale MJ, Jelinek MV, Best JD, Santamaria JD. Coaching patients with coronary heart disease to achieve the target cholesterol: a method to bridge the gap between evidence-based medicine and the "real world"--randomized controlled trial. *Journal of Clinical Epidemiology* 2002;55(3):245-52.


318. Worcester MU, Murphy BM, Mee VK, Roberts SB, Goble AJ. Cardiac rehabilitation programmes: predictors of non-attendance and drop-out.


351. Etter JF. Comparing the efficacy of two Internet-based, computer-tailored smoking cessation programs: a randomized trial. *Journal of Medical Internet Research* 2005;7(1).


383. NHS Centre for Reviews and Dissemination. Undertaking systematic reviews of research on effectiveness. CRD Guidelines for those carrying out or commissioning reviews. London: NHS Centre for Reviews and Dissemination, 1996.


411. National Health and Medical Research Council ARC, Australian Vice-Chancellors’ Committee. Review of the National Statement on Ethical Conduct in Research Involving Humans. 2004; First consultation draft.


416. NSW Health Department. NSW Policy Standards for Cardiac Rehabilitation: NSW Health Department, 1997.


Reducing Risk in Heart Disease 2007

Guidelines for preventing cardiovascular events in people with coronary heart disease

National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand
Guidelines for preventing cardiovascular events in people with coronary heart disease

Notes:

- The guidelines were developed using a consensus approach which involved an independent assessment of key Australian and international evidence-based clinical guidelines, scientific articles and trial data, which are incomplete in some areas.

- The guidelines provide a general framework for appropriate practice, to be followed subject to the practitioner's judgement in each individual case. All treatments should be individualised according to the patient's comorbidities, drug tolerance, lifestyle/habits, circumstances and wishes.

- For all medications observe usual contraindications, be mindful of the potential for significant and possibly adverse drug interactions and allergies, and carefully monitor and review patients regularly.

- Where drug therapy is recommended for indefinite use, these recommendations have been based on the extrapolated findings of clinical trials which are by their nature, of limited duration.

- Patients are often discharged from hospital after an acute coronary event on low doses of medications such as beta-blockers, ACE inhibitors and statins. In the majority of cases, it is recommended that the dose of each individual medication be increased to the recommended maximum target dose as required and tolerated.

- Any improvement in risk factors and movement towards the ideal risk factor 'goals' and 'targets' will be beneficial. Risk factor modification should be considered as a total package, so that for example, attention is not diverted from addressing smoking cessation while treating dyslipidaemia, hypertension and diabetes.

- Diabetes, renal impairment, and non-coronary heart disease manifestations of atherosclerosis such as cerebrovascular disease or peripheral vascular disease indicate higher risk for coronary events. Patients with coronary heart disease (CHD) should be screened for these conditions and managed appropriately.

- It is important to monitor and support patients' adherence to lifestyle advice and medications on an ongoing basis. Where appropriate, consider using ancillary measures (e.g. special clinics, telephone support, 'coaching').

- Recommendations are not necessarily congruent with current PBS criteria for eligibility for subsidy in all areas.

---

1 This guide can also be used for those with other manifestations of atherosclerosis e.g. aortic, carotid, and peripheral vascular disease. For recommendations on the management of patients with heart failure please refer to the Heart Foundation's 'Guidelines for the prevention, detection and management of chronic heart failure in Australia, 2006'.

Lifestyle/behavioural risk factors and management

Motivational interviewing/behavioural change assessment: Establish goals appropriate for patient's readiness to change, in accordance with patient's risk factor profile.

Referral when indicated: Heartline 1800 36 27 87, and appropriately trained health professionals (cardiac rehabilitation practitioners, dietitian, psychologist, etc).

## Smoking

**GOALS:**
- Complete cessation.
- Avoidance of second-hand smoke.

- Strongly encourage patient and family to stop smoking. Provide smokers and those exposed to second-hand smoke with appropriate facts. Even 3–5 minutes of time spent to encourage smokers to attempt to quit can increase cessation success.
- Refer to Heartline (1800 36 27 87) and consider referral to smoking cessation programs.
- Consider pharmacotherapy for patients smoking >10 cigarettes per day.
  - If used, aim to combine pharmacotherapy with behavioural and psychosocial support.
  - Nicotine replacement therapy (NRT) is the first line of medication.
  - NRT can be used safely in smokers with stable cardiovascular disease, but should be used with caution in people with recent myocardial infarction (MI), unstable angina, severe arrhythmias or recent cerebrovascular event.
  - Although not a first line agent, bupropion can be considered as a treatment option for patients with stable cardiovascular disease. Note: Safety of bupropion in patients who have had an acute coronary event has not been established.
  - Bupropion in combination with NRT can be considered for patients requiring additional assistance.
- Consider high risk of continuing to smoke when assessing benefits and risks of pharmacotherapy.

## Nutrition

**GOAL:** Establish/maintain healthy eating including saturated + trans fatty acid intake no more than 8% of total energy intake.

- Consumption of approximately 1g/1000ml of Polyunsaturated fatty acid (PUFA) + 1g/1000ml of Omega-3 fatty acid (DHA) and 1g/1000ml of Omega-6 fatty acid (ALFA) daily.

- In order to achieve this goal patients will need to follow the Heart Foundation's 'Enjoy Healthy Eating' messages. (Call Heartline for a free single copy of the brochure 'Enjoy Healthy Eating'). These messages encourage patients to choose:
  - Mostly plant-based foods - vegetables, fruits and legumes (stewed peas, dried beans and lentils) and grain-based foods (preferably whole grains such as bread, pasta, noodles and rice)
  - Moderate amounts of lean meat, poultry, fish and reduced fat dairy products
  - Moderate amounts of polyunsaturated or monounsaturated fats.
  - Avoid adults with CHD to consume approximately 1g of combined EPA and DHA per day through a variety of preferably oily fish and marine n-3 fish oil capsules supplements, as well as ≤5g/day of ALFA.
- A referral to a dietitian.

## Alcohol

**GOAL:** Low risk alcohol consumption.

- Assess patient medications for potential interactions with alcohol and advise as appropriate.
- Encourage patients with hypertension who drink alcohol to limit intake to no more than 2 standard drinks per day (men), or 1 standard drink per day (women).
- It is not recommended that abstainers should take up drinking or that drinkers should increase their alcohol intake.

## Physical activity

**GOALS:**
- Progress, over time, to the recommended goal of at least 30 minutes of moderate intensity physical activity* on most, if not all, days of the week (i.e. 150 minutes/week).
- Can be accumulated in shorter bouts of 10 minutes duration.
- For those with advanced heart disease the 'dose' may have to be reduced.

- Assess patient's physical activity habits together with severity of disease and comorbidities. Conditions that require clinical assessment or referral of physical activity include unstable angina, uncontrolled or severe hypertension, severe aortic stenosis, uncontrolled diabetes, complicated chronic obstructive pulmonary disease (COPD), heart failure or severe exacerbations of exacerbations, and cardiac cachexia or anemia.

- Discuss physical activity needs/capabilities/functional ability to encourage the patient to be active. Discuss and provide written guidelines for everyday physical activity tasks, including a light moderate walking program or equivalent. General practitioners should consider using the 'Lifesport' tools.

- Begin at low intensity and gradually increase intensity over several weeks, particularly in the post-acute event period. Advise the patient to begin with one or two activities for a short time at low intensity. Gradually increase the time spent, followed by the intensity, and the variety of activities over several weeks, towards achieving specific goals. Note: vigorous physical activity is generally not encouraged for people with CHD.

- Refer to a cardiac rehabilitation program and/or exercise physiologist where appropriate and available. This is particularly useful in the post-acute event period.

- Monitor progress response to the physical activity regimen in consultation with the patient.

- Moderate activity causes a moderate increase in depth and rate of breathing and still being able to talk comfortably. Examples include: walking on level firm ground, swimming, water aerobics, and light to moderate physical activity.

## Healthy weight

**GOALS:**
- Waist circumference
  - Male ≤94 cm
  - Female ≤80 cm
- BMI = 18.5–24.9 kg/m²

- Assess and continue to monitor both waist circumference and Body Mass Index (BMI). BMI is weight (kg)/height (m²).
- Set intermediate, achievable goals.

- Encourage healthy eating and regular physical activity. For weight loss to occur, it is necessary to use up more energy (kilocalories) through regular physical activity and consume less energy (kilocalories) from food and drinks.

- Goals based mainly on evidence of increased risk of death in European populations and may not be appropriate for large groups and ethnic groups. This issue is under review. Evidence-based advice exists regarding the role of BMI target for people with CHD.
Biomedical risk factors/medical management

### Lipids

- **GOAL**
  - LDL-C: <2.0 mmol/L
  - HDL-C: >1.0 mmol/L
  - Triglycerides (TG): <1.5 mmol/L

- **Lifestyle:** All patients should receive healthy eating advice.
- **Statins:** Since statins have been shown to be beneficial in patients with CHD regardless of their total or LDL-cholesterol (LDL-C) level, and since very early initiation of therapy has been shown to be safe and possibly beneficial, statin therapy is recommended for all patients with CHD (apart from exceptional circumstances) and in hospitalized patients should be commenced during that admission.\(^{16,21}\)
- **Benefit of treatment in high-risk groups:** In patients with diabetes and other manifestations of arterial disease (such as previous ischaemic stroke, has been confirmed.\(^{17,21}\)
- **Statin efficacy in reducing cardiovascular risk in those with type 2 diabetes:** High TG, low HDL-C, or who are overweight.\(^{19}\)
- **The combination of statins and a statin should be prescribed with caution, although there is a lower risk of myopathy with concomitant renin inhibitor therapy, compared to gemfibrozil.**\(^{9}\)
- **Lifestyle interventions:** Lower LDL by 15–20% as monotherapy or when added to a statin. Further long-term safety data are awaited.\(^{20}\)
- **For patients with elevated triglycerides:** Marine n-3 fortified foods and drinks and/or marine n-3 FA capsules are recommended.\(^{20}\)
- **Referral to dietitian:** a referral to Heartline 1300 36 27 87.

### Blood pressure

- **Adults 26 years:** Adults with diabetes and/or renal insufficiency and/or proteinuria ≥0.25 g/day
  - GOAL: <140/90 mm Hg
- **Adults 26 years:** Adults with renal insufficiency and/or diabetes and/or proteinuria 0.25–1.0 g/day
  - GOAL: <130/85 mm Hg
- **Adults with proteinuria ≥1.0 g/day:** (i.e. people with and without diabetes)
  - GOAL: <125/75 mm Hg

### Diagnosis of Hypertension

- **If SBP ≥140 or DBP ≥90 mm Hg on several occasions, consider diagnosis of hypertension.**
- **Investigate an appropriate excluded secondary hypertension.**
- **Refer to specialist if SBP 160 or DBP ≥110 mm Hg, or if secondary hypertension is suspected, or if hypertension proves difficult to manage.

### Urinary Protein

- **In those without diabetes with proteinuria:** If proteinuria detected on urinalysis, determine 24-hour urinary protein excretion or protein/creatinine ratio on a spot urine sample (note when ≥1+ on dipsticks).

- **In people with diabetes and hypertension:** Knowledge of urinary albumin excretion determines the intensity of antihypertensive therapy. The best screening test (if available) is the urinary albumin/creatinine ratio on a spot urine. In patients with values at least in the microalbuminuric range, a 24-hour urine collection should be obtained for accurate quantification.

### Management of Hypertension

- **Lifestyle:** Weight management, physical activity. Limit alcohol intake to no more than 2 standard drinks per day (men), 1 standard drink per day (women), low salt diet.
- **Unless there are good reasons for an alternative choice:** ACE inhibitors (ACEIs) are recommended as first-line antihypertensive in patients with pre-existing cardiovascular disease, including CHF, stroke and peripheral vascular disease and in diabetic patients who are hypertensive.
- **In diabetic patients with proteinuria:** commence treatment with either an ACE or angiotensin II receptor antagonists (ARBs) if ACE-intolerant.
- **Most individuals need appropriate drug combinations to reach blood pressure goals.** Combination therapy can also minimise adverse effects.
- **For those who demonstrate significant "white coat" effect, home management on "home" or "ambulatory" rather than clinic readings.
- **Referral to dietitian:** a referral to Heartline 1300 36 27 87.

### Diabetes

- **GOALS:** Identify those with previously undiagnosed Type 2 Diabetes.
  - In patients with diabetes maintain optimal blood sugar level (BSL) (HbA1c: <7%).

  **Definition of diabetes:**
  - Fasting Plasma Glucose ≥7.0 mmol/L or 2 h post-glucose load ≥11.1 mmol/L
  - **Definition of Impaired Glucose Tolerance:**
  - Fasting Plasma Glucose <7.0 mmol/L and 2 h post-glucose load ≥7.8 and <11.1 mmol/L

- **Diabetes:** All people with CHD should be screened for diabetes. Acute coronary syndromes (ACS) often unmask glucose intolerance or diabetes.\(^{12}\)
  - **Finger prick glucose testing:** is not recommended for diagnosis of diabetes.
  - **Measure plasma glucose on a fasting venous sample.** Analysis should be undertaken by an accredited laboratory.
  - **For fasting plasma glucose levels 5.5–6.9 mmol/L, random 5.5–11.0 mmol/L perform an oral glucose tolerance test.**

- **A definitive diagnosis of previously undiagnosed type 2 diabetes:** should be made during an acute cardiovascular event and results suggestive of undiagnosed diabetes should be confirmed 2 months after the acute event.

### Management of Type 2 Diabetes

- **First line management of hyperglycaemia:** is, in most cases, lifestyle intervention: physical activity, healthy eating and weight management. Then if required, addition of appropriate hypoglycaemic therapy to achieve near normal levels of glycemia, as indicated by HbA1c.
  - **Treatment of other risk factors:** including dyslipidaemia, hypertension, obesity, smoking and so on is particularly important for patients with diabetes.
  - **Tight glucose control with insulin or oral therapy may be considered in patients with diabetes with ACS.**\(^{32,41}\)
  - **In people with diabetes with proteinuria:** commence treatment with either an ACE or ARB if ACE-intolerant.
**Pharmacological management**

### Antiplatelet agents
- All patients should be taking aspirin 75–150 mg/day unless contraindicated.**
- Clopidogrel is an alternative when aspirin is contraindicated and should be considered in combination with aspirin in patients who have recurrent cardiac ischemic events.**
- Clopidogrel is recommended in combination with aspirin in the acute management of ST-elevation myocardial infarction (STEMI) and high-risk non-ST-elevation ACS.**
- There is evidence that clopidogrel, 75 mg/day, should be continued for at least 1 month after fibrinolytic therapy and for up to 12 months after stent implantation, depending on the particular type of stent and circumstances of implantation.**
- Clopidogrel use carries an increased risk of bleeding during surgery.

### ACE Inhibitors (ACEis)/Angiotensin II Receptor Antagonists (ARAs)
- Consider ACEis in all patients; especially in those at high risk, unless contraindicated.**
  - Start early post-MI.**
- Consider ARAs for patients who develop unacceptable side effects on ACEis.

### Beta-blockers
- Start in all post-MI patients unless contraindicated and continue indefinitely, especially in high risk patients.**
  - High risk patients are defined as those with:
    - significant myocardial infarction
    - left ventricular systolic dysfunction
    - previous evidence of ischemia
    - ventricular arrhythmias

### Statins
- Statin therapy is recommended for all patients with CHD (apart from in exceptional circumstances), and in hospitalised patients should be commenced during that admission (see Lipids).**

### Anticoagulants
- Warfarin is recommended in survivors of MI at high risk of systemic thromboembolism because of atrial fibrillation, mural thrombus, or previous embolisation. It may sometimes be combined with aspirin but in this circumstance patients should be observed closely for signs of bleeding.**

### Aldosterone antagonists
- Eplerenone may be prescribed early (0–14 days) post-MI in those with left ventricular systolic dysfunction and symptoms of heart failure.**

### Other

#### ANTIARRHYTHMICS**
- Due to the potential lethal pro-arrhythmic effects of antiarrhythmic agents, the routine usage of these drugs following ACS is not recommended, especially in patients with depressed left ventricular function. Careful balance of benefits and risks. Avoid use to suppress ventricular ectopic activity. Patients with documented sustained ventricular tachycardia should usually be referred for specialist opinion. Amiodarone is often chosen to treat symptomatic ventricular tachycardia, and may reduce the incidence of arrhythmic death in patients post-MI, but has no effect on total mortality.

#### CALCIUM CHANNEL BLOCKERS
- Calcium channel blockers of the non-dihydropyridine group (nilutamide, verapamil) may be used as antianginal agents for patients in whom beta-blocker therapy is contraindicated*. Provided there is no evidence of chest pain at rest, these calcium channel blockers can be used as an alternative to beta-blockers. In addition, controlled-release verapamil has been shown to reduce the incidence of cardiovascular events in patients with stable angina. It may decrease the risk of reinfarction and death after MI.**

#### INFLUENZA AND PNEUMOCOCCAL VACCINATIONS
- All patients should receive pneumococcal and annual influenza vaccinations (unless contraindicated).**

#### OESTROGENS & PROGESTINS
- Should not be prescribed for primary or secondary prevention of CHD. If hormone replacement therapy is prescribed for other conditions, risks and benefits must be considered.**

#### ANTIOXIDANTS
- Vitamin A, Vitamin C, Vitamin E
- There are no large-scale trial data to recommend antioxidant supplements for the prevention or treatment of CHD.**
Other considerations

Ongoing prevention/cardiac rehabilitation programs (OP/CR)\textsuperscript{27}

**GOAL:**
All patients with cardiovascular disease have access to and are actively referred to comprehensive ongoing prevention and cardiac rehabilitation services.

- OP/CR describes all measures used to assist patients to return to their normal activities, and reduce their risk of further cardiovascular events.
- OP/CR provides patients and their families/significant others with a program of education, information, physical activity and support, including advice on return to vocational activity, driving and resumption of sexual activity.
- Programs are preferably run by a multidisciplinary team and can be delivered in a variety of ways (group or individualised) and in a variety of settings (outpatients, general practice, home-based, telephone, web-based etc).
- The service should be provided in consultation with, and integrated into the ongoing care provided by the patient's general practitioner.

Management of chest pain/discomfort

**GOAL:**
All patients to have a written action plan to follow in the event of chest pain.

- All patients with known CHD should be prescribed a short-acting nitrate and provided with a written action plan for chest pain which includes:
  - Rest and self-administration of short-acting nitrites;
  - Telling someone nearby about the symptoms;
  - Calling an ambulance (dial 000) if symptoms are severe, get worse quickly or last for 10 minutes.

Chronic heart failure (CHF)

**GOAL:**
Early diagnosis and optimal management of patients progressing to CHF.

- People with known athrombosis disease (even without LV dysfunction) are at increased risk of developing CHF. Maintain a high index of suspicion in patients with previous MI or recognised CHD.\textsuperscript{9}
- Patients with suspected CHF should undergo an electrocardiogram (ECG), chest x-ray and echocardiogram, even if the physical signs are minimal.

Implantable cardiac defibrillators (ICD)

**GOAL:**
Early diagnosis and optimal management of patients progressing to CHF.

- ICD implantation should be considered in some patients who, despite optimal medical therapy, have persistently depressed left ventricular function after STEMI.\textsuperscript{14}
- Consider referral to a cardiac electrophysiologist.

Psychosocial factors and assessment

Psychological management\textsuperscript{28}

**GOAL:**
All patients with coronary heart disease assessed for comorbid depression. Patients with depression receive appropriate psychological and medical management.

- Depression is a significant independent risk factor for CHD.\textsuperscript{27}
- CHD and depression frequently coexist and all patients with CHD should be assessed for depression and treated if indicated.\textsuperscript{28}
- The Selective Serotonin Reuptake Inhibitor (SSRI) class of antidepressants has been shown to be safe and effective in the management of depression in patients with coronary CHD.\textsuperscript{29}
- Tricyclic antidepressants should be avoided in patients with CHD due to their class III antiarrhythmic effect.\textsuperscript{30}
- Cognitive-behavioral therapy delivered by a mental health professional specifically trained in this form of therapy (alone or in combination with medication) is also effective in the management of depression.
- Anxiety and/ or panic attacks should be assessed and managed accordingly.

Social management

**GOAL:**
All patients assessed for their level of social support.

- Social isolation and lack of social support are significant risk factors for CHD.\textsuperscript{31}
- Assess level of social support and provide follow up for those considered at risk through referral to cardiac rehabilitation services and/or referral to social worker or psychologist.
- Heartline (03) 7883 2787 has current contact details of local support groups including Heart Support Australia and walking groups.
For further copies of these guidelines and an extensive range of other professional resources, please contact Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost). Heartline also has a wide range of consumer information on healthy eating, physical activity, blood pressure, cholesterol, heart disease and other topics.

Visit www.heartfoundation.com.au for the complete range of Heart Foundation professional resources and guidelines as well as heart health information for the general public.

Encourage your patients to call Heartline on 1300 36 27 87 or visit www.heartfoundation.com.au for more information.

References

5. National Heart Foundation of Australia. Fish, fish oil and long chain omega 3 fatty acids. A position statement of the National Heart Foundation of Australia. NHFA 2006.
Appendix 2  Verification of study eligibility

Effect of brief structured interventions on risk factor modification for patients with coronary heart disease – A systematic review

VERIFICATION OF STUDY ELIGIBILITY

<table>
<thead>
<tr>
<th>AUTHOR AND YEAR</th>
<th>JOURNAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>__________________</td>
<td>__________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>__________________</td>
</tr>
</tbody>
</table>

INCLUSION CRITERIA

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Randomised control trial</th>
<th>Yes [ ] No [ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects:</td>
<td>Human</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Setting:</td>
<td>Hospital</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Community</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Lab</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>__________________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention:</th>
<th>Does the study describe an intervention for risk factor modification</th>
<th>Yes [ ] No [ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome:</td>
<td>Does the study evaluate the effect of the intervention on</td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Body mass index</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Cholesterol level</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Dietary habits</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Blood sugar levels</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
<tr>
<td>Incidence of hospital admissions</td>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
</tbody>
</table>

YOU should answer Yes to at least 1 question in each of the above four groups. If not please do not complete the rest
Appendix 3  Search Strategies

CINAHL SEARCH STRATEGY

1. Myocardial Diseases/
2. Myocardial Reperfusion Injury/
3. exp Myocardial Ischemia/
4. (myocard$ adj3 (infarct$ or isch?emi$ or disease$)).mp.
5. (heart adj3 (infarct$ or isch?emi$ or disease$ or attack$)).mp.
6. (coronary adj3 (disease$ or syndrome$ or event$ or thrombo$ or occlud$ or occlus$ or stenos$ or stenot$ or arteriosclero$)).mp.
7. (cardio$ or cardiac or heart$ or angina$).mp.
8. exp myocardial revascularization/
9. (myocard$ adj3 (revascular$ or re-vascular$ or reperfus$ or re-perfus$)).mp.
10. (coronary adj3 (angioplast$ or bypass$ or graft$ or atherectom$)).mp.
11. Cardiac Patients/
12. or/1-11
13. exp Rehabilitation, Cardiac/
14. (rehabilitat$ adj3 (heart$ or cardi$)).mp.
15. intervention$.mp.
16. exp Interviews/
17. (motivational interview$ or interview$).mp.
18. exp Counseling/
19. counsel$.mp.
20. exp Motivation/
21. motivat$.mp.
22. (self help or selfhelp).mp.
23. stages of change.mp.
24. (stage$ adj2 chang$).mp.
25. pamphlets/
26. (pamphlet$ or brochure$ or booklet$).mp.
27. or/13-26
28. Body Mass Index/
29. (body mass index or bmi).mp.
30. exp Dietary Fats/
31. cholesterol$ .mp.
32. Hypercholesterolemia/
33. (hypercholesterol$ or hyper-cholesterol$).mp.
34. exp Fish Oils/
35. ((omega 3 or omega3 or n 3 or n3) adj3 fat$).mp.
36. Food Habits/
37. Diet Therapy/
38. Diet, Reducing/
39. Diet, Fat-Restricted/
40. diet, sodium-restricted/
41. diet/ or diet$ .mp.
42. obesity/
43. (obesity or obese).mp.
44. (overweight or over weight or overeat$ or over eat$).mp.
45. Weight Loss/
46. weight control/
47. weight reduction programs/
48. (weight adj2 (loss$ or reduc$ or control$)).mp.
49. exp Hypertension/
50. (hypertens$ or blood pressure or diastolic or systolic).mp.
51. Smoking Cessation/
52. smoking/ or smoking.mp.
53. exp Exercise/
54. exp Therapeutic Exercise/
55. Physical Fitness/
56. "Physical Education and Training"/
57. exp sports/ or sport$ .mp.
58. (physical$ adj3 (fit$ or train$ or activ$ or endur$)).mp.
59. (exercis$ adj3 (train$ or physical$ or activ$ or aerobic$)).mp.
60. walking/ or walk$.mp.
61. exp Life Style/
62. Life Style Changes/
63. ((lifestyle adj3 chang$) or (lifestyle adj3 modif$)).mp.
64. ((life adj style adj3 chang$) or (life adj style adj3 modif$)).mp.
65. behavioral changes/
66. exp behavior modification/
67. (behavior$r$ adj3 (change$ or modify$ or therapy$)).mp.
68. exp Health Behavior/
69. 68 and (change$ or modify$).mp.
70. or/28-67,69
71. 12 and 27 and 70
72. 12 and 70
73. limit 72 to consumer patient teaching materials
74. 71 or 73
75. limit 74 to (adult <19 to 44 years> or middle age <45 to 64 years> or aged <65 to 79 years> or "aged <80 and over"))
76. limit 75 to clinical trial
77. exp Clinical Trials/
78. (clinical$ adj trial$).mp.
79. ((single$ or double$ or triple$ or triple$) adj (blind$ or masked$)).mp.
80. (randomi?ed control$ trial$ or rct$).mp.
81. Random Assignment/
82. (random$ adj2 (allocate$ or assign$)).mp. [mp=title, subject heading word, abstract, instrumentation]
83. placebo$ or placebo$.mp.
84. or/77-83
85. 76 or (75 and 84)

MEDLINE SEARCH STRATEGY
1. myocardial reperfusion injury/
2. exp Myocardial Ischemia/
3. (myocard$ adj3 (infarct$ or isch?emi$ or disease$)).mp.
4. (heart adj3 (infarct$ or isch?emi$ or disease$ or attack$)).mp.
5. (coronary adj3 (disease$ or syndrome$ or event$ or thrombo$ or occlud$ or occlus$ or stenos$ or stenot$ or arteriosclero$)).mp.
6. (cardio$ or cardiac or heart$ or angina$).mp.
7. exp Myocardial Revascularization/
8. (myocard$ adj3 (revascular$ or re-vascular$ or reperfus$ or re-perfus$)).mp.
9. (coronary adj3 (angioplast$ or bypass$ or graft$ or atherectom$)).mp.
10. or/1-9
11. (rehabilitat$ adj3 (heart$ or cardi$)).mp.
12. intervention$.mp.
13. interviews/
14. (motivational interview$ or interview$).mp.
15. exp counseling/
16. counsel$.mp.
17. exp motivation/
18. motivat$.mp.
19. self-help groups/
20. (self help or selfhelp).mp.
21. stages of change.mp.
22. (stage$ adj2 chang$).mp.
23. pamphlets/
24. (pamphlet$ or brochure$ or booklet$).mp.
25. or/11-24
26. body mass index/
27. (body mass index or bmi).mp.
28. exp dietary fats/
29. cholesterol$.mp.
30. hypercholesterolemia/ or (hypercholesterol$ or hyper-cholesterol$).mp.
31. exp fish oils/
32. ((omega 3 or omega3 or n 3 or n3) adj3 fat$).mp.
33. food habits/
34. diet therapy/
35. caloric restriction/
36. diet, fat-restricted/
37. diet, reducing/
38. diet, sodium-restricted/
39. diet/ or diet$.mp. [mp=ti, hw, ab, it, ot, nm]
40. obesity/
41. (obesity or obese).mp.
42. (overweight or over weight or overeat$ or over eat$).mp.
43. weight loss/
44. (weight adj2 (loss$ or reduc$ or control$)).mp.
45. exp hypertension/
46. (hypertens$ or blood pressure or diastolic or systolic).mp.
47. smoking cessation/
48. smoking/ or smoking.mp.
49. exercise/
50. exercise therapy/
51. physical fitness/
52. "physical education and training"/
53. exp sports/ or sport$.mp.
54. (physical$ adj3 (fit$ or train$ or activ$ or endur$)).mp.
55. (exercise$ adj3 (train$ or physical$ or activ$ or aerobic$)).mp.
56. walking/ or walk$.mp.
57. exp life style/
58. ((lifestyle adj3 chang$) or (lifestyle adj3 modif$)).mp.
59. ((life adj style adj3 chang$) or (life adj style adj3 modif$)).mp.
60. exp behavior therapy/
61. (behavior adj3 (chang$ or modif$ or therap$)).mp.
62. exp health behavior/
63. 62 and (chang$ or modif$).mp.
64. or/26-61,63
65. 10 and 25 and 64
66. limit 65 to "all adult (19 plus years)"
67. limit 66 to (clinical trial or randomized controlled trial)
68. Randomized Controlled Trials/
69. random allocation/
70. double blind method/
71. single blind method/
72. exp clinical trials/
73. (clinical$ adj trial$).mp.
74. ((single$ or double$ or treble$ or triple$) adj (blind$ or mask$)).mp.
75. (random?ed control$ trial$ or rct$).mp.
76. (random$ adj2 (allocate$ or assign$)).mp.
77. placebos/ or placebo$.mp.
78. or/68-77
79. 67 or (66 and 78)

EMBASE SEARCH STRATEGY
1. exp Intracardiac Thrombosis/
2. exp ischemic heart disease/
3. exp myocardial disease/
4. exp coronary artery disease/
5. (coronary adj3 (disease$ or syndrome$ or event$ or thrombo$ or occlud$ or occlus$ or stenos$ or stenot$ or arteriosclero$)).mp.
6. (heart adj3 (infarct$ or isch?emi$ or disease$ or attack$)).mp.
7. (myocard$ adj3 (infarct$ or isch?emi$ or disease$)).mp.
8. (cardio$ or cardiac or heart$ or angina$).mp.
9. exp coronary artery surgery/ or heart muscle revascularization/
10. (myocard$ adj3 (revascular$ or re-vascular$ or reperfus$ or re-perfus$)).mp.
11. (coronary adj3 (angioplast$ or bypass$ or graft$ or atherectom$)).mp.
12. or/1-11
13. heart rehabilitation/
14. (rehabilitat$ adj3 (heart$ or cardi$)).mp.
15. intervention$.mp.
16. interview/
17. (motivational interview$ or interview$).mp.
18. exp counseling/
19. counsel$.mp.
20. MOTIVATION/
21. motivat$.mp.
22. self help/
23. (self help or selfhelp).mp.
24. stages of change.mp.
25. (stage$ adj2 chang$).mp.
26. (pamphlet$ or brochure$ or booklet$).mp.
27. or/13-26
28. body mass/
29. (body mass or bmi).mp.
30. exp fat intake/
31. cholesterol$.mp.
32. exp Hypercholesterolemia/
33. (hypercholesterol$ or hyper-cholesterol$).mp.
34. Fish Oil/
35. Omega 3 Fatty Acid/
36. ((omega 3 or omega3 or n 3 or n3) adj3 fat$).mp.
37. exp feeding behavior/
38. diet therapy/
39. diet therapy/
40. low calory diet/
41. low fat diet/
42. diet restriction/
43. caloric restriction/
44. sodium restriction/
45. exp fat intake/
46. caloric intake/
47. diet/ or diet$.mp.
48. obesity/
49. (obesity or obese).mp.
50. (overweight or over weight or overeat$ or over eat$).mp.
51. weight reduction/
52. Body Weight/
53. (weight adj2 (loss$ or reduc$ or control$)).mp.
54. exp Hypertension/
55. (hypertens$ or blood pressure or diastolic or systolic).mp.
56. smoking cessation/
57. cigarette smoking/ or smoking/ or smoking habit/ or smoking.mp.
58. exp exercise/
59. exp kinesiotherapy/
60. exp physical activity/
61. fitness/
62. training/
63. exp sport/ or sport$.mp.
64. (physical$ adj3 (fit$ or train$ or activ$ or endur$)).mp.
65. (exercis$ adj3 (train$ or physical$ or activ$ or aerobic$)).mp.
66. walking/ or walk$.mp.
67. lifestyle/
68. ((lifestyle adj3 chang$) or (lifestyle adj3 modif$)).mp.
69. ((life adj style adj3 chang$) or (life adj style adj3 modif$)).mp.
70. behavior therapy/
71. behavior modification/
72. (behavio?r$ adj3 (chang$ or modif$ or therap$)).mp.
73. exp health behavior/
74. 73 and (chang$ or modif$).mp.
75. or/28-72,74
76. 12 and 27 and 75
77. limit 76 to (adult <18 to 64 years> or aged <65+ years>)
78. Clinical Trial/
79. Randomized Controlled Trial/
80. randomization/
81. Single Blind Procedure/
82. Double Blind Procedure/
83. Crossover Procedure/
84. (clinic$ adj trial$).mp.
85. (randomi?ed control$ trial$ or rct$).mp.
86. (random$ adj2 (allocat$ or assign$)).mp.
87. ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).mp.
88. placebo/ or placebo$.mp.
89. or/78-87
90. 77 and 89
COCHRANE LIBRARY SEARCH STRATEGY

#1 Myocardial Reperfusion Injury

#2 Myocardial Ischemia explode all trees

#3 (myocard* near/3 (infarct* or isch*mi* or disease*))

#4 (heart near/3 (infarct* or isch*mi* or disease* or attack*))

#5 (coronary near/3 (disease* or syndrome* or event* or thrombo* or occlud* or occlus* or stenos* or stenot* or arteriosclero*))

#6 (cardio* or cardiac or heart* or angina*)

#7 Myocardial Revascularization explode all trees

#8 (myocard* near/3 (revascular* or re-vascular* or reperfus* or re-perfus*))

#9 (coronary near/3 (angioplast* or bypass* or graft* or atherectom*))

#10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)

#11 (rehabilitat* near/3 (heart* or cardi*))

#12 (intervention*)

#13 Interviews, this term only

#14 ("motivational interview*" or interview*)

#15 Counseling explode all trees

#16 (counsel*)

#17 Motivation explode all trees

#18 (motivat*)

#19 Self-Help Groups, this term only

#20 "self help" or selfhelp

#21 "stages of change"

#22 (stage* near/2 chang*)

#23 Pamphlets, this term only

#24 (pamphlet* or brochure* or booklet*)
#25 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24)

#26 Body Mass Index, this term only

#27 "body mass index" or bmi

#28 Dietary Fats explode all trees

#29 (cholesterol*)

#30 Hypercholesterolemia, this term only

#31 (hypercholesterol* or hyper-cholesterol*)

#32 Fish Oils explode all trees

#33 ("omega 3" or omega3 or "n 3" or n3) near/3 fat*

#34 Food Habits, this term only

#35 Diet Therapy, this term only

#36 Caloric Restriction, this term only

#37 Diet, Fat-Restricted, this term only

#38 Diet, Reducing, this term only

#39 Diet, Sodium-Restricted, this term only

#40 Diet, this term only

#41 (diet*)

#42 Obesity, this term only

#43 (obesity or obese)

#44 (overweight or "over weight" or over-weight or overeat* or "over eat*" or over-eat*)

#45 Weight Loss, this term only

#46 (weight near/2 (loss* or reduc* or control*))

#47 Hypertension explode all trees

#48 (hypertens* or "blood pressure" or diastolic or systolic)
#49 Smoking Cessation, this term only
#50 Smoking, this term only
#51 (smoking)
#52 Exercise, this term only
#53 Exercise Therapy, this term only
#54 Physical Fitness, this term only
#55 Physical Education and Training, this term only
#56 Sports explode all trees
#57 (sport*)
#58 (physical* near/3 (fit* or train* or activ* or endur*))
#59 (exercis* near/3 (train* or physical* or activ* or aerobic*))
#60 Walking, this term only
#61 (walk*)
#62 Life Style explode all trees
  (lifestyle near/3 chang*) or (lifestyle near/3 modif*) or ("life style" near/3 chang*) or ("life style" near/3 modif*) or (life-style near/3 chang*) or (life-style near/3 modif*)
#63 Behavior Therapy explode all trees
#65 (behavi* near/3 (chang* or modif* or therap*))
#66 Health Behavior explode all trees
#67 (#66 AND ( chang* OR modif* ))
  (#26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #67)
#69 (#10 AND #25 AND #68)
#70 Adult explode all trees

#71 (adult or aged or "middle age*" or elderly)

#72 (#70 OR #71)

#73 (#69 AND #72)
Appendix 4  JBI Critical Appraisal Checklist for Experimental Studies
EFFECT OF BRIEF INTERVENTIONS FOR RISK FACTOR MODIFICATION FOR CORONARY HEART DISEASE A – SYSTEMATIC REVIEW

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes (3)</th>
<th>No (2)</th>
<th>Unclear(1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to treatment groups random?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Were participants blinded to treatment allocation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Was allocation to treatment groups concealed from the allocator?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Were the control and treatment groups comparable at entry?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Were groups treated identically other than for the named interventions?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Were outcomes measured in the same way for all groups?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Were outcomes measured in a reliable way?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Was there adequate follow-up (&gt;80%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Was appropriate statistical analysis used?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall appraisal: Include □ Exclude □ Seek further info □

Comments (Including reasons for exclusion)

__________________________________________________________
__________________________________________________________
__________________________________________________________
__________________________________________________________
### Appendix 5  Quality Assessment of Included Trials

Effect of brief structured interventions on risk factor modification for patients with coronary heart disease – A systematic review

<table>
<thead>
<tr>
<th>Author</th>
<th>Assignment Random</th>
<th>Participants blinded to treatment group</th>
<th>Allocation to groups concealed from allocator</th>
<th>Outcomes of people who withdrew described and those assessing outcomes blind to the outcomes blind to the entry</th>
<th>Groups comparable at entry</th>
<th>Groups treated identically other than the way outcomes measured in the same way for all outcomes measured in a reliable way</th>
<th>Adequate follow up &gt;80%</th>
<th>Appropriate statistical analysis used</th>
<th>TOTAL</th>
<th>Method of allocation</th>
<th>Sample size calculation stated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolman 346</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>cRCT</td>
</tr>
<tr>
<td>Dalgård 377</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Not stated</td>
</tr>
<tr>
<td>Dornelas 379</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Echeverry 384</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Alternation</td>
</tr>
<tr>
<td>Feder 385</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>cRCT</td>
</tr>
<tr>
<td>Feeney 380</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Froelicher 382</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Permuted block randomisation</td>
</tr>
<tr>
<td>Grace 376</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Block randomisation</td>
</tr>
<tr>
<td>Author</td>
<td>Assignment Random</td>
<td>Participants blinded to treatment group</td>
<td>Allocation to groups concealed from allocator</td>
<td>Outcomes of people who withdrew described and outcomes blind to the group</td>
<td>Groups comparable at entry</td>
<td>Groups treated identically other than the intervention</td>
<td>Outcomes measured in the same way for all groups</td>
<td>Outcomes measured in a reliable way</td>
<td>Adequate follow up &gt;80%</td>
<td>Appropriate statistical analysis used</td>
<td>Method of allocation</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>---------------------------------</td>
<td>-----------------------------</td>
<td>----------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Hajek</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Heller</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Levetan</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Lewin</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Mahler</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Not stated</td>
</tr>
<tr>
<td>Reid</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Southard</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Taylor</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
<tr>
<td>Vale</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Random list</td>
</tr>
</tbody>
</table>
Effect of brief structured interventions on risk factor modification for patients with coronary heart disease – A systematic review

Please identify the groups and complete the following for each group
* If more than 3 groups, please add an extra column.

<table>
<thead>
<tr>
<th>PARTICIPANTS</th>
<th>Group</th>
<th>Group</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number in each group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender F / M</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principal diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants excluded from the study</td>
<td>Number:___</td>
<td>Number :___</td>
<td>Number:___</td>
</tr>
<tr>
<td>Reason:________</td>
<td>Reason:________</td>
<td>Reason:________</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTERVENTION</td>
<td>Group</td>
<td>Group</td>
<td>Group</td>
</tr>
<tr>
<td>Description of intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention delivered by (eg Nurse, Dr )</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>Group</td>
<td>Group</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Frequency of delivery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of time for delivery of BI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method of delivery (eg face to face contact, telephone)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BI targeted at patient’s stage of change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of follow-ups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of follow-ups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schedule of follow-up (eg 3 months, 6 months)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### OUTCOMES

#### Risk factor modification

<table>
<thead>
<tr>
<th>Risk factor modification</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fat intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood sugar level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure level</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Others

<table>
<thead>
<tr>
<th>Hospital admission for Acute coronary syndrome/chest pain/stroke</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Group</td>
<td>Group</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge relating to CHD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health related quality of life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other Relevant Comments**

___________________________________________________
___________________________________________________
___________________________________________________
___________________________________________________
Appendix 7  Studies excluded from the review


   **Reason for exclusion** Length of home visits not stated


   **Reason for exclusion** Extensive intervention


   **Reason for exclusion** Inadequate description of the intervention.


   **Reason for exclusion** Report


   **Reason for exclusion** Compares the education strategies and not impact on patients.


   **Reason for exclusion** Extensive intervention


   **Reason for exclusion** Unable to translate.

*Reason for exclusion* Non cardiac patients.


*Reason for exclusion* Inadequate data from abstract. Unable to contact authors


*Reason for exclusion* Inadequate data from abstract. Unable to contact authors


*Reason for exclusion* Extensive intervention.


*Reason for exclusion* Data for individual groups not presented.

*Reason for exclusion* not an RCT.


*Reason for exclusion* Extensive intervention.


*Reason for exclusion* Inadequate description of the intervention.


*Reason for exclusion* Inadequate description of the intervention.


*Reason for exclusion* Extensive intervention.


*Reason for exclusion* No behavioural outcomes measured
### Appendix 8  Summary tables

#### Brief structured interventions targeting diet

<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Dalgard 577 | RCT | Patients with IHD attending outpatient cardiovascular unit | **Intervention Group** (Brief Counseling) (n=17)  
The dietary counseling consisted of a single 10-minute session during which the patients were offered 5 pieces of behavior advice that focused on total diet quality and provided simple advice on behavioral changes. No information regarding methods of cooking, preferred fat choices, or other nutrient information was provided.  
**Control Group** (Comprehensive Counseling) (n=19)  
Patients received a 40- to 50-minute counseling session during which a dietitian provided comprehensive details on dietary fat and cholesterol and the blood lipids. Information on "limits" for fat and saturated fat were also provided.  
**1 year follow up**  
| **Intervention Group**  
% of energy from fat  
Baseline 31%  
Follow-up 32%,  
% of energy from saturated fat  
Baseline 11%  
Follow up 12%  
% of energy from carbohydrate  
Baseline 53%  
Follow up 52% | Observer blinded  
**Theoretical Model**  
Stages of Change  
**Intervention delivered by**  
Dieticians  
Not stated whether training for dieticians was provided |
<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grace <strong>376</strong></td>
<td>RCT</td>
<td>14 hyperlipidemic patients referred by the cardiac rehabilitation centre.</td>
<td><strong>Intervention group (n= 8)</strong> Advice and information package which contained details on improving practical implementation of a low fat diet.</td>
<td><strong>Control Group</strong> 44 g/day <strong>Median intakes of fruit</strong> 346 g/day <strong>Intervention Group</strong> 129 g/day <strong>Control Group</strong> 172 g/day <strong>Median intakes of vegetables</strong> 562 g/day <strong>Intervention Group</strong> 224 g/day <strong>Control Group</strong> 315 g/day There was no significant difference within or between the groups.</td>
<td>FFQ used to assess total and daily fat intake. Total time 10-15 minutes</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>RCT</td>
<td>14 hyperlipidemic patients referred by the cardiac rehabilitation centre.</td>
<td><strong>Control group (n=5)</strong> Advice only</td>
<td><strong>Mean change at 12 week follow up</strong></td>
<td><strong>Theoretical Model</strong> No model</td>
</tr>
<tr>
<td>Levetan <strong>376</strong></td>
<td>RCT</td>
<td>Hospitalized patients with documented CVD on the cardiology service</td>
<td><strong>Intervention group (n=37)</strong> Patients received by mail a computer-generated customized laminated color poster that graphically depicted their LDL-C, HDL-C, blood pressure, and weight status</td>
<td><strong>6 month follow-up</strong></td>
<td><strong>Theoretical Model</strong> No model stated</td>
</tr>
<tr>
<td>USA</td>
<td>RCT</td>
<td>Hospitalized patients with documented CVD on the cardiology service</td>
<td><strong>Intervention group (n=37)</strong> Patients received by mail a computer-generated customized laminated color poster that graphically depicted their LDL-C, HDL-C, blood pressure, and weight status</td>
<td><strong>6 month follow-up</strong></td>
<td><strong>Theoretical Model</strong> No model stated</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>transfusion during their hospital stay, were being evaluated for acute myocardial infarction, with an underlying illness, such as malignancy, which was expected to impact their survival over the following 6 months</td>
<td>a list of personalized goals and steps for goal achievement a personalized wallet card that included their baseline lipid and blood pressure status, with room to document subsequent values. One postcard per month which informed the relationship between LDL-C and atherosclerosis and provided an action step for LDL-C lowering one phone call (lasting &lt;10 minutes) from a health educator to discuss their poster.</td>
<td>Baseline 187.2 (10.4) Follow-up 174.7 (9.71) p&lt; 0.02</td>
<td>Intervention delivered by Nurse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Base line characteristics</td>
<td></td>
<td>Control Group</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No significant differences between the groups in baseline age, education level, race, cholesterol levels, and comorbidities</td>
<td></td>
<td>Control group</td>
<td></td>
</tr>
<tr>
<td>Age (year, mean ± SD) Control 59.0 (±15.8) Intervention 62.5 (±9.1)</td>
<td>LDL-C mg/dL (mmol/l)</td>
<td></td>
<td>LDL-C mg/dL (mmol/l)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control Group (n=45)</td>
<td></td>
<td>Control group</td>
<td></td>
</tr>
<tr>
<td>Received usual advice which included hospital discharge materials on cardiovascular health and additional information provided by their physician. Patients did not receive a personalized report, follow-up phone call or monthly postcards.</td>
<td>Baseline 117.8 (6.54) Follow-up 116.7 (6.48) p= 0.43</td>
<td></td>
<td>Total cholesterol mg/dL (mmol/l)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control group</td>
<td></td>
<td>Knowledge of types of cholesterol from baseline to follow-up</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Significant increase in knowledge in the intervention group</td>
<td></td>
</tr>
</tbody>
</table>

Appendices A-317
## Brief structured interventions targeting smoking cessation

<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Dornelas USA     | RCT        | 100 cigarette smokers admitted during 1996 to hospital with MI | **Intervention group (n=54)**: Bedside cessation counseling using motivational interviews telephone calls at 1, 4, 8, 12, 16, 20, and 26 weeks post discharge. **Control group (n=46)**: Verbal and written recommendation to watch an on-line patient education video entitled “Active Partnership: Toward a HealthierHeart” during hospitalization and referral to the American Heart Association or American Lung Association for smoking cessation in the patient’s community. | **Smoking cessation at 6 month follow-up**<br>Intervention group 35/48 (73%)<br>Control group 19/41 (46%)<br>p<0.01<br><br>**Intention to Treat analysis**<br>Intervention group 67%<br>Control group 43%

p<0.05 | Outcomes assessed using Fagerstrom Tolerance Questionnaire. The Smoking Cessation Self-Efficacy Questionnaire, Short Form 36 Survey (SF-36) The report of a significant other was used to validate smoking status Number of completed telephone calls for the intervention group ranged from one to seven mean 5.1, SD 5 1.8. **Theoretical model** Transtheoretical Model **Intervention Delivered by** Psychologist Total time spent 10 minutes. |
<p>| Bolman Netherlands | cRCT       | Patients admitted for CHD who smoked | <strong>Intervention group (n=388)</strong>: Short quit smoking advice by the cardiologist. 15–30 min of individual counseling (C-MIS ) by a nurse. Setting a quit date, self-help materials (booklets) <strong>Control group (n=401)</strong> | <strong>Smoking cessation at 3 months</strong>&lt;br&gt;Point prevalence&lt;br&gt;Intervention group 201/388&lt;br&gt;Control group 156/401&lt;br&gt;&lt;br&gt;<strong>Continuous abstinence</strong>&lt;br&gt;Intervention group 167/388&lt;br&gt;Control group 136/401 | All the nurses in the intervention sites received training on the CMIS Smoking cessation assessed using self reported point prevalence. <strong>Theoretical model</strong> Stages of change |</p>
<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeney</td>
<td>RCT</td>
<td>Current smokers admitted to coronary care with an AMI</td>
<td>Intervention group (n=79)</td>
<td>12 month followup</td>
<td>Tobacco cessation validated by cotinine levels</td>
</tr>
<tr>
<td>Australia</td>
<td>Method of Allocation: Random list of numbers</td>
<td>Tobacco use in the week before hospitalization. Patients with AMI, documented by two or more of the following: elevated serum creatine phosphokinase, history of prolonged ischaemic chest pain and the appearance of new Q waves or evolving ST segment change on an electrocardiogram.</td>
<td>Attending cardiologist advised all patients to stop smoking. Patients were given the Stanford Heart Attack Staying Free programme manual designed to identify high-risk situations for relapse. Two audiotapes for home use were included Telephone contact weekly for 4 weeks and at 2, 3, 6 and 12 months.</td>
<td>No. of patients who quit</td>
<td>The level of nicotine dependence was measured by the Fagerstrom tolerance questionnaire</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Base line characteristics</td>
<td>Control group (n=62)</td>
<td>Control group</td>
<td>Theoretical Model</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No significant differences between the groups in baseline gender, age and risk factors.</td>
<td>Didactic verbal and printed advice about tobacco cessation. Patients watched an educational video. Outpatient supportive counseling and follow up was offered at 3-, 6-, 12-month intervals. All patients advised by the attending cardiologist to stop smoking.</td>
<td>1/62 (2%)</td>
<td>No model stated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Behavior targeted</td>
<td></td>
<td></td>
<td>Intervention Delivered by Nurse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Smoking</td>
<td></td>
<td></td>
<td>Training for nurse not stated</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td><strong>Hajek</strong> 277 United Kingdom</td>
<td>RCT Method of Allocation Random list of numbers</td>
<td>Patients recruited from 17 hospitals in England.</td>
<td>Intervention group (n=274) Participants received verbal advice to remain abstinent, a British Heart Foundation booklet <em>Smoking and your Heart</em> a carbon monoxide reading, a booklet on smoking and cardiac recovery that provided advice on avoiding relapse; a written quiz on the contents of the booklet, an offer to be put in contact with another cardiac patient who had also recently stopped smoking. Participants had to sign a declaration of commitment not to smoke. The intervention took about 20 minutes of nurses’ time.</td>
<td>Abstinence at 6 weeks Continuous abstinence Intervention group 159/267 (60%) Control group 152/259 (59%) p=0.84</td>
<td>Sample size calculation stated Definitions Continuous abstinence smoked no more than five cigarettes since recruitment and had not smoked at all in the past week. expired carbon monoxide reading &lt; 10 ppm and, at 12 months, a salivary cotinine concentration &lt; 20 ng/ml. Point prevalence abstinence as a self report of not having smoked at all for the past week and an expired carbon monoxide reading &lt; 10 ppm or, for the 12 month outcome, a salivary cotinine concentration &lt; 20 ng/ml. Theoretical Model No model stated</td>
</tr>
<tr>
<td><strong>Reid</strong> 381 Canada</td>
<td>RCT Method of allocation</td>
<td>254 cigarette smokers hospitalized with CAD</td>
<td>Intervention group Brief Individual Counseling (n=126) 5- to 10-minute session in</td>
<td>Smoking cessation at 3 month follow-up Point prevalence abstinence Intervention group All 54/128 (42%)</td>
<td>Current smoking was defined as 5 or more cigarettes per day during the month preceding</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Stratified sample</td>
<td>Patients admitted for coronary angiography, PTCA, MI, or CABG identified as cigarette smokers. 18</td>
<td>which all the participants were advised to quit in a personalized manner.</td>
<td>Angio/PTCA 29% MI 58% CABG 44% Control group All 67/126 (53%) Angio/PTCA 48% MI 56% CABG 67%</td>
<td>admission. Abstinence was defined as a self-report of no smoking (not even a puff) in the preceding 7 days.</td>
</tr>
<tr>
<td></td>
<td>Random numbers</td>
<td>years of age or older</td>
<td>Willingness to make a quit attempt was assessed. A self-help booklet was provided.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exclusion Criteria Users of pipes, cigars, or smokeless tobacco, individuals with unresolved unstable angina, life-threatening arrhythmias, vasospastic diseases pregnant or lactating women, those who lived more than 1 hour of travel time away.</td>
<td>Participants were informed to contact their primary care physician for additional assistance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Base line characteristics</td>
<td>Control group (n=128) Brief Individual Counseling + Stepped Care Treatment</td>
<td></td>
<td>Biochemical validation of abstinence was performed in a random sample of 25 self-reported nonsmokers at 1 year.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The groups were balanced for age, gender, education level, reason for admission, cigarettes per day,</td>
<td>Contacted 4 weeks after hospital discharge, positive reinforcement provided and reminded about relapse prevention information in the booklet. Nurse counseling consisted of three 20-minute face-to-face counseling sessions over an 8-week period. NRT initiated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fagerstrom score, years of smoking, quit attempts, motivational readiness to quit smoking, self-efficacy, and preference for cessation assistance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Behavior targeted Smoking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sivarajan</td>
<td>RCT</td>
<td>All women who had smoked cigarettes during the month before their admission to the coronary care</td>
<td>Intervention group (n=142) The intervention included a 30- to 45-minute</td>
<td>Abstinence at 6 months Point prevalence for nonsmoking Intervention group</td>
<td>The Stanford Dependency Index 16 was used to measure degree of addiction to nicotine. Point prevalence determinations at 24 and 30 months were not confirmed by cotinine testing.</td>
</tr>
<tr>
<td>Froelicher</td>
<td>Method of allocation</td>
<td>unit, intensive care unit, or selected medical or surgical wards of any of the 12 participating hospitals</td>
<td>individualized counseling session with multimedia aids that study participants were given before their discharge from the hospital. During the session, the women viewed a 17-minute videotape from the</td>
<td>71/137 (51.5%) Control group 54/133 (40.8%) p=NS</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Permuted block</td>
<td></td>
<td></td>
<td>Abstinence at 12 months Intervention group</td>
<td></td>
</tr>
<tr>
<td></td>
<td>stratified by hospitals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>Taylor ^83</td>
<td>RCT</td>
<td>Hospital in-patients with acute myocardial infarction</td>
<td>Intervention group (n=86) Counseling about benefits of not smoking after infarction. Patients given a 18-page</td>
<td>64/134 (47.6%) Control group 55/132 (41.7%) p=NS Abstinence at 24 months Intervention group 62/127 (48.5%) Control group 60/129 (46.2%) p=NS Abstinence at 30 months Intervention group 63/125 (50%) Control group 64/128 (50%) p=NS</td>
<td>Patients who reported smoking cigarettes, cigarillos, or using any other form of tobacco in</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
|               | Random numbers      | Patients 70 years of age or younger. Myocardial infarction was documented by two or more of the following conditions: elevation of the serum creatinine phosphokinase level, a history of prolonged ischemic chest pain, and the appearance of new Q waves or evolving ST-segment changes on an electrocardiogram. | Staying Free manual and two audio tapes that emphasized how to identify and cope with high-risk situations for smoking relapse. Patients were given counseling on how to cope with any high-risk situation. Telephone contact with patients once per week for the first 2 to 3 weeks and then monthly for the next 4 months. Patients were asked to sign a contract to quit smoking and to set a quit date. | 12 month follow-up  
No. of patients who quit  
Intervention group 51/84 (61%)  
Control group 26/82 (32%)  
p<0.001  
Intention to quit at 12 month follow-up  
Little or no intention to quit/Number actually quit  
Intervention group 6/2  
Control group 9/1  
Probable intention to quit/Number actually quit  
Intervention group 14/9  
Control group 7/1  
Definite intention to quit/Number actually quit  
Intervention group 49/37  
Group B 38/23 | the 6 months preceding myocardial infarction were classified as smokers.  
Nurses participated in an initial 4-hour didactic session and two 4-hour follow-up workshops conducted by the investigators and the program nurse coordinator  
Smoking measured using expired CO level and serum thiocyanate level  
**Theoretical Model**  
Social learning theory combined with addiction models for nicotine  
**Intervention Delivered by**  
Nurse |
### Brief structured interventions targeting multiple risk factors

<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Echeverry</strong>&lt;sup&gt;384&lt;/sup&gt; USA</td>
<td>RCT</td>
<td><strong>Inclusion criteria</strong>&lt;br&gt;Patients 55 years or older with diabetes of any type hospitalized with an acute myocardial infarction, congestive heart failure exacerbation, or unstable angina, returned home after discharge, individuals who would be followed by a primary care provider.</td>
<td><strong>Intervention group (n=103)</strong>&lt;br&gt;Patients received a brochure explaining the relationship between heart disease and diabetes and were told about risk factors for heart disease in a brief, scripted discussion. They were given a reminder card to take to their physician. 2 weeks following discharge, 2&lt;sup&gt;nd&lt;/sup&gt; copy of the brochure and the reminder card were mailed. Two weeks later, the individuals were phoned. Monthly follow-up phone calls for the first 6 months.</td>
<td><strong>6 month follow-up</strong>&lt;br&gt;- BP &gt;130/85 mm Hg&lt;br&gt;  <strong>Intervention Group</strong> 38/71 (53.5%)&lt;br&gt;  <strong>Control Group</strong> 41/70 (58.6%)&lt;br&gt;- Triglycerides &gt;400 mg/dL&lt;br&gt;  <strong>Intervention Group</strong> 3/49 (6.1%)&lt;br&gt;  <strong>Control Group</strong> 2/46 (4.4%)&lt;br&gt;- LDL &gt;100 mg/dL&lt;br&gt;  <strong>Intervention Group</strong> 13/47 (27.7%)&lt;br&gt;  <strong>Control Group</strong> 11/45 (24.4%)&lt;br&gt;- No model stated</td>
<td>Out come assessed using self reports.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Exclusion criteria</strong>&lt;br&gt;Patients discharged to a nursing home or skilled nursing facility or other institution. Individuals who would be followed by a cardiologist or an endocrinologist.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Baseline characteristics</strong>&lt;br&gt;No significant differences between the groups in baseline gender, age comorbidities and risk factors.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Risk factor targeted</strong>&lt;br&gt;Blood pressure, lipid, A1C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Feder</strong>&lt;sup&gt;385&lt;/sup&gt; United Kingdom</td>
<td>cRCT</td>
<td>52 general practices in east London, 44 of which had received facilitation of local guidelines for coronary heart disease. 328 patients admitted to hospital for myocardial infarction or unstable angina.</td>
<td><strong>Intervention group (n=172)</strong>&lt;br&gt;Leaflets containing recommendations about lowering the risk of another coronary event, including changes to lifestyle and drug</td>
<td><strong>Follow up at 6 months</strong>&lt;br&gt;- Made change to food, drugs, or exercise&lt;br&gt;  <strong>Intervention group</strong> 83% (92/111)&lt;br&gt;  <strong>Control group</strong> 83% (91/109)&lt;br&gt;- p &gt;0.05</td>
<td>The accuracy of data collection was tested by assessment of a random sample of one in eight medical records.</td>
</tr>
<tr>
<td></td>
<td>Method of Allocation</td>
<td>Computerised minimisation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Table of Inclusion Criteria**

- Patients 55 years or older with diabetes of any type hospitalized with an acute myocardial infarction, congestive heart failure exacerbation, or unstable angina.
- Returned home after discharge.
- Followed by a primary care provider.

**Exclusion Criteria**

- Discharged to a nursing home or skilled nursing facility.
- Followed by a cardiologist or an endocrinologist.

**Baseline Characteristics**

- No significant differences between the groups in baseline gender, age comorbidities and risk factors.

**Risk Factor Targeted**

- Blood pressure, lipid, A1C

**Intervention**

- Patients received a brochure explaining the relationship between heart disease and diabetes and were told about risk factors for heart disease in a brief, scripted discussion.
- Reminder card to take to their physician.
- 2<sup>nd</sup> copy of brochure and reminder card mailed 2 weeks following discharge.
- Telephone follow-up 2 weeks later.
- Monthly follow-up phone calls for the first 6 months.

**Results**

- BP >130/85 mm Hg:
  - Intervention Group: 38/71 (53.5%)
  - Control Group: 41/70 (58.6%)
- Triglycerides >400 mg/dL:
  - Intervention Group: 3/49 (6.1%)
  - Control Group: 2/46 (4.4%)
- LDL >100 mg/dL:
  - Intervention Group: 13/47 (27.7%)
  - Control Group: 11/45 (24.4%)

**Follow up at 6 Months**

- Made change to food, drugs, or exercise:
  - Intervention Group: 83% (92/111)
  - Control Group: 83% (91/109)
- p >0.05
<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heller 2016</td>
<td>cRCT</td>
<td>Inclusion criteria: Diagnosis of myocardial infarction or unstable angina before discharge. Base line characteristics: No significant differences between the groups in baseline gender, age comorbidities and risk factors. Behavior targeted: Diet, smoking.</td>
<td>Intervention (n=213): Received a letter written to the subject’s general practitioner regarding the benefits of aspirin and Bblocking drugs in secondary prevention, and the first of 3 mail-out packages to the subject that comprised of “Facts on Fat” kit, a walking program and information on the “Quit for Life” program for subjects who smoked and magnetic reminder sticker for walking. Each subject was given a specific target for fat reduction and letters of encouragement. Contact was maintained over 4 months. Two supplementary telephone calls were made.</td>
<td>Follow up at Six-Months: Exercise (3 times weekly) Intervention group 124/168 (61%) Control group 112/207 (67%) Mean fat score (SD) Intervention group 13.1 (6.5) Control group 15.3 (7.1) Current smoker: Intervention group 18/168 (11%) Control group 26/207 (13%) Mean blood cholesterol (SD) mmol/L Intervention group 5.73 (1.01) Control group 5.61 (0.98) Mean blood cholesterol (SD) mg/dL Intervention group 221.6 (39) Control group 216.9 (38)</td>
<td>All general practices within the study area were stratified according to the number of doctors within the practice group and randomly allocated to intervention or usual care within those strata. Intervention began within 1 week of hospital discharge. Self reported outcomes for fat intake and physical activity and quality of life. Cholesterol levels based on laboratory results. Theoretical Model: Not stated.</td>
</tr>
</tbody>
</table>

| Control group (n=156): No communication with patients and general practitioners. | | | | |

| Inclusion criteria: All subjects aged <70 years with a suspected heart attack. Exclusion Criteria: Patients with renal failure or other special dietary requirements and those considered by their physicians to have “endstage” heart disease. Base line characteristics: There were no significant differences in demographic characteristics, medical history or patterns of consumption of tobacco, alcohol and fat. Behavior targeted: Diet, smoking. | Outcomes assessed using self report: | Theoretical Model: No model stated. |

<p>| Intervention Delivered by Physician: | | | | |</p>
<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Lewin 387     | RCT        | All patients entering the coronary care unit at 2 hospitals | **Intervention group** (n=114) 30 minute advice on coronary heart disease and lifestyle modification and relaxation tape. Separate tape for the patients’ partner or carer. On the tape the advice was presented as a dialogue between a patient and a doctor | **Intervention group** 1.14 (0.41)  
**Control group** 1.10 (0.32)  
**Mean HDL cholesterol (SD) mg/dl**  
**Intervention group** 44.1 (16)  
**Control group** 42.5 (12)  
**Quality of life Emotional score**  
**Intervention group** (n=168) 5.40 ± 1.12  
**Control group** (n=207) 5.15 ± 1.24  
**Quality of life Physical score**  
**Intervention group** (n=168) 5.40 ± 1.21  
**Control group** (n=206) 5.22 ± 1.29  
**Quality of life Social score**  
**Intervention group** (n=168) 5.86 ± 1.10  
**Control group** (n=205) 5.75 ± 1.14  
**Follow up at Six-Months**  
**Return to work if previously employed**  
**Intervention group** 20 (56%)  
**Control group** 16 (47%)  
**Returned to work in same capacity**  
**Intervention group** 10 (50%)  
**Control group** 11 (79%)  
**Undertook vigorous activity at least once per week**  
**Intervention group** 38 (51%)  
**Control group** 43 (49%)  
**Tried to increase amount of exercise**  
**Intervention group** 58 (81%)  
**Control group** 53 (62%)  | Unclear  
Outcomes assessed using self reports QOL assessed using QLMI  
Patients asked not to discuss content of the tapes with other patients  
Anxiety and depression assessed using HAD scale  
Self reported outcomes  
**Theoretical Model**  
Not stated  

**Method of allocation** Predetermined  
**Inclusion criteria**  
**Exclusion criteria**  
**Base line characteristics** No significant differences between the two groups  
**Behaviour targeted** Smoking, physical activity, diet  

**Control Group** (n=129) Patients given a music tape opera, classical, folk, pop and
<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Study Type</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>rock music. Patients were told that they could exchange their chosen tape for another music</td>
<td>Current smoker</td>
<td>Intervention Delivered by Nurse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention group</td>
<td>15 (16%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>17 (18%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seriously tried to give up smoking</td>
<td>Intervention group</td>
<td>28 (30%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>34 (36%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seriously tried to lose weight</td>
<td>Intervention group</td>
<td>59 (80%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>65 (76%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Psychological outcomes at 6 months</td>
<td>Anxiety Mean (SD)</td>
<td>Intervention group</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>6.6 (4.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Depression Mean (SD)</td>
<td>Intervention group</td>
<td>3.7 (3.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>4.1 (3.4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac misconceptions Mean (SD)</td>
<td>Intervention group</td>
<td>71 (17)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>59 (18)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Quality of life: total Mean (SD)</td>
<td>Intervention group</td>
<td>144 (27)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>137 (33)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Quality of life: emotional Mean (SD)</td>
<td>Intervention group</td>
<td>5.5 (3.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>5.2 (1.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Quality of life: physical Mean (SD)</td>
<td>Intervention group</td>
<td>5.2 (1.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>4.9 (1.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Quality of life: social Mean (SD)</td>
<td>Intervention group</td>
<td>5.5 (1.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Control group</td>
<td>5.3 (1.4)</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>Mahler 388  USA</td>
<td>RCT</td>
<td>Hospital Two hundred sixteen male and female CABG patients</td>
<td><strong>Intervention group A</strong> <em>(n=unclear)</em>  Received a mastery tape designed to provide information and was supplemented by patient narration of the descriptions of their experiences. The Mastery tape was made to depict these patients as calm and confident at the time of release,  <strong>Intervention group B</strong> <em>(n=unclear)</em>  Received Coping tape which had the same information as the mastery tape but patients expressed concerns about hospital release,  <strong>Control group</strong> <em>(n=unclear)</em>  Standard hospital information at discharge</td>
<td>Follow-up at 1 month  <strong>Self efficacy for diet</strong>  Intervention group A 4.54 (0.43)  Intervention group B 4.43 (0.58)  Control group 4.27 (0.62)  <strong>Self efficacy for exercise</strong>  Intervention group A 4.45 (0.56)  Intervention group B 4.38 (0.64)  Control group 4.27 (0.64)  <strong>Diet habits</strong>  Intervention group A 74.27 (10.47)  Intervention group B 72.99 (10.13)  Control group 70.70 (9.55)</td>
<td>Anxiety measured using the Positive and Negative Affect Schedule (PANAS).  <strong>Diet Compliance.</strong> Measured using the cholesterol-saturated fat subscale of the Diet Habit Survey (DHS)  <strong>Theoretical Model</strong> No model stated  <strong>Intervention Delivered by</strong> Unclear</td>
</tr>
<tr>
<td>Southard 247  USA</td>
<td>RCT</td>
<td>104 subjects with CVD, Approval of the primary care physician, cardiologist, or both, access to the Internet. Diagnosed coronary heart disease</td>
<td><strong>Intervention group (n=53)</strong>  Participants had to use the computer at least once a week for 30 minutes, completing education modules and communicating with a case manager. Participants had online discussion group and links to related sites on the Internet. Small rewards valued at $0.50 to $1.50 were given for active participation.</td>
<td>Follow up at 6 months  <strong>SBP, mm Hg</strong>  Control group 130.9 (19.8)  Intervention group 130.1 (17.5)  <strong>DBP, mm Hg</strong>  Control group 2.1 (9.2)  Intervention group 73.9 (10.0)  <strong>Weight, lbs</strong>  Control group 196.2 (32.8)  Intervention group 203.6 (50.2)  <strong>Body mass index, kg/m2</strong>  Control group 29.2 (4.8)  Intervention group 31.1 (6.8)</td>
<td>Quality of Life assessed using the Dartmouth COOP.  Dietary survey done using MEDFICTS  <strong>Theoretical Model</strong> No model stated  <strong>Intervention Delivered by</strong> Case manager and dietitian</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Behaviour targeted</td>
<td>Participants had access to a registered dietitian</td>
<td>Total cholesterol, mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diet, weight, blood pressure</td>
<td>Control group (n=51) Not stated</td>
<td>Control group 182.6 (35.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention group 183.8 (43.1)</td>
<td>Low-density lipoprotein, mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 108.6 (25.4)</td>
<td>Intervention group 110.9 (36.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 41.5 (11.7)</td>
<td>Intervention group 39.8 (11.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Triglycerides, mg/dL</td>
<td>Control group 160.8 (105.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low-density lipoprotein</td>
<td>Intervention group 186.4 (122.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Smoking</td>
<td>Control group 5.9% (n=3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Minutes of weekly exercise</td>
<td>Intervention group 7.5% (n=4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 142.39 (127.96)</td>
<td>MINUTES OF WEEKLY EXERCISE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention group 45.06 (118.10)</td>
<td>MEDFICTS Score (Diet)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 32.47 (30.00)</td>
<td>Quality of Life (Dartmouth COOP Score) at 6 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention group 40.47 (31.92)</td>
<td>Fitness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 2.73 (1.13)</td>
<td>Control group 2.70 (1.26)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention group 2.06 (1.03)</td>
<td>Feelings</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 1.86 (1.04)</td>
<td>Control group 1.98 (0.99)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention group 2.11 (1.09)</td>
<td>Intervention group 2.06 (1.03)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Social activities</td>
<td>Daily activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Control group 1.65 (1.04)</td>
<td>Control group 1.86 (1.04)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention group 1.72 (0.99)</td>
<td>Intervention group 2.11 (1.09)</td>
<td></td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>Vale^99</td>
<td>RCT</td>
<td>Six university teaching hospitals 792 patients</td>
<td>Intervention group (n=398) Patients and medical care giver received information on lipid and other coronary risk-factor levels and a 1-page chart of risk factor targets for the secondary prevention of CHD. Coaching sessions were delivered by telephone in 5 sessions over 6 months. Control group (n=394) A 1-page chart of risk factors was mailed with the</td>
<td>6 month follow up Mean reduction in Total cholesterol from baseline to 6 months Intervention group 0.54 mmol/L Control group 0.18 mmol/L p&lt;.0001 More patients in the intervention were taking lipid-lowering drugs at 6 months than those in the usual care group (p=.002). Mean reduction in Triglyceride from baseline to 6 months Intervention group 0.17 mmol/L Control group 0.14 mmol/L p=0.76</td>
<td>Intervention Delivered by Two dieticians and 4 nurses. Part-time training program for 2 weeks provided for coaches Trained by one of the dieticians and the head coach. Median duration of coaching 30 minutes Smoking cessation was by self reports. Theoretical Model</td>
</tr>
<tr>
<td>Author/Country</td>
<td>Study Type</td>
<td>Participants</td>
<td>Intervention</td>
<td>Results</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>involving lipids; lived too far from, or were unwilling to travel to the hospital for follow-up visits; were too ill to be interviewed; would not provide signed consent</td>
<td>discharge summary to the usual medical care giver. Patients were contacted only once after discharge, at 24 weeks, to arrange a follow-up assessment.</td>
<td><strong>Mean increase in HDLc from baseline to 6 months</strong></td>
<td><strong>No model stated</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline characteristics</td>
<td>No significant difference in baseline characteristics. Age Intervention: 58.6 years Usual care: 58.3 years</td>
<td><strong>Intervention group</strong> 0.08 mmol/L <strong>Control group</strong> 0.10 mmol/L <strong>p=0.76</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Mean reduction in body weight from baseline to 6 months</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Intervention group</strong> 1.3 kg <strong>Control group</strong> 0.4 kg mmol/L <strong>p&lt;0.001</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Mean reduction in BMI from baseline to 6 months</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Intervention group</strong> 0.05 kg <strong>Control group</strong> 0.1 mmol/L <strong>p=0.001</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Mean reduction in BGL from baseline to 6 months</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Intervention group</strong> 0.2 mmol/L <strong>Control group</strong> 0.2 mmol/L <strong>p=0.76</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Mean reduction in Total fat from baseline to 6 months</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Intervention group</strong> 15.3 g <strong>Control group</strong> 10.5g mmol/L <strong>p=0.04</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Smoking cessation</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Intervention group</strong> 53/106 <strong>Control group</strong> 41/97 <strong>p=0.27</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Taken up walking</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Intervention group</strong> 120/173 <strong>Control group</strong> 64/147 <strong>p&lt;0.001</strong></td>
<td></td>
</tr>
</tbody>
</table>
PARTICIPANT INFORMATION SHEET

Implementation of evidence based guidelines for preventing cardiovascular events in patients with Coronary Heart Disease

Dear (Participant name)

The Centre for Applied Nursing Research in collaboration with the National Heart Foundation of Australia (NSW Division) are currently undertaking a project that aims to determine the facilitators and barriers to the implementation of the guidelines titled “Reducing Risk in heart disease 2004”. This project will be conducted by a telephone interview of Cardiac Rehabilitation Coordinators across NSW. Coordinators will be asked questions relating to their programs, including content and information such as attendance, referral procedures and patterns.

As a clinical expert in the field of cardiac rehabilitation, you have been randomly selected to provide a professional perspective on the implementation of the evidence based guidelines in your centre. If you agree to take part in this study you will be asked to participate in a telephone interview. The interview will be held at a mutually convenient time and will last for approximately 90 minutes. An audio-recording of the discussion will be made and notes taken during the discussion to allow the researcher to have a concise record of the conversation for later analysis.

All participants will be allocated a unique code number that will be used only to monitor the response rate. All information will be stored securely in locked archive facilities and destroyed at the end of the NHMRC recommended period of data retention. No individual staff members will be identified in reports or publications. Participation is voluntary and, should you decide to withdraw at any time, your decision will be respected. This study has been approved as a Research Project by the SSWAHS --(Western Zone) Ethics Review Committee.

We hope you will participate in this study. If you have any further questions, please contact Ritin Fernandez 9828 6589. Results from this project will inform the development of an evidence based strategy for risk factor modification in patients with acute coronary syndrome. We hope you will agree to participate.

Yours sincerely
Ritin Fernandez

Date: 27th June 2005
Ms Ritin Fernandez  
CANRE  
Liverpool Health Service  
Locked Bag 7103  
LIVERPOOL BC 1871  

Dear Ms Fernandez,  

Project No 2005/056 - Implementation of Evidence Based Guidelines for Preventing Cardiovascular Events in Patients with Coronary Heart Disease  

The SSWAHS Human Research Ethics Committee wishes to acknowledge receipt of your correspondence with regards to the above project.  

As all of the issues raised by the Committee have now been satisfactorily addressed, formal approval is hereby granted for this study to proceed as a Category A Project.  

Ethics clearance is granted for periods of up to twelve months. This project will be due for renewal on 31st May, 2006 and you must provide a Progress Report (attached) or final report by this date. If no report is supplied, ethics clearance for this project may be cancelled.  

Your attention is drawn to the attached document Guidelines for Investigators which sets out not only the principles under which research should be conducted, but also the conditions under which Ethics approval is granted by the Committee. Also enclosed for your information, is a copy of the document Guidelines for Responsible Practice in Research and Dealing with Problems of Research Misconduct.  

Please note that the Committee must be notified IMMEDIATELY of any untoward or unexpected complications or side affects arising during the project or of any ethical or medico-legal problems that may arise. Also, any changes to the original protocol must be submitted to the Committee for approval.  

Would you please quote the above project number in all future correspondence relating to this project.  

Yours sincerely,  

PROFESSOR HUGH DICKSON  
Chairperson  
SSWAHS Research Ethics Committee  

For: Dr Diana Horvath, AO  
Chief Executive, SSWAHS  

Category A: Projects with limited risk potential, including quality assurance surveys.  
Category B: Projects with significant patient risks.  
Category C: Drug trials (international/national) sponsored by drug companies and already covered for risk evaluation and monitoring of adverse reactions.
PARTICIPANT CONSENT FORM

Implementation of evidence based guidelines for preventing cardiovascular events in patients with Coronary Heart Disease

1. I, ........................................................................................................... of ..................................................

..........................................................................................................., aged ........................................ years,
agree to participate as a subject in the study described in the subject information statement set out above (or: attached to this form).

2. I acknowledge that I have read the Subject Information Statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this Consent Form, I have been given the opportunity to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation. I have received satisfactory answers to any questions that I have asked.

4. My decision whether or not to participate will not prejudice my present or future employment or my relationship with South Western Sydney Area Health Service or any other institution cooperating in this study or any person treating me. If I decide to participate, I am free to withdraw my consent and to discontinue my participation at any time without prejudice.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact the study researcher Ms Ritin Fernandez on telephone (02) 98286589, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Subject Information Statement.

Complaints may be directed to the Ethics Secretariat, South Western Sydney Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 5727, fax 9828 5962, email jennie.grech@swsahs.nsw.gov.au).

Signature of subject __________________________  Signature of witness __________________________

Please PRINT name __________________________  Please PRINT name __________________________

Date __________________________  Date __________________________

Signature(s) of investigator(s) __________________________

Please PRINT Name RITIN FERNANDEZ

Date: 12/05/2005
I am now going to ask you some questions about smoking cessation in your CR program

a. What strategies do you have in place to address smoking cessation in your rehabilitation program?

b. How would you rate the process you have in place relating to the following?

<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encouraging patients to stop smoking</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Encouraging family to stop smoking</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Providing smokers and passive smokers with facts on smoking</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Referral to quit line</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Pharmacotherapy for those smoking &gt;10 cigarettes/day</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Advice on GP visit for Nicotine replacement therapy</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>
Behavioural and psychosocial support

<table>
<thead>
<tr>
<th>Smoking</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>stop smoking</td>
<td>☐1</td>
<td>☐2</td>
</tr>
<tr>
<td>maintain nonsmoking status</td>
<td>☐1</td>
<td>☐2</td>
</tr>
<tr>
<td>strengthen their intention to stop smoking</td>
<td>☐1</td>
<td>☐2</td>
</tr>
<tr>
<td>are more confident about stopping smoking</td>
<td>☐1</td>
<td>☐2</td>
</tr>
<tr>
<td>are more confident about maintaining nonsmoking status</td>
<td>☐1</td>
<td>☐2</td>
</tr>
<tr>
<td>are taking active steps to stop smoking</td>
<td>☐1</td>
<td>☐2</td>
</tr>
</tbody>
</table>

Use the following prompts to elicit more information about smoking assessment

Smoking

Does your program monitor the number (%) of smokers who

- stop smoking
- maintain nonsmoking status
- strengthen their intention to stop smoking
- are more confident about stopping smoking
- are more confident about maintaining nonsmoking status
- are taking active steps to stop smoking

c) In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

d) If you were given all the resources what strategies would you put in place to address smoking cessation?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

2) NUTRITION

I am now going to ask you some questions about nutrition in your CR program

a. What strategies do you have in place to address nutritional needs in your rehabilitation program?

________________________________________________________________________

b. How would you rate the process you have in place relating to the following?
<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encourage patients to choose healthy foods</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Referring patients to a dietician</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

*Use the following prompts to elicit more information*

**Dietary habits**

- Does your program monitor the number (%) of patients whose dietary habits are assessed?
  - Yes □1  No □2
- Consume less saturated fat
  - Yes □1  No □2
- Overweight or obese patients who reduce their total daily caloric intake
  - Yes □1  No □2
- Strengthen their intention to change their dietary habits
  - Yes □1  No □2
- Who are more confident about changing/maintaining improved dietary habits
  - Yes □1  No □2
- Taking active steps to change their dietary habits
  - Yes □1  No □2

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

d) If you were given all the resources what strategies would you put in place to address dietary habits?

________________________________________

________________________________________

**ALCOHOL**

*I am now going to ask you some questions about alcohol consumption management in your CR program*

a. What strategies do you have in place to address alcohol consumption in your rehabilitation program?

________________________________________

b. How would you rate the process you have in place relating to the following?
Assess patient medications for potential interactions with alcohol and advise as appropriate

Encourage patients with hypertension who drink alcohol to limit intake to 2 or less standard drinks per day

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

d) If you were given all the resources what strategies would you put in place to address alcohol problems?

3) PHYSICAL ACTIVITY

I am now going to ask you some questions about physical activity in your CR program

a. What strategies do you have in place to address physical activity in your rehabilitation program?

b. How would you rate the process you have in place relating to the following?

<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess patients physical activity habits</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Discuss physical activity needs/ capabilities/ barriers</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Discuss and provide written guidelines for everyday physical activity tasks</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Monitor progress /response to physical activity</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>
Use the following prompts to elicit more information

Physical activity

Does your program monitor the number (%) of patients

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>whose level of physical activity is assessed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>who walk or who are physically active 30 minutes daily or on most days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>who are more confident about increasing their level of physical activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>who are more confident about maintaining their level of physical activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>taking active steps to increase their physical activity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

_________________________________________________

_________________________________________________

_________________________________________________

_________________________________________________

_________________________________________________

d) If you were given all the resources what strategies would you put in place to address physical inactivity?

_________________________________________________

_________________________________________________

_________________________________________________

_________________________________________________

_________________________________________________

4) WEIGHT MANAGEMENT

I am now going to ask you some questions about weight management in your CR program

a. What strategies do you have in place to address weight management in your rehabilitation program?

_________________________________________________

_________________________________________________

_________________________________________________
b. How would you rate the process you have in place relating to the following?

<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess and monitor both waist circumference and Body mass index</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Set intermediate achievable goals</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Encourage healthy eating and physical activity</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

*Use the following prompts to elicit more information*

**Body weight**
- Does your program monitor the number (%) of patients who know their weight: Yes □1 No □2
- whose weight is measured: Yes □1 No □2
- obese or overweight who reduce their weight by >2 kgs: Yes □1 No □2
- who strengthen their intention to lose weight: Yes □1 No □2
- who are more confident about losing weight: Yes □1 No □2
- who are more confident about maintaining weight loss: Yes □1 No □2
- overweight patients taking active steps to reduce weight: Yes □1 No □2
- who strengthen their intention to lose weight: Yes □1 No □2

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

d) If you were given all the resources what strategies would you put in place to address weight management?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
5) LIPID MANAGEMENT

I am now going to ask you some questions about lipid management in your CR program

a. What strategies do you have in place to address lipid management in your rehabilitation program?

b. How would you rate your services relating to the following?

<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy eating advice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral to GP for statin therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral to dietician</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Use the following prompts to elicit more information

Cholesterol  Does your program monitor the number (%) of patients

- who know their total cholesterol level
- whose cholesterol is measured by the GP or program staff
- with high cholesterol on cholesterol lowering diet
- with high cholesterol on medication

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

d) If you were given all the resources what strategies would you put in place to address lipid management?
6) BLOOD PRESSURE

I am now going to ask you some questions about blood pressure management in your CR program

a. What strategies do you have in place to address blood pressure problems in your rehabilitation program?

b. How would you rate the process you have in place relating to the following?

<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral to GP for 24 hour urinary protein</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Referral to specialist</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

Use the following prompts to elicit more information

Blood pressure

Does your program monitor the number (%) of patients

- who know their blood pressure Yes □1 No □2
- whose blood pressure is measured Yes □1 No □2
- with high blood pressure on medication Yes □1 No □2
- with high blood pressure whose blood pressure is reduced Yes □1 No □2

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?

d) If you were given all the resources what strategies would you put in place to address blood pressure management?
7) DIABETES

I am now going to ask you some questions about diabetes management in your CR program

a. What strategies do you have in place to address diabetes in your rehabilitation program?

b. How would you rate your services relating to the following?

<table>
<thead>
<tr>
<th>Area</th>
<th>V. Poor</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening for diabetes</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>Referral to GP</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

In your opinion as a CR coordinator what do you perceive are the barriers to implementation of the recommendations?


d) If you were given all the resources what strategies would you put in place to address diabetes management?


8) WORK (PAID EMPLOYMENT)

I am now going to ask you some questions about working status of the patients in your CR program

Does your program monitor the number (%) of patients

- formerly in the workforce who resume work Yes □1 No □2
- formerly in the workforce who resume within 3 months of the event Yes □1 No □2
- with work difficulties who receive additional assistance from occupational therapist and/or receive a work visit after resuming work Yes □1 No □2
- working at one year Yes □1 No □2
- reporting satisfactory occupational adaptation at work Yes □1 No □2
11) PHARMACOLOGICAL MANAGEMENT

I am now going to ask you some questions about pharmacological management in your CR program

1. Antiplatelet therapy is recommended for patients with ACS. Do you think that patients are receiving this treatment? If not what are some of the reasons why they do not receive this treatment?

Comment

2. Following stent implantation Clopidogrel has been recommended, do you think patients are receiving this treatment. If not why not?

Comment

3. Are patients who have had myocardial infarction treated with ACE Inhibitors? If not why not?

Comment

4. Are beta-blockers used as recommended in patients following ACS?

Comment

5. Is statin therapy commenced for patients following ACS?

Comment

6. In your opinion as a CR coordinator what do you perceive are the barriers to implementation of these recommendations?
12) NON PHARMACOLOGICAL MANAGEMENT

I am now going to ask you some questions about non pharmacological management in your CR program

- a. Secondary prevention/ Cardiac rehabilitation (Send Questionnaire)
- b. Chest pain action Plan Are patients given written action plans to follow in the event of chest pain?

Comment

Are patients given advice on use of antianginal medication and emergency action if chest pain is not completely relieved in 10-15 minutes

13) PSYCHOSOCIAL FACTORS AND ASSESSMENT

I am now going to ask you some questions about assessment of psychosocial factors in your CR program

a. Are all patients assessed for co morbid depression? If yes what instrument is used to diagnose depression?

b. If depression is diagnosed what support is provided?

c. Do you provide/ refer elsewhere for cognitive behavioural therapy for management of depression?

d. Do you assess all patients for level of social support and provide follow-up for those considered at risk?
### Implementation of evidence based guidelines for preventing cardiovascular events in patients with Coronary Heart Disease

Please answer all questions. Most questions require you to tick a box to indicate your answer. Choose the box that best matches your answer.

<table>
<thead>
<tr>
<th>These first questions ask general information about your program</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Name of your cardiac rehabilitation Centre</td>
</tr>
<tr>
<td>2. In what year(s) did your program(s) begin?</td>
</tr>
<tr>
<td>Name of Program</td>
</tr>
<tr>
<td>Name of Program</td>
</tr>
<tr>
<td>3. Where is your outpatient program located? (You can tick more than one if necessary)</td>
</tr>
<tr>
<td>1. Hospital</td>
</tr>
<tr>
<td>2. Physician office or medical clinic</td>
</tr>
<tr>
<td>3. School or college</td>
</tr>
<tr>
<td>4. Fitness facility</td>
</tr>
<tr>
<td>4. Is the coordinator of your CR program a?</td>
</tr>
<tr>
<td>1. Registered Nurse</td>
</tr>
<tr>
<td>2. Enrolled Nurse</td>
</tr>
<tr>
<td>3. Assistant in Nursing</td>
</tr>
<tr>
<td>4. Exercise Physiologist</td>
</tr>
<tr>
<td>5. Physiotherapist</td>
</tr>
<tr>
<td>11. Others (please state)</td>
</tr>
</tbody>
</table>
5. How long have you been the coordinator of the CR program? ___________ months

6. What is the staff profile of your cardiac rehabilitation program? (Please answer by recording the number of FTE’S (Full time equivalents)

   **Example**  
   2 full time nurses at 40 hours per week = 2.00 FTE
   1 part time nutritionist at 20 hours per week = 0.50 FTE

<table>
<thead>
<tr>
<th>Number</th>
<th>Role</th>
<th>FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Registered Nurse</td>
<td>FTE</td>
</tr>
<tr>
<td>2</td>
<td>Enrolled Nurse</td>
<td>FTE</td>
</tr>
<tr>
<td>3</td>
<td>Assistant in Nursing</td>
<td>FTE</td>
</tr>
<tr>
<td>4</td>
<td>Exercise Physiologist</td>
<td>FTE</td>
</tr>
<tr>
<td>5</td>
<td>Physiotherapist</td>
<td>FTE</td>
</tr>
<tr>
<td>6</td>
<td>Occupational Therapist</td>
<td>FTE</td>
</tr>
<tr>
<td>7</td>
<td>Dietician</td>
<td>FTE</td>
</tr>
<tr>
<td>8</td>
<td>Social Worker</td>
<td>FTE</td>
</tr>
<tr>
<td>9</td>
<td>Student (please specify)</td>
<td>FTE</td>
</tr>
<tr>
<td>10</td>
<td>Pharmacist</td>
<td>FTE</td>
</tr>
<tr>
<td>11</td>
<td>Cardiologist</td>
<td>FTE</td>
</tr>
<tr>
<td>12</td>
<td>General practitioner</td>
<td>FTE</td>
</tr>
<tr>
<td>13</td>
<td>Psychologist</td>
<td>FTE</td>
</tr>
<tr>
<td>14</td>
<td>Other (please list)</td>
<td>FTE</td>
</tr>
</tbody>
</table>

7. How many days per week do you offer CR services? ___________ day/s per week

8. Are your classes conducted in (please tick more than one if required)

<table>
<thead>
<tr>
<th>Number</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mornings</td>
</tr>
<tr>
<td>2</td>
<td>Afternoons</td>
</tr>
<tr>
<td>3</td>
<td>Evening</td>
</tr>
<tr>
<td>6</td>
<td>Weekends</td>
</tr>
<tr>
<td>7</td>
<td>Other (please list)</td>
</tr>
</tbody>
</table>
### The next few questions asks about attendance at your Cardiac rehabilitation programs

9. During 2004 how many patients that attending your cardiac rehabilitation program were

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>------------------</td>
</tr>
<tr>
<td>Female</td>
<td>------------------</td>
</tr>
</tbody>
</table>

10. During 2004 how many of the participants enrolled following

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction (MI)</td>
<td>--------------------</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>--------------------</td>
</tr>
<tr>
<td>Coronary Artery Bypass Graft</td>
<td>--------------------</td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention without MI</td>
<td></td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention following MI</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>--------------------</td>
</tr>
<tr>
<td>Others (please list)</td>
<td>--------------------</td>
</tr>
</tbody>
</table>

11. During 2004 how many participants attended following

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction (MI)</td>
<td>--------------------</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>--------------------</td>
</tr>
<tr>
<td>Coronary Artery Bypass Graft</td>
<td>--------------------</td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention without MI</td>
<td></td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention following MI</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>--------------------</td>
</tr>
<tr>
<td>Others (please list)</td>
<td>--------------------</td>
</tr>
</tbody>
</table>

12. During 2004 how many participants with the following diagnosis completed the program

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction (MI)</td>
<td>--------------------</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>--------------------</td>
</tr>
<tr>
<td>Coronary Artery Bypass Graft</td>
<td>--------------------</td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention without MI</td>
<td></td>
</tr>
<tr>
<td>Percutaneous Coronary Intervention following MI</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>--------------------</td>
</tr>
<tr>
<td>Others (please list)</td>
<td>--------------------</td>
</tr>
</tbody>
</table>

### The next few questions ask about referral patterns to outpatient cardiac rehabilitation
13. Are all patients who have experienced a cardiac event informed of the CR program?

☐ 1. Yes  ☐ 2. No  ☐ 3. Unsure

14. Who refers patients to the cardiac rehabilitation program? (You can tick more than one)

☐ 1. Nurse on the ward  ☐ 4. Cardiologist
☐ 2. Clinical Nurse Consultant  ☐ 5. General Physician
☐ 3. Cardiac rehabilitation nurse  ☐ 6. Other (please list) _______________

15. Is there a waiting list for enrolment into the CR program?

☐ 1. Yes  ☐ 2. No

16. If yes what was the longest a patient had to wait before participating in the program?

______________ days/weeks/months patients

17. Do you refer patients to an alternative Cardiac Rehabilitation program because of the waiting list?

☐ 1. Yes  ☐ 2. No

18. These are some of the barriers to referral to outpatient cardiac rehabilitation programs. Please indicate how much you agree with each of the reasons (Please tick one box only for each line)

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Absence of a local program</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>b. Failure of attendant doctors to consider</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>c. Lack of clinician awareness of program</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>d. Absence of a dedicated program</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>e. Insufficient time to arrange referrals</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>f. Unfamiliarity of clinicians and hospital</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>g. Distance transport problems</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>h. Other</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
</tbody>
</table>
19. These are some of the reasons why people do not attend an outpatient cardiac rehabilitation program. Please indicate how much you agree with each of the reasons *(Please tick one box only for each line)*

<table>
<thead>
<tr>
<th>Reason</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Not informed about the rehab program</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>b. Long waiting list for rehab program</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>c. Not contacted by rehab staff</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>d. Lack of support / referral from doctor</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>e. Doctor said it was unnecessary</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>f. Personally thought it was unnecessary</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>g. Too far from home</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>h. Do not have time</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>i. Rehab class time is not suitable</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>j. Lack of family support</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>k. Lack of motivation</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>l. Fear of further pain</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>m. Language difficulties</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>n. Conflict with work</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>o. Do not like group activities</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
<tr>
<td>Others (Please specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

You have finished!

THANK YOU VERY MUCH FOR PARTICIPATING IN THIS SURVEY.
Please return the questionnaire as soon as possible.

If you have any questions, please contact

Ms Ritin Fernandez  
South Western Sydney Centre for Applied Nursing Research  
Locked Bag 7103  
LIVERPOOL BC 1871  
telephone: (02) 9828 6538  
email: ritin.fernandez@swsahs.nsw.gov.au
Appendix 14  Self administered Angioplasty Questionnaire

Follow-up (12-18 months) of patients discharged after Percutaneous Coronary Intervention (Angioplasty)

Please answer all questions. Most questions require you to tick a box(es) to indicate your answer. Choose the box(es) that best matches your answer.

Section A: These first questions ask general information about yourself and your household.
You may choose not to answer them.

1. Are you? Female ☐1, Male ☐2

2. How old are you? _______________ years

3. How tall are you? _______________ cms / feet / inches

4. How much do you weigh? _______________ kg / stone / pounds

5. How many dependant children do you have? _______________

6. What is your highest level of education? (Please tick one box only)

☐1. Did not complete primary school
☐2. Completed primary school only
☐3. Left high school before intermediate or school certificate
☐4. Intermediate or School Certificate (Year 10)
☐5. Leaving or High School Certificate (Year 11/12)
☐6. Apprenticeship / Trade Qualification
☐7. University Degree
☐8. Other (Please specify) __________________________________________________________

7. What is your marital status? (Please tick one box only) ☐1. Married / De-facto → Please go to Q8

☐2. Single / Divorced
☐3. Widowed

8. Is your spouse/partner employed? (Please tick one box only)

☐1. Employed full-time
☐2. Employed part-time / casual
☐3. Unemployed

The next question asks you about your household income. You may choose not to answer it.
9. How much is your household total annual income, roughly? *(Please tick one box only)*

- [ ] 1. Nil - $9,999 per year
- [ ] 2. $10,000 - $19,999 per year
- [ ] 3. $20,000 - $49,999 per year
- [ ] 4. $50,000 - $79,999 per year
- [ ] 5. $80,000 - $99,999 per year
- [ ] 6. $100,000 or over per year

**Section B:** The following questions relate to your occupation.

10. At the time of your angioplasty, what was your occupation? *(Please tick one box only)*

- [ ] 1. Retired → Please go to Q14
- [ ] 2. Unemployed → Please go to Q11
- [ ] 3. Manager / Administrator
- [ ] 4. Professional
- [ ] 5. Trade person
- [ ] 6. Clerk / Public servant
- [ ] 7. Labourer or related worker
- [ ] 8. Plant and machine operator / driver
- [ ] 9. Volunteer worker
- [ ] 10. Student
- [ ] 11. Others (Please specify) ________________________________________________

11. Could you please tell us why you were unemployed at the time of your angioplasty?

*(Please tick all that apply)*

- [ ] a. Redundancy
- [ ] b. Unable to find work
- [ ] c. Poor health
- [ ] d. Others (Please specify) ________________________________________________
12. What is your current occupation?  *(Please tick one box only)*

- [ ] 1 Retired
- [ ] 2 Unemployed
- [ ] 3 Manager / Administrator
- [ ] 4 Professional
- [ ] 5 Trade person
- [ ] 6 Clerk / Public servant
- [ ] 7 Labourer or related worker
- [ ] 8 Plant and machine operator / driver
- [ ] 9 Volunteer worker
- [ ] 10 Student
- [ ] 11 Others *(Please specify)*  
  _______________________________________________________

*Please go to Q14*

*Please go to Q13*

13. How many hours per week are you currently working?  

_______________ hrs/week

Section C: The next few questions ask about your general health and medications

14. Do you have any of the following health problems?  *(Please tick all that apply)*

- [ ] a Diabetes
- [ ] b Over weight / Obesity
- [ ] c Asthma
- [ ] d Other chronic lung diseases
- [ ] e High blood pressure
- [ ] f High blood cholesterol
- [ ] g Heart problems
- [ ] h Stroke / Cerebro-vascular accident
- [ ] i Depression / Anxiety
- [ ] j Kidney problems
- [ ] k Back problems
- [ ] l Cancer
- [ ] m Others *(Please specify)*  
  _______________________________________________________

15. Are you taking any medications for the following reasons?  *(Please tick all that apply)*

- [ ] a For diabetes
- [ ] b For a heart condition (e.g Digoxin)
- [ ] c For breathing difficulties
- [ ] d For depression / Anxiety
- [ ] e For pain relief
- [ ] f To control body weight
- [ ] g To control blood cholesterol
- [ ] h To control blood pressure
- [ ] i To prevent blood clots (e.g Aspirin)
- [ ] j To quit smoking (e.g Nicorette gum)
- [ ] k Others *(Please specify)*  
  _______________________________________________________
16. Are there any medications you are taking but unsure what they are for?

   Yes ☐ 1          No ☐ 2

If Yes, please list them __________________________________________________________

17. People often have difficulties taking their tablets for one reason or another. We are trying to learn more about these experiences.

   a. Do you regularly miss taking your medications? ................................. Yes ☐ 1  No ☐ 2
   b. Have you missed any of your medications in the last week for any reasons? ................................................................. Yes ☐ 1  No ☐ 2
   c. If Yes, How many tablets have you missed? _________ Or Do not know / remember ☐ 999
   d. Do you sometimes stop taking medications if you feel better? .......... Yes ☐ 1  No ☐ 2
   e. Do you sometimes stop taking medications if you feel worse? .......... Yes ☐ 1  No ☐ 2
   f. Do you sometimes stop taking a medication when going out, thinking it may interfere with what you are doing? ........................................ Yes ☐ 1  No ☐ 2
   g. Do you keep medications in the original containers? ......................... Yes ☐ 1  No ☐ 2
   h. Do you keep all medications in one container? ................................. Yes ☐ 1  No ☐ 2
   i. Do you use anything that helps organise your medications? .............. Yes ☐ 1  No ☐ 2
   j. If Yes, please list them ________________________________________________
   k. Do you have any special systems to remind you to take medications? Yes ☐ 1  No ☐ 2
   l. If Yes, please list them ________________________________________________

Section D: The next few questions ask about your chest pain

18. Over the past 4 weeks, on average, how often have you had to take nitros (e.g. nitroglycerin spray or anginine tablets) for your chest pain, chest tightness (angina)?

   (Please tick one box only)

   ☐ 1  None over the past 4 weeks
   ☐ 2  Less than once a week
   ☐ 3  1-2 times per week
   ☐ 4  3 or more times per week
   ☐ 5  1- 3 times per day
   ☐ 6  4 or more times per day
19. How bothersome is it for you to take your pills for chest pain, chest tightness, or angina as prescribed? (Please tick one box only)

☐ 1. Very bothersome
☐ 2. Moderately bothersome
☐ 3. Somewhat bothersome
☐ 4. A little bothersome
☐ 5. Not bothersome at all
☐ 6. My doctor has not prescribed any pills

Section E: The next questions relate to the angioplasty procedure

20. How was your angioplasty procedure organised? (Please tick one box only)

☐ 1. Planned in advance (Elective)
☐ 2. Performed following a heart attack (Rescue)
☐ 3. Performed after being admitted to hospital
☐ 4. Others (Please specify) __________________________________________________________

21. Who explained the procedure to you before your angioplasty? (Please tick all that apply)

☐ a. No-one
☐ b. Family doctor / GP
☐ c. Nurse
☐ d. Doctor on ward
☐ e. Cardiologist (heart doctor)
☐ f. Spouse / Partner
☐ g. Child
☐ h. Cannot remember
☐ i. Others (Please specify) __________________________________________________________
22. Were you given adequate explanation about
   a. Why angioplasty was being recommended? .............. Yes □ 1  No □ 2  I did not want to know □ 3
   b. What alternative treatments were available? .......... Yes □ 1  No □ 2  I did not want to know □ 3
   c. How the procedure works? ................................ Yes □ 1  No □ 2  I did not want to know □ 3
   d. Sedation / anaesthetic choices? ......................... Yes □ 1  No □ 2  I did not want to know □ 3
   e. Pain? .......................................................... Yes □ 1  No □ 2  I did not want to know □ 3
   f. What you can do after the procedure? ................. Yes □ 1  No □ 2  I did not want to know □ 3
   g. The expected results of the procedure? ............... Yes □ 1  No □ 2  I did not want to know □ 3
   h. Possible complications during and after the procedure? Yes □ 1  No □ 2  I did not want to know □ 3

23. Were you given the following before the procedure? (Please tick all that apply)
   □ a  A pink/yellow booklet called Coronary Artery Disease and Angioplasty
   □ b  Other printed materials such as brochures, booklets, flyers
   □ c  Visual materials such as videotapes, CDs, DVDs
   □ d  Website referral
   □ e  Others (Please specify) ................................................

24. Were issues about coronary artery / heart diseases discussed with you?
    Yes □ 1  No □ 2

25. Were issues about heart disease management discussed with you?
    Yes □ 1  No □ 2

26. How well prepared did you feel before undergoing the angioplasty? (Please tick one box only)
    □ 1  Completely  □ 2  Somewhat  □ 3  Not at all  □ 4  Cannot remember

27. Did the procedure go as you had expected? (Please tick one box only)
    □ 1  Completely  □ 2  Somewhat  □ 3  Not at all  □ 4  Cannot remember

28. Were you given written instructions after discharge from hospital?
    Yes □ 1  No □ 2
Section F: These questions relate to cardiac rehabilitation

29. Did you enrol into a cardiac rehabilitation program after discharge from hospital?
   ☐ 1 Yes ➔ Please go to Q30
   ☐ 2 No ➔ Please go to Q32

30. Did you complete the cardiac rehabilitation program?
   ☐ 1 Yes ➔ Please go to Q31
   ☐ 2 No ➔ Why not?

________________________________________________________________________

Go to Q33

31. Why did you attend the cardiac rehabilitation program? (Please tick all that apply)
   ☐ a Recommended by your specialist / GP
   ☐ b Recommended by a nurse
   ☐ c Recommended by other health professional
   ☐ d Received a reminder by mail or phone
   ☐ e Personally felt it is necessary
   ☐ f Saw benefits of attendance in people that you know
   ☐ g Others (Please specify) __________________________________________________________________________

Go to Q33

32. These are some of the reasons why people do not enrol in a cardiac rehabilitation program.
    Please indicate how much you agree with each of the reasons relating to your decision not to participate in a rehabilitation program. (Please tick one box only for each line)

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Not informed about the rehab program</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b. Long waiting list for rehab program</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c. Not contacted by rehab staff</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d. Lack of support / referral from doctor</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>e. Doctor said it was unnecessary</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>f. Personally thought it was unnecessary</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>g. Too far from home</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>h. Do not have time</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
i. Rehab class time is not suitable .................................. □1 □2 □3 □4 □5
j. Lack of family support ................................................. □1 □2 □3 □4 □5
k. Lack of motivation ....................................................... □1 □2 □3 □4 □5
l. Fear of further pain ...................................................... □1 □2 □3 □4 □5
m. Language difficulties ................................................... □1 □2 □3 □4 □5
n. Conflict with work ...................................................... □1 □2 □3 □4 □5
o. Do not like group activities ............................................. □1 □2 □3 □4 □5
p. Others (Please specify) ____________________________________ □1 □2 □3 □4 □5

33. Please indicate how important you consider the following elements of a cardiac rehabilitation program? (Please tick one box for each line)  

<table>
<thead>
<tr>
<th>Element</th>
<th>Little Important</th>
<th>Important</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Set own goals</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>b. Receive individualised attention</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>c. Receive exercise advice</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>d. Exercise with someone</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>e. Not getting overtired</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>f. Not having pain while exercising</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>g. Ease of learning exercise</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>h. Exercises are not boring</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>i. Nutritional counselling</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>j. Vocational counselling</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>k. Stress management</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>l. See progress</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>m. Discussion about progress</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>n. Encouragement from health professional</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>o. Long-term staff</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>p. Distance from home to the program</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>q. Convenient parking</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>r. Flexible hours</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
<tr>
<td>s. Does not interfere with other everyday activities</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
</tr>
</tbody>
</table>
t. Available transportation ........................................... □1 □2 □3
u. Support from other patients ........................................... □1 □2 □3
v. Others (Please specify) ............................................................................................................... □1 □2 □3

Section G: The next few questions are about your smoking status

34. Which of the following best describes your cigarette smoking status before your angioplasty? (Please tick one box only)
   □1 Never smoked
   □2 Ex-smoker
   □3 Do not smoke everyday
   □4 Smoke from 1 to 10 cigarettes a day
   □5 Smoke more than 10 cigarettes a day

35. Which of the following best describes your current cigarette smoking status? (Please tick one box only)
   □1 Never smoked
   □2 Ex-smoker
   □3 Do not smoke everyday
   □4 Smoke from 1 to 10 cigarettes a day
   □5 Smoke more than 10 cigarettes a day

36. Did your doctor / cardiologist / nurse or health educator

   a. ask if you smoked? ........................................... Yes □1 No □2
   b. advise you to quit? ........................................... Yes □1 No □2 Not applicable □3

Section H: The next few questions are about your physical activity

37. In the last week, how many times have you walked continuously, for at least 10 minutes for recreation, or exercise or to get to and from places?
   ____________________ times Or Do not remember □999

38. What was total time roughly that you spent walking that way in the last week?
   ____________________ minutes / hours Or Do not remember □999

39. How active are you compared with before your angioplasty? (Please tick one box only)
About the same
Less active
More active

**Section I: The next few questions are about your blood pressure and cholesterol**

40. **When did you have your last blood pressure measured?** *(Please tick one box only)*

- [ ] Within last 3 months
- [ ] 4-6 months ago
- [ ] 7-12 months ago
- [ ] More than 12 months ago
- [ ] Cannot remember

41. **What was the level of your last blood pressure reading?** *(Please tick one box only)*

- [ ] High
- [ ] Low *(Value if known __________________ mmHg)*
- [ ] Right for my age
- [ ] Cannot remember

42. **When did you have your last blood cholesterol tested?** *(Please tick one box only)*

- [ ] Within last 6 months
- [ ] 7-12 months ago
- [ ] More than 12 months ago
- [ ] Cannot remember

43. **What was the level of your last blood cholesterol result?** *(Please tick one box only)*

- [ ] High
- [ ] Low *(Value if known __________________ mmol/l)*
- [ ] Right for my age
- [ ] Cannot remember
**Section J:** The following questions are about your understanding of coronary artery disease. There are no grades. Tick the box to indicate your answer.

44. Coronary artery disease is a disease in which *(Please tick one box only)*
   - [ ] 1. Coronary arteries are unable to supply the heart with adequate amount of blood and oxygen
   - [ ] 2. Coronary arteries become narrowed as a result of atherosclerotic plaque build up
   - [ ] 3. Heart muscle is unable to obtain adequate amounts of oxygen from blood
   - [ ] 4. All of the above

45. Which statement about consequences of coronary artery disease is true? *(Please tick one box only)*
   - [ ] 1. Not enough supply of carbon dioxide to the heart muscle
   - [ ] 2. Not enough supply of oxygen to the valves of the heart
   - [ ] 3. Not enough supply of oxygen to the heart muscle
   - [ ] 4. Don’t know the consequences of coronary artery disease

46. Smoking increases the risk of heart disease because *(Please tick one box only)*
   - [ ] 1. Inhaled nicotine causes blood vessels to decrease in size
   - [ ] 2. The smoke from cigarettes slows the heart rate
   - [ ] 3. Cigarette smoking has no effect on your heart, only on your lungs
   - [ ] 4. Cigarette smoking is less harmful after your first heart attack.

47. High blood pressure can sometimes be lowered by eating foods *(Please tick one box only)*
   - [ ] 1. Low in fats and salt
   - [ ] 2. High in cholesterol
   - [ ] 3. High in carbohydrates
   - [ ] 4. High in vitamin D
   - [ ] 5. I do not know

48. Which of the following risk factors of heart disease do you think can be changed? *(Please tick all that apply)*
   a. Gender ........................................... [ ]
   b. Age ............................................... [ ]
   c. Family history ................................. [ ]
   d. National origin ............................... [ ]
   e. High blood cholesterol .................... [ ]
49. What should you do if you experience chest discomfort during exercise?

(Please tick one box only)

- [ ] 1. Slow down immediately and stop if it does not improve within 2-3 minutes
- [ ] 2. Slow down immediately and stop if it does not improve within 10-15 minutes
- [ ] 3. Continue to exercise at the same intensity level, only slow down or stop if it gets worse
- [ ] 4. Keep exercising and work through it
- [ ] 5. I do not know what to do

50. What should you do if chest discomfort is not relieved by anginine tablets/ nitroglycerin spray?

(Please tick one box only)

- [ ] 1. Lie down until the discomfort improves
- [ ] 2. Take another nitroglycerin tablet and wait another 5 minutes to see how you feel
- [ ] 3. Dial 000 immediately
- [ ] 4. Wait until the next morning and see how you feel
- [ ] 5. I do not know what to do

51. What should you do if you have chest pain while driving?

(Please tick one box only)

- [ ] 1. Stop and lie down
- [ ] 2. Stop, take a anginine tablet/ nitroglycerin spray and signal for help
- [ ] 3. Drive home
- [ ] 4. Drive to the nearest hospital
- [ ] 5. I do not know what to do

52. Sexual relations for the patients with coronary artery disease are

(Please tick one box only)

- [ ] 1. Forbidden
- [ ] 2. OK after approved by your doctor

f. High blood pressure

g. Smoking

h. Obesity

i. Diabetes

j. Stress

k. Physical inactivity
☐ 3. Not necessary at your age
☐ 4. I do not know

53. What should you do if you have rash, muscle cramps, or nausea/vomiting lasting more than one day and you feel they may be side effects of medications you are taking?  
*(Please tick one box only)*
☐ 1. Stop taking your medications until the next time you see your doctor
☐ 2. Decrease the dose and see if that helps
☐ 3. Buy an over-the-counter medicine to help you feel better
☐ 4. Notify your doctor before making any changes in your medications
☐ 5. I do not know what to do

54. Which statement is true about anginine (nitroglycerin) tablets (Tablets that are placed under the tongue when you get chest pain)?  
*(Please tick one box only)*
☐ 1. Anginine (nitroglycerin) should be stored in tightly sealed light-resistant glass or metal bottle, away from temperature extremes, and replaced 6-12 months after opening
☐ 2. Anginine (nitroglycerin) can be wrapped in tissues, kept in a purse or pocket, no need to replace
☐ 3. Anginine (nitroglycerin) should be kept in the refrigerator, and need to replace
☐ 4. Anginine (nitroglycerin) can be placed in a pill container with your other pills, replace after one ye
☐ 5. I do not know

55. Angina pain can be felt in the  
*(Please tick one box only)*
☐ 1. Back
☐ 2. Jaw
☐ 3. Chest
☐ 4. All of the above
☐ 5. I do not know

56. Which one of the following foods is the highest source of cholesterol?  
*(Please tick one box only)*
☐ 1. Breads and pasta
☐ 2. Vegetables and fruits
☐ 3. Egg yolks, bacon and sausage
☐ 4. I do not know
Section K: This section is about your physical and emotional conditions over the past week.
There are no right and wrong answers. Tick the box to indicate your answer.

57. Please indicate how much the following statements applied to you over the past week.

The rating scale is as follows:

0  Did not apply to me at all
1  Applied to me to some degree, or some of the time
2  Applied to me to a considerable degree, or a good part of time
3  Applied to me very much, or most of the time

(Please tick one box only for each line)

a. I found it hard to wind down ........................................... □ 0  □ 1  □ 2  □ 3
b. I was aware of dryness of my mouth .................................. □ 0  □ 1  □ 2  □ 3
c. I couldn't seem to experience any positive feeling at all .......... □ 0  □ 1  □ 2  □ 3
d. I experienced breathing difficulty (eg excessively rapid breathing or breathlessness in the absence of physical exertion) ........... □ 0  □ 1  □ 2  □ 3
e. I found it difficult to work up the initiative to do things ........... □ 0  □ 1  □ 2  □ 3
f. I tended to over-react to situations .................................... □ 0  □ 1  □ 2  □ 3
g. I experienced trembling (eg, in the hands) .......................... □ 0  □ 1  □ 2  □ 3
h. I felt that I was using a lot of nervous energy ........................ □ 0  □ 1  □ 2  □ 3
i. I was worried about situations in which I might panic and make a fool of myself ....................................................... □ 0  □ 1  □ 2  □ 3
j. I felt that I had nothing to look forward to ......................... □ 0  □ 1  □ 2  □ 3
k. I found myself getting agitated ......................................... □ 0  □ 1  □ 2  □ 3
l. I found it difficult to relax ................................................. □ 0  □ 1  □ 2  □ 3
m. I felt down-hearted and blue ............................................ □ 0  □ 1  □ 2  □ 3
n. I was intolerant of anything that kept me from what I was doing .. □ 0  □ 1  □ 2  □ 3
o. I felt I was close to panic .................................................. □ 0  □ 1  □ 2  □ 3
p. I was unable to become enthusiastic about anything ............. □ 0  □ 1  □ 2  □ 3
q. I felt I wasn't worth much as a person ................................ □ 0  □ 1  □ 2  □ 3
r. I felt that I was rather touchy ............................................. □ 0  □ 1  □ 2  □ 3
s. I was aware of the action of my heart in the absence of physical exertion (eq. sense of heart rate increase, heart missing a beat) …

t. I felt scared without any good reason …………………………….

u. I felt that life was meaningless ……………………………………….

**Section L:** This section is about how you have been feeling during the last two weeks.

*Tick the box to indicate your answer.*

58. In the last two weeks, how much of the time did you feel

(Please tick one box only for each line)

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>Most of the time</th>
<th>Almost all of the time</th>
<th>All of the time</th>
</tr>
</thead>
</table>

a. very confident and sure that you could deal with your heart problem?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

b. relaxed and free of tension?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

59. During the last two weeks, how much have you been

(Please tick one box only for each line)

<table>
<thead>
<tr>
<th>Extremely limited</th>
<th>Very limited</th>
<th>Limited quite a bit</th>
<th>Moderately limited</th>
<th>Somewhat limited</th>
<th>Limited a little</th>
<th>Not limited at all</th>
</tr>
</thead>
</table>

a. limited in doing sports or exercise as a result of your heart problem?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

b. restricted or limited as a result of your heart problem

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

c. physically restricted or limited as a result of your heart problem

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

60. How much shortness of breath have you experienced during the last 2 weeks while doing your day-to-day physical activity? (Please tick one box only)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Extreme shortness of breath</td>
</tr>
<tr>
<td>1</td>
<td>Very short of breath</td>
</tr>
</tbody>
</table>
3. Quite a bit of shortness of breath
4. Moderate shortness of breath
5. Some shortness of breath
6. A little shortness of breath
7. No shortness of breath

61. In general, how much of the time during the last 2 weeks have you felt

(Please tick one box only for each line)

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. frustrated, impatient or angry?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. worthless or inadequate?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. discouraged or down in the dumps?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. worn out or low in energy?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. restless, or as if you were having difficulty trying to calm down?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. tearful, or like crying?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. as though you were more dependent than you were before your heart problem?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. unable to do your usual social activities, or social activities with your family?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. as if others no longer have the same confidence in you as they did before your heart problem?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j. chest pain while doing your day-to-day activities?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>k. unsure of yourself or lacking in self-confidence?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>l. been bothered by aching or tired legs</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>m. apprehensive or frightened?</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
n. dizzy or light-headed? .................  □1  □2  □3  □4  □5  □6  □7

o. unsure as to how much exercise or physical activity you should be doing? □1  □2  □3  □4  □5  □6  □7

p. as if your family is being over-protective toward you? .................. □1  □2  □3  □4  □5  □6  □7

q. as if you were a burden on others?..... □1  □2  □3  □4  □5  □6  □7

r. excluded from doing things with other people because of your heart problem? .................. □1  □2  □3  □4  □5  □6  □7

s. unable to socialise because of your heart problem? .................. □1  □2  □3  □4  □5  □6  □7

62. How often during the last 2 weeks have you felt your heart problem limited or interfered with sexual intercourse? (Please tick one box only)

□3 Not applicable
□1 All of the time
□2 Most of the time
□3 A good bit of the time
□4 Some of the time
□5 A little of the time
□6 Hardly any of the time
□7 None of the time

63. How happy, satisfied, or pleased have you been with your personal life during the last 2 weeks? (Please tick one box only)

□1 Very dissatisfied, unhappy most of the time
□2 Generally dissatisfied, unhappy
□3 Somewhat dissatisfied, unhappy
□4 Generally satisfied, pleased
□5 Happy most of the time
□6 Very happy most of the time
□7 Extremely happy, could not have been more satisfied or pleased
64. In general, would you say your health is? (Please tick one box only)


1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

65. Compared to before your angioplasty, how would you rate your health in general now? (Please tick one box only)


1. Much better now than before the angioplasty
2. Somewhat better now than before the angioplasty
3. Somewhat worse now than before the angioplasty
4. Much worse now than before the angioplasty
5. No difference

Section M: This section seeks your opinions about coronary artery disease in general.

66. Is it important to you as a patient to understand and keep up-to-date on medical research and new treatment for coronary artery disease? (Please tick one box only)

Yes 1  No 2

67. Is there any information you wish you had been given before your angioplasty?

Yes 1  No 2

If Yes, what information? __________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

68. What kinds of information and support do you think would be helpful for coronary artery disease patients to whom angioplasty may be recommended?

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

Appendices
69. Would you like to learn about your heart disease from

a. Your general practitioner?  
   Yes ☐  No ☐

b. A specialist?  
   Yes ☐  No ☐

c. Another health professional?  
   Yes ☐  No ☐

d. Own private reading?  
   Yes ☐  No ☐

e. The Internet?  
   Yes ☐  No ☐

f. Others (Please specify) _________________________________________________

70. Did you need any assistance to answer this questionnaire?  
   Yes ☐  No ☐

You have finished
THANK YOU VERY MUCH FOR PARTICIPATING IN THIS SURVEY
Please return the questionnaire as soon as possible in the envelope provided.
You do not need a postage stamp

If you have any questions, please contact
Ms Ritin Fernandez
Centre for Applied Nursing Research
South Western Sydney Area Health Service
Locked Bag 7103
LIVERPOOL BC 1870
Phone: (02) 9828 6589
Email: ritin.fernandez@swsahs.nsw.gov.au
Appendix 15  Ethics approval from SSWAHS (Western zone) for the PCI study

SOUTH WESTERN SYDNEY AREA HEALTH SERVICE

Human Research Ethics Committee
Locked Bag 7017, LIVERPOOL BC, NSW, 1871
Phone:  02 9828 5727
Facsimile:  02 9828 5962

July 31, 2008

Ms Ritin Fernandez
CANRE
Liverpool Health Service
Locked Bag 7103
LIVERPOOL BC  1871

Dear Ms Fernandez,

Project No  04/064 - Long term (12-18 month) follow-up of patients discharged following Percutaneous Coronary Intervention (PCI) for Coronary Artery Disease

The SWSAHS Human Research Ethics Committee wishes to acknowledge receipt of your correspondence with regards to the above project.

As all of the issues raised by the Committee have now been satisfactorily addressed, formal approval is hereby granted for this study to proceed as a Category A Project.

Ethics clearance is granted for periods of up to twelve months.  This project will be due for renewal on 31st May, 2005 and you must provide a Progress Report (attached) or final report by this date.  If no report is supplied, ethics clearance for this project may be cancelled.

Your attention is drawn to the attached document Guidelines for Investigators which sets out not only the principles under which research should be conducted, but also the conditions under which Ethics approval is granted by the Committee.  Also enclosed for your information, is a copy of the document Guidelines for Responsible Practice in Research and Dealing with Problems of Research Misconduct.

Please note that the Committee must be notified IMMEDIATELY of any untoward or unexpected complications or side affects arising during the project or of any ethical or medico-legal problems that may arise.  Also, any changes to the original protocol must be submitted to the Committee for approval.

Would you please quote the above project number in all future correspondence relating to this project.

Yours sincerely,

PROFESSOR HUGH DICKSON
Chairperson
SSWAHS Research Ethics Committee

For:  Dr Diana Horvath, AO
Administrator, SWSAHS

Category A:  Projects with limited risk potential, including quality assurance surveys.
Category B:  Projects with significant patient risks.
Category C:  Drug trials (international/national) sponsored by drug companies and already covered for risk evaluation and monitoring of adverse reactions.
Appendix 16  Ethics approval from University of Western Sydney for the PCI study

14 December 2004

Ms Ritin Fernandez
CANRE
Liverpool Health Service
Locked Bag 7103
Liverpool BC 1871

Dear Ritin

Re: HREC 04/181 Long Term (12-18 month) follow up of patients discharged following Percutaneous Coronary Intervention (PCI) for Coronary Artery Disease

The Committee reviewed your responses to the issues previously raised and as all issues have now been clarified this Committee has agreed to formally note the ethics approval granted by the South Western Sydney Area Health Service Human Research Ethics Committee.

You are advised that the Committee should be notified of any further change/s to the research methodology should there be any in the future. You will be required to provide a report on the ethical aspects of your project at the completion of this project. The form is located on the Research Services Web Page.

The Protocol Number HREC 04/181 should be quoted in all future correspondence about this project. Your approval will expire 30 December 2005. Please contact the Human Ethics Officer, Kay Buckley on tel: 02 4570 1136 if you require any further information.

The Committee wishes you well with your research.

Yours sincerely

[Signature]

Professor Elizabeth Deane
Chairperson
UWS Human Research Ethics Committee
Cc South Western Sydney Area Health Service Human Research Ethics Committee
Appendix 17  The CREO Scale

Q These are some of the reasons why people do not enrol in a cardiac rehabilitation program.

Please indicate how much you agree with each of the reasons relating to your decision not to participate in a rehabilitation program. *(Please tick one box only for each line)*

<table>
<thead>
<tr>
<th>Reason</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not informed about the rehab program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long waiting list for rehab program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not contacted by rehab staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of support / referral from doctor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor said it was unnecessary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personally thought it was unnecessary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Too far from home</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not have time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rehab class time is not suitable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of family support</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of motivation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fear of further pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Language difficulties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conflict with work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not like group activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 18  Recruitment script

Hello, My name is________________________ and I am from Liverpool Health Service.
I am inviting you to participate in a study to test if a Health related lifestyle management (HeLM) intervention will improve the risk factors status of cardiac patients.

- If you decide to participate you will be required to complete a questionnaire.
- Completion of the questionnaire over the phone will take approximately 25-30 minutes.
- You may choose not to answer certain questions. Please let me know if this so.
- You will be required to attend a one hour follow up at Liverpool hospital 6 weeks after you have been discharged. You will be given a parking voucher for Liverpool hospital
- As part of the study, we also seek you consent to obtain medical information from your inpatient records.
- We will require to measure your CO status, weight and waist measurement.
- Your cardiologist is aware of the study and has given her/his approval.
- Your individual responses will remain confidential. Your personal information will not be released.
- This survey has been approved by the SWSAHS Human Research Ethics Committee and by the University of Western Sydney Ethics Review Committee (Human Subjects).

Have you been provided information about CR?
If no please identify closest CR centre and enforce participation
(In some instances CR has been documented in the notes, please show the patient)

THIS STUDY IS NOT AN ALTERNATIVE TO CR
Please let me know if you wish to participate.
Dear __________________

You are invited to participate in a pilot study, which is trialing a new method to help patients who have had chest pain or heart attack change their risk factors so that they decrease their chances of further heart disease. The aim of this small study is to test if (1) it is possible to conduct the same study on a larger scale to (2) patients accept the intervention (3) patients complete the program and (4) patients modify their cardiac risk factor profile. We would also like to describe the barriers and facilitators to implementing the intervention.

You were selected as a possible participant in this study because you have coronary heart disease and receiving medical care in Liverpool hospital which is a facility participating in this study.

If you decide to participate, the research assistant will ask you to complete a questionnaire which takes approximately ½ hour before your discharge from hospital. After you complete the questionnaire you will be allocated to one of two groups. Both groups will receive all information provided in the hospital. Following discharge you may receive additional written information and phone calls from the research assistant inquiring about your progress. At the end of eight weeks you will be required to come to Liverpool hospital for a follow-up which will include checking your blood pressure, height, weight, waist measurement, smoking status, and completing a second questionnaire. We will conduct a short interview to obtain your feedback about the intervention. This interview will be digitally recorded and all information provided will be kept strictly confidential. Your GP and cardiologist will be informed that you are participating in the study. Information regarding your medical treatment will be obtained from your medical records.

This research will not alter your treatment. Your GP and/or your cardiologist will make decisions about your care. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or except as required by law. If you give us your permission by signing this document, we plan to publish the results in peer reviewed journals. In any publication, information will be provided in such a way that you cannot be identified.

It is not anticipated that you will incur any additional costs if you participate in this study. You will receive a parking voucher when you attend the research centre for the follow-up. Participation in this study is entirely voluntary. Your decision whether or not to participate...
will not prejudice your present or future treatment or your relationship with Sydney South
West Area Health Service If you decide to participate, you are free to withdraw your consent
and to discontinue your participation at any time without prejudice.

If you have any questions, please feel free to ask us. If you have any additional questions
later, your study researcher Ms Ritin Fernandez ((02) 98286589) will be pleased to answer
them.

Your participation in this study will be extremely valued.

Complaints may be directed to the Ethics Secretariat, South Western Sydney Area Health
Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 5727, fax 9828 5962,
email jennie.grech@swsahs.nsw.gov.au).

This form is for you to keep.
CONSENT FORM

Health related lifestyle management in patients with acute coronary syndrome (the HeLM study)—A Pilot study

2. I, ..........................................................................................................................of
................................................................................................................................., aged ........................................years, agree to

- participate as a subject in the study described in the subject information statement set out above (or: attached to this form). □ Yes □ No
- have the researchers obtain a copy my health information from the medical records
  □ Yes □ No
- have the researchers obtain a copy of my laboratory test results
  □ Yes □ No
- have the researcher obtain my information from my GP/pathology services
  □ Yes □ No

2. I acknowledge that I have read the Subject Information Statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. I have been given the opportunity to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation. I have received satisfactory answers to any questions that I have asked.

4. My decision whether or not to participate will not prejudice my present or future treatment or my relationship with South Western Sydney Area Health Service or any other institution cooperating in this study or any person treating me. If I decide to participate, I am free to withdraw my consent and to discontinue my participation at any time without prejudice.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact the study researcher Ms Ritin Fernandez on telephone (02) 98286589, who will be happy to answer them.

7. I acknowledge receipt of a copy of the Subject Information Statement.

Complaints may be directed to the Ethics Secretariat, South Western Sydney Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 5727, fax 9828 5962, email jennie.grech@swsahs.nsw.gov.au).

Signature of subject ______________________________ Signature of witness________________________

Please PRINT name ______________________________ Please PRINT name ______________________________

Date ______________________________ Date ______________________________

Signature(s) of investigator(s) __________________________________________

Please PRINT Name RITIN FERNANDEZ________________________

Date: 01/07/2006 ______________________________
Appendix 21  Self administered questionnaire (HeLM study)

HEALTH RELATED LIFESTYLE MANAGEMENT IN PATIENTS WITH ACUTE CORONARY SYNDROME
(THE HELM STUDY)

Data Collection form for

Place patient identification sticker
Include address

Phone number  Home  Mobile  Other

This questionnaire is to be completed by the patient
**SECTION A These questions are about your medications**

1. People often have difficulties taking their tablets for one reason or another. We are trying to learn more about these experiences.

(a) Do you regularly miss taking your medications? Yes □₁ No □₂

(b) Have you missed any of your medications in the last week for any reasons? Yes □₁ No □₂

   If Yes, How many tablets have you missed? __________________________

(c) Do you sometimes stop taking medications if you feel better? Yes □₁ No □₂

(d) Do you sometimes stop taking medications if you feel worse? Yes □₁ No □₂

(e) Do you sometimes stop taking a medication when going out, thinking it may interfere with what you are doing? Yes □₁ No □₂

(f) Do you keep medications in the original containers? Yes □₁ No □₂

(g) Do you keep all medications in one container? Yes □₁ No □₂

(h) Do you use anything that helps organise your medications? Yes □₁ No □₂

   If Yes, please list them

   ________________________________________________________________

(i) Do you have any special systems to remind you to take medications? Yes □₁ No □₂

   If Yes, please list them______________________________________________
SECTION B These next few questions are about your smoking status

1. Which of the following best describes your current cigarette smoking status? (Please tick one box only)
   - Never smoked
   - Quit within the last 6 months
   - Quit more than 6 months ago
   - Do not smoke every day
   - Smoke everyday

2. Are you seriously thinking of quitting smoking? (Please tick one box only)
   - No not thinking of quitting
   - Yes within the next 6 months
   - Yes within the next 30 days

3. How soon after you awake do you smoke your first cigarette? (Please tick one box only)
   - Within 5 minutes
   - 6-30 minutes
   - 31-60 minutes
   - After 60 minutes

4. How many cigarettes a day do you smoke? (Please tick one box only)
   - 10 or less
   - 11-20
   - 21-30
   - 31 or more
SECTION C These next few questions are about your physical activity

Regular Exercise is any planned physical activity (e.g., brisk walking, aerobics, jogging, bicycling, swimming, rowing, etc.) performed to increase physical fitness. Physical activity should be undertaken 3 to 5 times per week for at least 30 minutes per session.

1. According to this definition Do you exercise regularly? (Please tick one box only)
   - No, and I do NOT intend to in the next 6 months.  
   - No, but I intend to in the next 6 months.  
   - No, but I intend to in the next 30 days.  
   - Yes, I have been for LESS than 6 months.  
   - Yes, I have been for MORE than 6 months.

The next questions are about any physical activities that you may have done in the last week

2. In the last week, how many times have you walked continuously, for at least 10 minutes, without stopping for recreation, exercise or to get to or from places? ____________times

3. What do you estimate was the total time that you spent walking in this way in the last week? ________________minutes/ hours

4. In the last week, how many times did you do any vigorous gardening or heavy work around the yard, which made you breathe harder or puff and pant? (for example heavy digging, tree lopping, pushing a wheelbarrow, moving large rocks, pushing a lawn mower and using a hand saw) _________________ _______times

5. What do you estimate was the total time that you spent doing vigorous gardening or heavy work around the yard in the last week? ________________minutes/ hours
The next questions exclude household chores, gardening or yard work:

6. In the last week, how many times did you do any vigorous physical activity which made you breathe harder or puff and pant? (e.g. jogging, cycling, aerobics, competitive tennis, football) __________ times

7. What do you estimate was the total time that you spent doing this vigorous physical activity in the last week? ______________ minutes/hours

8. In the last week, how many times did you do any other more moderate physical activities that you have not already mentioned? (e.g. gentle swimming, social tennis, golf) __________ times

9. What do you estimate was the total time that you spent doing these activities in the last week? ____________________ minutes/hours
**SECTION C** These next few questions are about your current eating habits

How many times *per week* do you (*Please place a tick (✓) in the box that is most applicable to you*)

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Less than once</th>
<th>1-2 times</th>
<th>3-5 times</th>
<th>6 or more times</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. eat fried food with a batter or breadcrumb coating?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>2. eat gravy, cream sauces or cheese sauces?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>3. add butter or sour cream to vegetables, cooked rice or spaghetti?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>4. eat casserole or pot roast meat?.....</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>5. eat meat fried in butter, ghee, lard or dripping?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>6. eat sausages, devon, salami, meat pies, hamburgers or bacon?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>7. eat hot chips or French fries?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>8. eat pastries, cakes, sweet biscuits or croissants?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>9. eat chocolate, chocolate biscuits or sweet snack bars?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>10. eat potato crisps, corn chips or nuts?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>11. eat cream?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>12. eat regular ice cream?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>13. eat cheddar, edam or other hard cheese, cream cheese or cheese like camembert?</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
<tr>
<td>14. use full cream milk in cooking or in</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
<td>□️</td>
</tr>
</tbody>
</table>
15. use condensed milk in cooking or in tea and coffee? 

16. Which of the following do you spread on your bread?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Margarine</td>
<td>Q1</td>
</tr>
<tr>
<td>Butter</td>
<td>Q2</td>
</tr>
<tr>
<td>Don’t use butter or margarine</td>
<td>Q3</td>
</tr>
</tbody>
</table>

17. How much of the skin on your chicken do you eat?

(If you never eat chicken, please mark the ‘none of the skin’ response)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the skin</td>
<td>Q1</td>
</tr>
<tr>
<td>Some of the skin</td>
<td>Q2</td>
</tr>
<tr>
<td>Most of the skin</td>
<td>Q3</td>
</tr>
</tbody>
</table>

18. How much of the fat on your meat do you eat?

(If you never eat meat, please mark the ‘none of the fat’ response)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the fat</td>
<td>Q1</td>
</tr>
<tr>
<td>Some of the fat</td>
<td>Q2</td>
</tr>
<tr>
<td>Most of the fat</td>
<td>Q3</td>
</tr>
</tbody>
</table>

19. How many servings of fruit do you usually eat each day? (Please place a tick (✓) in the box that is most applicable to you)

1  2  3  4  5  6  More than 6
20. How many servings of vegetables do you usually eat each day? (Please place a tick (✓) in the box that is most applicable to you)

1  2  3  4  5  6  More than 6

21. Which of the following statements apply to you (Please tick one box only)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Square</th>
</tr>
</thead>
<tbody>
<tr>
<td>I haven't given the matter of the fat in my diet any thought at all</td>
<td>☐️1</td>
</tr>
<tr>
<td>I think about the fat in my diet from time to time, and then put the</td>
<td>☐️2</td>
</tr>
<tr>
<td>matter out of my head</td>
<td></td>
</tr>
<tr>
<td>I keep meaning to do something to lessen the fat in my diet, but don't</td>
<td>☐️3</td>
</tr>
<tr>
<td>actually get around to it</td>
<td></td>
</tr>
<tr>
<td>From time to time I avoid fat in my diet, but at other times I go back</td>
<td>☐️4</td>
</tr>
<tr>
<td>to eating too much fat</td>
<td></td>
</tr>
<tr>
<td>I have been consciously avoiding fat in my diet for 6 months or less</td>
<td>☐️5</td>
</tr>
<tr>
<td>I have been consciously avoiding fat in my diet for longer than the</td>
<td>☐️6</td>
</tr>
<tr>
<td>last 6 months</td>
<td></td>
</tr>
</tbody>
</table>
SECTION D  These next few questions are about your physical and emotional conditions over the past week. There are no right and wrong answers.

Please indicate how much the following statements applied to you over the past week. (Tick the box to indicate your answer).

The rating scale is as follows

0  Did not apply to me at all
1  Applied to me to some degree, or some of the time
2  Applied to me to a considerable degree, or a good part of time
3  Applied to me very much, or most of the time

1. I found it hard to wind down
2. I was aware of dryness of my mouth
3. I couldn't seem to experience any positive feeling at all
4. I experienced breathing difficulty (eg excessively rapid breathing or breathlessness in the absence of physical exertion)
5. I found it difficult to work up the initiative to do things
6. I tended to over-react to situations
7. I experienced trembling (eg, in the hands)
8. I felt that I was using a lot of nervous energy
9. I was worried about situations in which I might panic and make a fool of myself

Continued on the next page
<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>I felt that I had nothing to look forward to</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>I found myself getting agitated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>I found it difficult to relax</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I felt down-hearted and blue</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I was intolerant of anything that kept me from what I was doing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>I felt I was close to panic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>I was unable to become enthusiastic about anything</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>I felt I wasn't worth much as a person</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>I felt that I was rather touchy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>I felt scared without any good reason</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>I felt that life was meaningless</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION L This section is about how you have been feeling during the last two weeks. There are no right and wrong answers. Tick the box to indicate your answer.

1. In the last two weeks, how much of the time did you feel (Please tick one box only for each line)

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>Most of the time</th>
<th>Almost all of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. very confident and sure that you could deal with your heart problem?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>b. relaxed and free of tension?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

2. During the last two weeks, how much have you been (Please tick one box only for each line)

<table>
<thead>
<tr>
<th>Extremely limited</th>
<th>Very limited</th>
<th>Limited quite a bit</th>
<th>Moderately limited</th>
<th>Some what limited</th>
<th>Limited a little</th>
<th>Not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. limited in doing sports or exercise as a result of your heart problem?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>b. restricted or limited as a result of your heart problem</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>c. physically restricted or limited as a result of your heart problem</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

3. How much shortness of breath have you experienced during the last 2 weeks while doing your day-to-day physical activity? (Please tick one box only)

- Extreme shortness of breath | 1 |
- Some shortness of breath | 5 |
- Very short of breath | 2 |
- A little shortness of breath | 6 |
Quite a bit of shortness of breath  □ 3  
Moderate shortness of breath  □ 4  
No shortness of breath  □ 7

4. In general, how much of the time during the last 2 weeks have you felt  *(Please tick one box only for each line)*

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a). frustrated, impatient or angry?.................................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>b) worthless or inadequate?........................................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>c) discouraged or down in the dumps?...............................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>d) worn out or low in energy? ...................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>e) restless, or as if you were having difficulty trying to calm down?........</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>f) tearful, or like crying? ......................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>g) as though you were more dependent than you were before your heart problem? ..................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
<tr>
<td>h) unable to do your usual social activities, or social activities with your family? ................</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
<td>□ 7</td>
</tr>
</tbody>
</table>
i) as if others no longer have the same confidence in you as they did before your heart problem?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

j) chest pain while doing your day-to-day activities?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

k) unsure of yourself or lacking in self-confidence?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

l) been bothered by aching or tired legs  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

m) apprehensive or frightened?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

n) dizzy or light-headed?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

o) unsure as to how much exercise or physical activity you should be doing?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

p) as if your family is being over-protective toward you?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

r) excluded from doing things with other people because of your heart problem?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

s) unable to socialise because of your heart problem?  

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>Hardly any of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

5. How often during the last 2 weeks have you felt your heart problem limited or interfered with sexual intercourse?  
(Please tick one box only)
Not applicable  □ 1
All of the time  □ 2
Most of the time  □ 3
A good bit of the time  □ 4
Some of the time  □ 5
A little of the time  □ 6
Hardly any of the time  □ 7
None of the time

6. **How happy, satisfied, or pleased have you been with your personal life during the last 2 weeks? (Please tick one box only)**

Very dissatisfied, unhappy most of the time  □ 1
Generally dissatisfied, unhappy  □ 2
Somewhat dissatisfied, unhappy  □ 3
Generally satisfied, pleased  □ 4
Happy most of the time  □ 5
Very happy most of the time  □ 6
Extremely happy, could not have been more satisfied or pleased  □ 7

7. **In general, would you say your health is? (Please tick one box only)**

Excellent  □ 1
Very good  □ 2
Good  □ 3
Fair  □ 4
Poor  □ 5
You have finished
THANK YOU VERY MUCH FOR PARTICIPATING IN THIS SURVEY

Please return the questionnaire as soon as possible in the envelope provided.
You do not need a postage stamp

If you have any questions, please contact
Ms Ritin Fernandez
Centre for Applied Nursing Research

South Western Sydney Area Health Service

Locked Bag 7103

LIVERPOOL BC 1870

Phone: (02) 9828 6589  Email: ritin.fernandez@swsahs.nsw.gov.au
Appendix 22  Medical records Audit Form

HEALTH RELATED LIFESTYLE MANAGEMENT IN PATIENTS WITH ACUTE CORONARY SYNDROME
(_THE HELM STUDY)_

Data Collection form for

Place patient Identification sticker
Include address

Phone number  Home
Mobile
Other

G.P. Name & phone No.

This questionnaire is to be completed by the researcher

CanR

University of Western Sydney
SECTION A: These first questions ask general information about yourself and your household. You may choose not to answer them.

1. Gender
   - Female □
   - Male □

2. Your age
   _______________ years

3. How many dependant children do you have
   ________________

4. What is your highest level of education? (Please tick one box only)

<table>
<thead>
<tr>
<th>Educational Level</th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not complete primary school</td>
<td>1</td>
</tr>
<tr>
<td>Completed primary school only</td>
<td>2</td>
</tr>
<tr>
<td>Left high school before intermediate or school certificate</td>
<td>3</td>
</tr>
<tr>
<td>Intermediate or School Certificate (Year 10 / 4th Form)</td>
<td>4</td>
</tr>
<tr>
<td>Leaving or High School Certificate (Year 11/12 / 6th Form)</td>
<td>5</td>
</tr>
<tr>
<td>Apprenticeship / Trade Qualification/ TAFE Certificate or Diploma</td>
<td>6</td>
</tr>
<tr>
<td>University, CAE or some other tertiary Institute degree</td>
<td>7</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>8</td>
</tr>
</tbody>
</table>

5. What is your marital status? (Please tick one box only)

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>□</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married / De-facto</td>
<td>1</td>
</tr>
<tr>
<td>Single / Divorced / separated</td>
<td>2</td>
</tr>
<tr>
<td>Widowed</td>
<td>3</td>
</tr>
</tbody>
</table>
6. Your height ________________________ cm/m/feet

7. Your weight ________________________ kg

8. Your waist measurement ____________________ cm

9. How would you describe your employment situation? *(Please tick one box only)*

<table>
<thead>
<tr>
<th>Employment Situation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Employed full time</td>
<td></td>
</tr>
<tr>
<td>Employed part time or casual</td>
<td></td>
</tr>
<tr>
<td>Unemployed (not retired or on pension)</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td></td>
</tr>
<tr>
<td>Permanently unable to work</td>
<td></td>
</tr>
<tr>
<td>Home duties</td>
<td></td>
</tr>
<tr>
<td>Student (part time or full time)</td>
<td></td>
</tr>
</tbody>
</table>

10. Could you please tell us why you are unemployed? *(Please tick one box only)*

<table>
<thead>
<tr>
<th>Reason</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Redundancy</td>
<td></td>
</tr>
<tr>
<td>Unable to find work</td>
<td></td>
</tr>
<tr>
<td>Poor health</td>
<td></td>
</tr>
<tr>
<td>Others <em>(Please specify)</em></td>
<td></td>
</tr>
</tbody>
</table>
### 11. Your past medical history

*(To be completed by the Research Assistant and confirmed with the patient. Please tick all that apply)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Ticked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin dependant diabetes (DM1)</td>
<td></td>
</tr>
<tr>
<td>Non insulin dependant diabetes (DM2)</td>
<td></td>
</tr>
<tr>
<td>Angina</td>
<td></td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
</tr>
<tr>
<td>Stress</td>
<td></td>
</tr>
<tr>
<td>Other chronic lung diseases</td>
<td></td>
</tr>
<tr>
<td>Kidney problems</td>
<td></td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
</tr>
<tr>
<td>Back problems</td>
<td></td>
</tr>
<tr>
<td>High blood cholesterol</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
</tr>
<tr>
<td>Stroke / Cerebro-vascular accident</td>
<td></td>
</tr>
<tr>
<td>Heart Attack (Myocardial infarction)</td>
<td></td>
</tr>
<tr>
<td>CABG (date)</td>
<td></td>
</tr>
<tr>
<td>PCI (date)</td>
<td></td>
</tr>
<tr>
<td>Others *(please specify)________________________</td>
<td></td>
</tr>
<tr>
<td>Current mobility status (specify): ambulant</td>
<td></td>
</tr>
<tr>
<td>Walks unaided: with aids:</td>
<td></td>
</tr>
<tr>
<td>Family history of heart disease</td>
<td></td>
</tr>
</tbody>
</table>
12. Reason for current admission

<table>
<thead>
<tr>
<th>Reason</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstable angina</td>
<td>☐ 1</td>
</tr>
<tr>
<td>ST elevation Myocardial infarction</td>
<td>☐ 2</td>
</tr>
<tr>
<td>Non ST elevation Myocardial infarction</td>
<td>☐ 3</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>☐ 4</td>
</tr>
<tr>
<td>Elective PCI</td>
<td>☐ 5</td>
</tr>
<tr>
<td>Others (Please specify) ____________________</td>
<td>☐ 6</td>
</tr>
</tbody>
</table>

13. Medications prescribed? *(Research assistant to complete. Please tick all that apply)*

<table>
<thead>
<tr>
<th>Type of medications</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta blockers</td>
<td>☐ 1</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>☐ 2</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>☐ 3</td>
</tr>
<tr>
<td>Statins</td>
<td>☐ 4</td>
</tr>
<tr>
<td>Anti platelet</td>
<td>☐ 5</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>☐ 6</td>
</tr>
<tr>
<td>Anti-arrhythmic agents</td>
<td>☐ 7</td>
</tr>
<tr>
<td>Fibrinolytics</td>
<td>☐ 7</td>
</tr>
<tr>
<td>Other 1 (Please specify)</td>
<td>☐ 8</td>
</tr>
<tr>
<td>Other 2 (Please specify)</td>
<td>☐ 9</td>
</tr>
<tr>
<td>Other 3 (Please specify)</td>
<td>☐ 10</td>
</tr>
<tr>
<td>PCI</td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td></td>
</tr>
</tbody>
</table>
SECTION C These next few questions are about your Blood pressure and cholesterol

14. Level of your last blood pressure reading? Value ________________ mmHg

15. Level of your last blood cholesterol result? Value __________ mmol/l

15a Level of HDL Value __________ mmol/l

15b Level of LDL Value __________ mmol/l

16a. Level of your last carbon monoxide CO result? Value __________

16b Level of CK Value __________ U/L

16c Level of CKMB Value __________ μg/L

16d. Level of Troponin Value __________ μg/L

16e. Level of CRP (C-reactive protein) Value __________

16f. LVF (left ventricular hypertrophy) present? Yes □₁ No □₂ (Check ECG)

16g. Creatinine level Value __________ μmol/L

16h. Haemoglobin level Value __________ g/L
### QUESTIONS FOR FOLLOW UP

<table>
<thead>
<tr>
<th>CARDIAC REHABILITATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Did you attend a Cardiac Rehabilitation Program?</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>2 If yes How many sessions did you attend?</td>
<td>______</td>
</tr>
<tr>
<td>3 If no were you contacted by the CR Nurse?</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

Patients comments

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
## HelM BOOKLET

<table>
<thead>
<tr>
<th></th>
<th>Do you think you received the HelM booklet at the appropriate time?</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>□ Too soon after discharge</td>
</tr>
<tr>
<td></td>
<td>□ Too late after discharge</td>
</tr>
<tr>
<td></td>
<td>□ Timing was appropriate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>To what extent did you read the HelM Booklet?</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>□ None of it</td>
</tr>
<tr>
<td></td>
<td>□ Only sections relevant to me</td>
</tr>
<tr>
<td></td>
<td>□ All of it</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Was the information provided (please circle one number not at all' (1) to ‘to a large extent’ (10))</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>□ easy to read 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td></td>
<td>□ could be understood easily 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td></td>
<td>□ Useful 1 2 3 4 5 6 7 8 9 10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>After reading the booklet were you able to (please circle one number not at all' (1) to ‘to a large extent’ (10))</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>□ see the benefits of adopting healthy habits 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td></td>
<td>□ increase your confidence in being healthy 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td></td>
<td>□ learned how to cope with difficult situations 1 2 3 4 5 6 7 8 9 10</td>
</tr>
</tbody>
</table>

Patients comments

___________________________________________________

___________________________________________________

___________________________________________________

___________________________________________________

___________________________________________________

___________________________________________________
<table>
<thead>
<tr>
<th></th>
<th>RISK FACTOR CARD</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Were you happy to receive the risk factor card</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Yes □ No □</strong></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Were you aware of your risk factors prior to receiving the card</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Yes □ No □ □ Some risk factors</strong></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Did the risk factor card make you think about the health related behaviour that you could change <em>(please circle one number not at all’ (1) to ‘to a large extent’ (10))</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patients comments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>TELEPHONE SUPPORT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Has the conversation with the nurse motivated you to make healthy changes to your lifestyle? <em>(please circle one number not at all’ (1) to ‘to a large extent’ (10))</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Was the information given in the telephone call useful? <em>(please circle one number not at all’ (1) to ‘to a large extent’ (10))</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Would you like the health professional to contact you after your discharge to follow up on your health? <em>(please tick one box only)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Yes □ No □ □ Unsure</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patients comments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>______________________________________________________________________________</td>
<td></td>
</tr>
</tbody>
</table>

Appendices A-401
## PATIENT DIARY

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Options</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Was the patient diary useful (please circle one number: not at all' (1) to `to a large extent' (10))</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>15</td>
<td>Have you entered any records</td>
<td>Yes ☐</td>
<td>No ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Overall rating of the intervention (please circle one number: not at all' (1) to `to a large extent' (10))</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

**Patients comments**

______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________
Appendix 24  Take the HeLM booklet

Congratulations
on your decision to read this guide. You have made an important decision to protect your health and have a healthy lifestyle. You will get the most out of this booklet when you write on it, underline/highlight and take note of the main points.

This booklet is unique because it recognises that you are different from other patients and you may or may not have already started a healthy lifestyle. Some of you will have already made changes to your lifestyle. Regardless of the progress that you have already made you will find this booklet extremely useful.

So why all this fuss about health lifestyle?
While in hospital you would have been informed that you have coronary artery disease and would have received information about heart disease but just to recap..............

What is Coronary Artery disease?
When you have coronary artery disease, the coronary arteries (those arteries supplying the heart with blood and oxygen) become narrowed or blocked due to a gradual build up of fatty and scar like materials (plaque) which leads to angina or heart attack. Coronary artery disease (CAD) is the largest single cause of death in Australia.

What can I do now?
Factors that increase your chances of further heart disease are called risk factors. Fortunately most of them can be controlled through healthy lifestyle changes.
Here is the list of risk factors. Tick how many you have?

- Age
- Male (Males have a higher incidence of heart attacks)
- Family history of heart disease
- High blood pressure (Do you know your blood pressure reading?)
- Smoking (You have more than twice the chance of heart attacks if you smoke)
- Diabetes (Do you know your blood sugar reading?)
- High cholesterol (Do you know your cholesterol reading?)
- Obesity (being overweight)
- Lack of exercise
- Stress

You cannot change these

These can be modified

START TODAY TO REDUCE YOUR RISK OF FUTURE HEART ATTACKS

Changing your lifestyle is not an easy process. People who make lifestyle changes generally travel through five different STAGES according to how they feel about the habits they want to change.

You cannot change these

These stages are:
- Not Intending To Change (Precontemplation)
- Thinking Seriously About Changing (Contemplation)
- Getting Ready To Change (Preparation)
- Changing To Healthy Habits (Action)
- Continuing The Healthy Habits (Maintenance)

As you experience these changes you will face challenges. This booklet will provide you with information and ideas you can use to help you make the changes and overcome the challenges.

HOW DO YOU FEEL ABOUT YOUR EXERCISE, DIET AND SMOKING HABITS?

Take the quiz below to find out.

Physical Activity Regular Exercise is any planned physical activity (e.g., brisk walking, aerobics, jogging, bicycling, swimming, rowing, etc.) performed to increase physical fitness. Physical activity should be undertaken 3 to 5 times per week for at least 30 minutes per session. According to this definition do you exercise regularly? (Please tick one box only)

- No, and I do NOT intend to in the next 6 months. (not intending to change)
- No, but I intend to in the next 6 months. (thinking about changing)
- No, but I intend to in the next 20 days. (getting ready to change)
- Yes, I have been for less than 6 months. (changing to healthy habits)
- Yes, I have been for more than 6 months. (maintaining change)
Fat intake (Please tick one box only)

- I haven't given the matter of the fat in my diet any thought at all. (not intending to change)
- I think about the fat in my diet from time to time, and then put the matter out of my head. (not intending to change)
- I keep meaning to do something to lessen the fat in my diet, but don't actually get around to it. (thinking about changing)
- From time to time I avoid fat in my diet, but at other times I go back to eating too much fat. (getting ready to change)
- I have been consciously avoiding fat in my diet for 6 months or less. (changing to healthy habits)
- I have been consciously avoiding fat in my diet for longer than the last 6 months. (maintaining change)

Smoking

Are you currently a smoker?

- Yes (please tick only one box in the section below)
- No, not thinking of quitting (not intending to change)

- Are you seriously thinking of quitting smoking?
  - Yes, within the next 6 months (thinking about changing)
  - Yes, within the next 30 days (getting ready to change)
  - No (please tick only one box in the section below)
  - I quit within the last 6 months (changing to healthy habits)
  - I quit more than 6 months ago (maintaining change)
  - I have never smoked

PLEASE WRITE DOWN YOUR STAGE OF CHANGE FOR:

- Physical activity _____________ (eg. not intending to change)
- Fat Intake _________________ (eg. thinking about change)
- Smoking _________________ (eg. getting ready to change)

HOW TO USE THIS BOOKLET

This HELM booklet has sections for each of the five STAGES OF CHANGE. Now that you have identified your stage of change for each of the health related behaviour, go to the appropriate section to identify strategies to enable you complete the journey. Each section is colour coded.

Think of adopting a healthy lifestyle as a journey with you at the HELM.
WHY DO PEOPLE SMOKE?

People have said that they smoke because they:

- Enjoy smoking
- Feel relaxed after smoking
- Can concentrate better after smoking
- Don’t have the willpower to break the habit
- Have been smoking for years so why stop now? The damage if any is already done.
- Have a stressful life/job and smoking helps them cope with difficult moments
- Are afraid of gaining weight if they quit smoking

WHY SHOULD I STOP SMOKING?

Here are some reasons why:

- Have more energy
- Be able to breathe better
- Stop coughing
- Prevent house fires
- Have a healthy heart
- Set a good example for others
- Have the satisfaction of winning the battle with cigarettes
- Live longer
- Spend less money
- Feel fresh in the morning after waking up
- Be less nervous
- Have fewer wrinkles
- Protect your children
- Have unstained teeth
- Improve your sense of taste
- Have a fresher breath
- Reduce the risk of many cancers

WHY DO I SMOKE?

Take the time to sit back and ask yourself why you smoke. Highlight the ones that apply to you from the above list. Add other reasons in the space below.

__________________________________________________________

__________________________________________________________

__________________________________________________________

LIST YOUR REASONS FOR QUITTING SMOKING:

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________
DID YOU KNOW?
- The risk of developing lung cancer drops to half after you have stopped smoking for 10 years.
- Regardless of your age and the number of years you smoked, stopping smoking is the most important thing you can do to protect your health.
- Smokers have more than twice the risk of getting a heart attack compared to non-smokers.

You now know how you will benefit by quitting smoking. It is entirely your decision to take the next step to quit. However, some doubts such as these might creep into your head:
- Is it worth the trouble?
- What if I fail?
- What will my friends think of me?

Have a look at the reasons that you have ticked and listed on page 7.

WHAT CAN I DO? HOW DO I START?
- Talk to your GP
- Contact the quit line (131 848)
- Read information on the harmful effects of smoking
- Keep a smoker's journal: before lighting up write the date, time, your mood, the strength of your urge to smoke, what triggered the urge to smoke as well as ways to resist them.
- Don't carry matches, try not to buy cigarettes
- Keep cigarettes out of reach
- Don't buy a new pack till you have finished the previous one
- Calculate the cost of smoking
- Keep asking yourself why you smoke
- Inform friends, family and colleagues and ask for support
- Talk to ex-smokers and other people like you who are trying to change
SIGN A CONTRACT WITH YOURSELF

I (Name) ___________________________
will start my action plan on the
Date __________ Month ______ Year ________
and by the following date I will be a non-smoker

Date __________ Month ______ Year ________

CERTAIN HIGH RISK SITUATIONS MIGHT DISRUPT YOUR PLAN TO QUIT. Here are some strategies to help you through them.

<table>
<thead>
<tr>
<th>HIGH RISK SITUATION</th>
<th>MANAGEMENT STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>When others are smoking</td>
<td>• Avoid them</td>
</tr>
<tr>
<td></td>
<td>• Choose non smoking places</td>
</tr>
<tr>
<td></td>
<td>• Prepare yourself for what you will say them</td>
</tr>
<tr>
<td>After a meal</td>
<td>Leave the table immediately</td>
</tr>
<tr>
<td>If you feel stressed</td>
<td>Try listening to relaxation tapes</td>
</tr>
<tr>
<td>When drinking</td>
<td>Cut down on alcohol</td>
</tr>
</tbody>
</table>

LIST YOUR HIGH RISK SITUATION
________________________________________________________
________________________________________________________
________________________________________________________
________________________________________________________

LIST YOUR MANAGEMENT STRATEGIES
________________________________________________________
________________________________________________________
________________________________________________________
________________________________________________________
CRISIS MANAGEMENT PLAN
(in case you smoke a cigarette)

- NEVER CONSIDER YOURSELF AS A FAILURE
- GET SUPPORT FROM FAMILY AND FRIENDS
- REFLECT ON THE REASONS THAT PROVOKED YOU TO SMOKE
- DO NOT PUNISH YOURSELF. AVOID MAKING YOURSELF FEEL GUILTY
- ABOVE ALL, AVOID GOING BACK TO REGULAR SMOKING
- DO NOT BUY CIGARETTES, AND THROW AWAY THE CIGARETTES IN YOUR POSSESSION
- TELL YOURSELF THAT THIS CIGARETTE IS GOING TO BE THE LAST ONE
- LOOK BACK. ANALYSE THE REASONS WHY YOU SMOKED
- REMIND YOURSELF OF YOUR DECISION NOT TO SMOKE
- CONSIDER THIS HITCH AS A NORMAL, LEARNING EXPERIENCE
- CALL ON THE HELP OF THOSE AROUND YOU

THE DAY HAS ARRIVED ...
YOU NOW NEED TO TAKE ACTIONS THAT ARE REQUIRED TO BRING ABOUT CHANGE

- Prepare yourself for the day.
- Make sure you have thrown out all cigarettes, ash trays and lighters
- Keep reminding yourself as to why you are doing this
- Ask family and friends for support
- Reward yourself (not with a chocolate)
- Set short term goals

STRATEGIES TO OVERCOME THIS STAGE

- DO NOT give up. As time goes by your chances of success increase
- DO NOT smoke even one cigarette. It is much easier to refuse the first cigarette than to refuse the second.
- USE your strategies for high risk situations
- USE your "Crisis Management Plan" in case you smoke again
- USE the nicotine replacement therapy (NRT) as advised by your GP
TO PREVENT RELAPSE

Remind yourself that:

- Your willpower is strong
- This is just a passing phase
- You can do without it
- If you get depressed:
  - see your GP
  - get support from family
  - get professional help if required
  - do not get annoyed
  - warn people around you

WHAT ELSE CAN I DO?

Here are some strategies to PREPARE yourself for symptoms of withdrawals

- Assure yourself that the feeling will pass away
- Do some exercise/Undertake a sport
- Cut down on coffee and/or alcohol
- Brush your teeth often to leave a fresh taste in your mouth
- Do deep breathing exercises when you get the urge
- If your partner is a smoker, urge him or her to quit too.
- Talk with your support person
- Consult your GP
- Make yourself busy
- Get plenty of rest
- Drink plenty of water
- Eat fresh fruit or vegetables
- Do crafts or activity with your hands
- Use a relaxation technique
- Be proud of yourself!

LIST YOUR STRATEGIES TO OVERCOME THE SYMPTOMS OF WITHDRAWAL:

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________
I HAVE SMOKED A CIGARETTE. WHAT NOW?

- It’s not the end of the world
- Do not consider yourself as a failure
- Use your "Crisis Management Plan"
- Re-read your lists of high-risk situations
- Identify methods that you can use to better resist cigarettes in these situations
- Think of all the efforts that you have already made and which will be lost if you start smoking again.
- Relapsing is quite common as part of the change process.
- You should not be ashamed of it
- Every attempt to stop smoking will increase your chance of success

CONGRATULATIONS FOR NOT SMOKING FOR AT LEAST 6 MONTHS
YOU SHOULD BE PROUD OF YOUR SUCCESS

Research has shown that the longer you stay a non-smoker the easier it becomes. Staying a non-smoker requires a strong will power as well as some additional support, skills and knowledge.

STRATEGIES FOR CONTINUING TO BE A NON-SMOKER

- Stay motivated
- Reread your list of the advantages of quitting.
- Refrain from picking up a cigarette
- Learn how to react without getting agitated
- Calm yourself by changing activities
- Do not let your guard down. Remember your commitment.
- Use your "Crisis Management Plan" in case you smoke again
- If, in the past, you have already attempted to quit and relapsed to smoking, a good way to prevent a future relapse consists of reflecting back on the circumstances under which you relapsed in the past.

It is VERY IMPORTANT not to take even a single drag of a cigarette. The first cigarette is easier to refuse than the second.
WHY SHOULD I BECOME PHYSICALLY ACTIVE? Here are some reasons why

**BY BEING PHYSICALLY ACTIVE YOU WILL:**
- Improve your muscle tone
- Control diabetes better
- Be able to concentrate better
- Lower the risk of falls
- Feel less stressed and anxious
- Improve symptoms of chronic disease such as arthritis
- Live longer
- Improve bone density, reducing the risk of osteoporosis (bone loss) and fractures as you get older.
- Lose weight if you are overweight
- Feel more confident and happy
- Sleep soundly
- Lower your blood pressure and cholesterol
- Feel less tired and have more energy
- Recover better if you have had a heart attack
- Set a good example for others
- Above all you will have fun

LIST YOUR REASONS FOR BEING PHYSICALLY ACTIVE:

---

DID YOU KNOW?

- Approximately 37% of coronary heart disease is caused due to physical inactivity.
- Being active for 10 minutes, 3 times a day is as good as one 30 minute period of activity.
- Exercising has even helped 80 and 90 year old people living in nursing homes to grow stronger and more independent.
You now know how you will benefit by being physically active. It is entirely your decision to take the next step to start exercising. However some doubts such as these might creep into your head.
- Is it worth the trouble?
- What if I fail?
- What will my friends think of me?

Have a look at the reasons that you have ticked and listed on page 22.

**WHAT ARE THE DIFFERENT TYPES OF ACTIVITIES**

**Moderate-intensity physical activity:**
Any activity that burns 3.5 to 7 Calories per minute (kcal/min). These can be
- walking briskly
- mowing the lawn
- dancing
- bicycling
- swimming for recreation

**Vigorous-intensity physical activity:**
Any activity that burns more than 7 Calories per minute (kcal/min). These could be
- jogging
- doing heavy yard work
- bicycling uphill
- swimming continuous laps
- participating in high-impact aerobic dancing

**WHAT CAN I DO? HOW DO I START?**
- Start by knowing the different types of activities
- Consult your GP before starting doing any form of exercise
- Make the time
- Discuss your concerns with peers, family, friends, or co-workers who are physically active. Find out what keeps them motivated
  - Think about:
  - How active your job is
  - How active are you during lunch or breaks at work
  - What activity do you do before or after work
  - How often do you participate in physical activity
  - What kind of activities do you do on the weekend or day off work
  - How often do you do active indoor/outdoor chores

**LIST SOME ACTIVITIES THAT YOU COULD USE TO MAKE PROGRESS:**

- 
- 
-
KEEP A TRACK OF WHAT EXERCISES YOU DO INCLUDING HOW MUCH YOU WALK FOR A WEEK

Physical Activity Log

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre breakfast</td>
<td>Between breakfast &amp; lunch</td>
<td>Between lunch and dinner</td>
<td>Post dinner</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DID YOU KNOW?
- You need 30 minutes of moderate-intensity physical activity on most, preferably all, days of the week to achieve health benefits (total 150 mins/week).

CONGRATULATIONS ON YOUR DECISION TO BE ACTIVE

HERE ARE SOME STRATEGIES TO PREPARE YOURSELF
- Read your list of reasons why you want to be active
- Get support
- Find friends, co-workers or family who will join you for evening walks
- Keep comfortable walking shoes at work or in the car
- Have an exercise bag packed and ready to go
- Post motivating messages in your day planner or on your bathroom mirror
- Find the time

SELECT ONE OF THE FOLLOWING AREAS IN WHICH YOU THINK YOU CAN MAKE REALISTIC CHANGES.

<table>
<thead>
<tr>
<th>Work</th>
<th>Weekends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lunch/Break time</td>
<td>Active indoor chores</td>
</tr>
<tr>
<td>Before/after work</td>
<td>Active outdoor chores</td>
</tr>
</tbody>
</table>

Find at least three slots that you could devote to physical activity during the next week, and write them down.
WHAT ELSE SHOULD I DO?

- Make physical activity a priority
- Reward yourself
- Monitor your progress using the log
- Keep in mind that occasional setbacks do not mean failure

SIGN A CONTRACT WITH YOURSELF

I (Name) __________________________
will start my action plan on the
Date __________ Month __________ Year __________
and by the following date I will be physically active
Date __________ Month __________ Year __________

IN CERTAIN HIGH RISK SITUATIONS YOU MIGHT BE TEMPTED TO GIVE UP. Here are some strategies to help you through them.

<table>
<thead>
<tr>
<th>HIGH RISK SITUATION</th>
<th>MANAGEMENT STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>When it rains</td>
<td>Hire a physical activity video and exercise at home</td>
</tr>
<tr>
<td>Lack of time</td>
<td>Select activities requiring minimal time, such as walking, jogging, or climbing stairs</td>
</tr>
<tr>
<td>Non-supportive friend</td>
<td>• Be assertive in your response</td>
</tr>
<tr>
<td></td>
<td>• Invite friends and family members to exercise with you. Plan social activities involving exercise</td>
</tr>
<tr>
<td></td>
<td>• Develop new friendships with physically active people</td>
</tr>
<tr>
<td></td>
<td>• Join a local health club</td>
</tr>
<tr>
<td>On vacation</td>
<td>• Put a jump rope in your suitcase</td>
</tr>
<tr>
<td></td>
<td>• Walk the halls and climb the stairs in hotels</td>
</tr>
<tr>
<td></td>
<td>• Stay in places with swimming pools or exercise facilities</td>
</tr>
<tr>
<td></td>
<td>• Visit the local shopping mall and walk for half an hour or more</td>
</tr>
<tr>
<td></td>
<td>• Carry a small tape recorder and your favourite aerobic exercise tape</td>
</tr>
</tbody>
</table>

LIST YOUR HIGH RISK SITUATION

_____________________________

LIST YOUR MANAGEMENT STRATEGIES

_____________________________
CRISIS MANAGEMENT PLAN
(In case you stop exercising)

- NEVER CONSIDER YOUR SELF AS A FAILURE
- GET SUPPORT FROM FAMILY AND FRIENDS
- REFLECT ON THE REASONS THAT MADE YOU STOP EXERCISING
- DO NOT PUNISH YOURSELF
- ABOVE ALL, DO NOT STOP EXERCISING
- TELL YOURSELF THAT THIS WAS GOING TO BE THE LAST DAY OF NO EXERCISE
- LOOK BACK. ANALYSE THE REASONS WHY YOU STOPPED EXERCISING
- REMIND YOURSELF OF YOUR DECISION TO EXERCISE
- CONSIDER THIS HITCH AS A NORMAL, LEARNING EXPERIENCE, AND NOT AS A FAILURE
- DO NOT PUNISH YOURSELF. AVOID MAKING YOURSELF FEEL GUILTY

THE DAY HAS ARRIVED ...

YOU NOW NEED TO TAKE ACTIONS THAT ARE REQUIRED TO BRING ABOUT CHANGE

- Prepare yourself for the day
- Make sure you have comfortable shoes for walking
- Keep reminding yourself as to why you are doing this
- Ask family and friends for support
- Set small goals that you can achieve
- Surround yourself with people who support your new, active lifestyle
- Leave encouraging notes to yourself at home, in the car or at the office
- Remember to park further away from the grocery store so that you can walk a few extra minutes
- Reward yourself to maintain motivation eg buy yourself a new pair of walking shoes
- Leave a pair of walking shoes at the office or in your car
STRATEGIES TO OVERCOME THIS STAGE

- DO NOT give up  As time goes by your chances of success increase
- USE your strategies for high risk situations
- USE your “Crisis Management Plan” in case you stop being physically active

TO PREVENT RELAPSE

Remember to stay motivated
- Remind yourself that
  - you have a strong willpower
  - this is just a passing phase
  - you can remain physically active
- Think of all the efforts that you have already made and which will be lost if you stop
- Be physically active
- Re-read your lists of high-risk situations and either identify the techniques that you can use to better resist or avoid these situations.

WHAT ELSE CAN I DO?

- Have a healthy diet
- Do sit-ups in front of the TV
- Walk during lunch hour
- Take a family walk after dinner
- Mow the lawn with a push mower
- Play with your kids for at least 30 minutes a day
- Dance to music
- Walk briskly in the mall
- Take the stairs instead of the elevator

LIST YOUR STRATEGIES FOR BEING PHYSICALLY ACTIVE:

<table>
<thead>
<tr>
<th>Exercise 1</th>
<th>Exercise 2</th>
<th>Exercise 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CONGRATULATIONS FOR UNDERTAKING PHYSICAL ACTIVITY FOR AT LEAST 6 MONTHS
YOU SHOULD BE PROUD OF YOUR SUCCESS

Research has shown that the longer you maintain these healthy changes the easier it becomes. Maintaining physical activity requires a strong willpower as well as some additional support, skills and knowledge.

STRATEGIES FOR CONTINUING TO BE PHYSICALLY ACTIVE

- Stay motivated
- Do not let your guard down. Instead, reaffirm your commitment
- Re read your list of the advantages of being physically active
- Use your “Crisis Management Plan” in case you stop being physically active
- If, in the past, you have already attempted to walk and relapsed a good way to prevent a future relapse is reflecting back on the circumstances under which you relapsed in the past

HELPFUL HINTS

- Choose activities that you like
- Make small changes so that physical activity becomes a part of each day
- Stop and check with your doctor right away if you develop sudden pain, shortness of breath, or feel ill.
- Exercise with a group, with a buddy, or alone. Pick easy and fun exercises
- Be realistic about what you can do
- Participate in exercise programs at the local gym or council
- Borrow books or tapes about exercise from your local library
- Mentor others. Being a role model will bring good feelings from helping others and will reinforce your motivation to stay with your active lifestyle

BARRIERS TO PHYSICAL ACTIVITY

- Inconvenient in the beginning
- Have to concentrate more on what activity you do throughout the day
- Have to plan ahead of time
- Having to deal with family members

MAKE A LIST OF SOME OF THE PROBLEMS YOU THINK YOU MIGHT HAVE TO OVERCOME:

<table>
<thead>
<tr>
<th>Problem 1</th>
<th>Problem 2</th>
<th>Problem 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
WHY DO PEOPLE EAT UNHEALTHY / HIGH FAT FOODS?

PEOPLE HAVE SAID THAT THEY DO NOT EAT HEALTHY FOODS
BECAUSE THEY:
- Cannot or have no time to cook
- Believe healthy foods have no taste
- Will not be able to eat their favourite food
- Don’t like trying new foods
- Feel that healthy foods are expensive
- Have a hard/stressful job and eating helps them to cope
- Are not overweight so why bother
- They are fit and healthy and healthy eating is only if you are sick
- Eat on the run
- Say there are not many healthy eating stops for truckies
- Feel that there is a lot of about healthy eating and it is confusing
- Believe in fate (if I have to get heart disease, I will get it no matter what I eat)

WHY DON’T I EAT HEALTHY FOODS?
Take the time to sit back and ask yourself why you continue to eat unhealthy foods. Highlight the ones that apply to from the above list. Add other reasons in the space below.

not intending to change thinking about change getting ready to change changing unhealthy habits maintaining change

BY HAVING HEALTHY EATING HABITS YOU WILL:
- Lower your risk of heart disease, diabetes, high blood pressure, osteoporosis, obesity and some types of cancers
- Feel energetic and be able to spend more time with grandchildren
- Lose weight if you are overweight
- Have better control over your health

LIST YOUR REASONS FOR HEALTHY EATING:

DID YOU KNOW?
- Half the Australian people have high cholesterol
- Baked foods, sauces, confectionery, cheese, snack foods, nuts, and coating on fried foods consist of nearly half the fats and oils in the Australian diet
- High fat foods provide only calories and no nutrients
- People like the taste and feel of fat so they over-consume without knowing
- 21% of the Australian population aged 25 years and over are obese
You now know how you will benefit by having healthy eating habits. It is entirely your decision to take the next step to start eating healthy. However some doubts such as these might creep into your head.

- Is it worth the trouble?
- What if I fail?
- What will my friends think of me?

Have a look at the reasons that you have ticked and listed on page 36.

WHAT CAN I DO? HOW DO I START?

- Start by eating less fat, particularly animal fat
- High fat increases your risk of getting heart disease, diabetes and some types of cancer
- Keep yourself informed of foods that are high in fats. These foods are:
  - Baked foods: cakes, muffins, pastries, fried foods, oil and fat used in cooking
  - Snacks: nuts, chips, chocolate
  - Toppings: salad dressings, butter, mayonnaise and gravy
  - Dairy foods: full cream cheese, whole milk, ice-cream, cream
  - Fat in meat and skin on the chicken
  - Watch your serving size
  - Be careful with choosing foods to be eaten on the run

LIST SOME ACTIVITIES YOU COULD USE TO MAKE PROGRESS:

- 
- 
- 

Healthy eating is eating all your favourite foods with making small changes in the way the food is prepared

Changing your eating habits is not an easy thing to do

<table>
<thead>
<tr>
<th>What is a Serving</th>
<th>A serving of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooked meat</td>
<td>Approximately the size of the palm of your hand, a deck of cards, or an audiocassette tape</td>
</tr>
<tr>
<td>Chopped vegetables or fruit</td>
<td>1/2 cup, or approximately half a baseball</td>
</tr>
<tr>
<td>Fresh fruit</td>
<td>One medium piece, or the size of a baseball</td>
</tr>
<tr>
<td>Cooked pasta, rice, or cereal</td>
<td>1/2 cup, or half a baseball</td>
</tr>
<tr>
<td>Cooked beans</td>
<td>1/2 cup, or half a baseball</td>
</tr>
<tr>
<td>Nuts</td>
<td>A level handful for an adult</td>
</tr>
</tbody>
</table>
KEEP A TRACK OF WHAT AND HOW MUCH YOU EAT INCLUDING SNACKS FOR A WEEK

My Food Analysis Chart

<table>
<thead>
<tr>
<th></th>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td>Morning Tea</td>
<td>Lunch</td>
<td>Dinner</td>
<td>Any other food</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

You now have an idea of how much fat you eat and how much you should cut out.

DID YOU KNOW?

- Fats contain twice the amount of calories of protein and carbohydrates.
- Eating a handful of nuts five times a week may reduce the risk of coronary heart disease by 30-51%.

CONGRATULATIONS ON YOUR DECISION TO CHANGE

HERE ARE SOME STRATEGIES TO PREPARE YOURSELF

- Read your list of reasons
- Reduce fat intake
- Introduce healthy foods gradually start with one serving of vegetables / day

SO WHAT SHOULD I EAT?

- Six or more servings of whole grain cereals, breads, pasta and other products
- Fish, poultry without skin and leaner cuts of meat instead of fatty ones
- Fat-free or 1% milk dairy products rather than whole milk dairy products.
- At least five servings of fruits and vegetables every day
- A wide variety of foods low in saturated fat and cholesterol
- Nuts and seeds in moderation
**WHAT ELSE SHOULD I DO?**

- Cut back on alcohol, coke and other caffeinated beverages
- Read food labels and choose foods low in saturated fat and cholesterol
- Use unsaturated vegetable oils like canola, corn, olive
- Enjoy 30-60 minutes of vigorous activities on most or all days of the week
- Drink plenty of water
- Maintain a healthy weight
- Keep yourself informed of alternate products that are available
- Learn the facts about cholesterol
- When shopping for foods PICK THE TICK
- Look for foods with the new GI symbol

**IN CERTAIN HIGH RISK SITUATIONS YOU MIGHT BE TEMPTED TO GIVE UP. Here are some strategies to help you through them.**

<table>
<thead>
<tr>
<th>HIGH RISK SITUATION</th>
<th>MANAGEMENT STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>When others are eating fatty foods</td>
<td>Avoid them, prepare yourself for what you will say them</td>
</tr>
<tr>
<td>If you feel stressed</td>
<td>Try to relax, try deep breathing</td>
</tr>
<tr>
<td>When drinking</td>
<td>Cut down on alcohol</td>
</tr>
<tr>
<td>Movies, parties, birthdays and other special events</td>
<td>Eat before you go out, Carry low fat cereal bars, Choose the lowest fat items, Plan ahead how you are going to deal with the situation</td>
</tr>
<tr>
<td>Eating out</td>
<td>Choose low fat foods</td>
</tr>
<tr>
<td>On waking up</td>
<td>Have some breakfast/snack</td>
</tr>
<tr>
<td>Coffee break at work</td>
<td>Have a healthy snack</td>
</tr>
<tr>
<td>Hungry, watching television, working late, travelling</td>
<td>Snack on raw vegetables</td>
</tr>
<tr>
<td>Driving past fast food outlets, seeing some one else eat your favourite high fat food</td>
<td>Talk yourself out of it</td>
</tr>
</tbody>
</table>

**LIST YOUR HIGH RISK SITUATION**

**LIST YOUR MANAGEMENT STRATEGIES**

---

Select a Day to start your Low fat diet.

SIGN A CONTRACT WITH YOURSELF

I (Name) __________________________________________________________________________

will start my action plan on the

Date __________ Month _______ Year __________

and by the following date I will be eating less fat

Date __________ Month _______ Year __________
CRISIS MANAGEMENT PLAN
(In case you start eating high fat foods)

- NEVER CONSIDER YOURSELF AS A FAILURE
- GET SUPPORT FROM FAMILY AND FRIENDS
- REFLECT ON THE REASONS THAT PROVOKED YOU TO START EATING HIGH FAT FOODS
- DO NOT PUNISH YOURSELF
- ABOVE ALL, AVOID STARTING EATING HIGH FAT FOOD REGULARLY. DO NOT BUY ADDITIONAL HIGH FAT FOODS AND THROW AWAY THOSE IN YOUR POSSESSION
- TELL YOURSELF THAT THIS PIECE OF FOOD WAS GOING TO BE THE LAST ONE
- REMIND YOURSELF OF YOUR DECISION TO EAT HEALTHY
- CONSIDER THIS MISTAKE AS A NORMAL, LEARNING EXPERIENCE, AND NOT AS A FAILURE

THE DAY HAS ARRIVED ...

YOU NOW NEED TO TAKE ACTIONS THAT ARE REQUIRED TO BRING ABOUT CHANGE

- Prepare yourself for the day
- Make sure you have thrown out all foods that are high in fat
- Keep fresh fruit and vegetables in the house
- Keep reminding yourself as to why you are doing this
- Ask family and friends for support
- Reward yourself (not with a chocolate)
- Set small goals
- Talk to others about changing your eating habits
- Experiment with new low-fat foods or recipes
- Remind yourself that changing behaviour takes time.
- You are determined to win
- You are nearly half way there

STRATEGIES TO OVERCOME THIS STAGE

- DO NOT give up. As time goes by your chances of success increase
- DO NOT eat any high fat food
- USE your strategies for high risk situations
- USE your "Crisis Management Plan" in case you eat high fat food again
TO PREVENT RELAPSE

- Stay busy
- Go to the movies, exercise
- Munch on carrots or celery sticks
- Do crafts or activity with your hands
- Listen to relaxation audiotapes
- Set smaller goals for each week
- Don’t keep high fat foods around you
- Choose places to eat where you can get low fat foods
- Eat before you go to a party
- Drink plenty of water
- Tell your family and friends of your plan
- Buy skim milk instead of full fat milk, low fat cheese slices and low fat ice-cream

WHAT ELSE CAN I DO?

- Use less fat in cooking, don’t fry or deep fry foods
- Remove visible fat from meat and poultry
- Choose low fat dairy products
- Choose lean meat & avoid eating the skin on the chicken or turkey
- Fry ground meat in a non stick pan and drain of excess fat
- Have fresh fruit for desert
- Use frozen mixed vegetables these can save you time
- Bake, broil or barbeque, grill foods
- Decrease your serving size
- The size of the meat should be as big as the palm of your hand
- Limit the number of slices of meat in sandwiches
- Fill up with more salads, vegetables and fruit
- Use mustard or low fat mayonnaise on sandwiches instead of butter or margarine

LIST YOUR STRATEGIES FOR EATING LOW FAT FOODS:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
CONGRATULATIONS FOR ACTIVELY EATING A DIET LOW IN FAT FOR AT LEAST 6 MONTHS
YOU SHOULD BE PROUD OF YOUR SUCCESS

Research has shown that the longer you maintain these healthy changes the easier it becomes. Eating healthy requires a strong will power as well as some additional support, skills and knowledge.

STRATEGIES FOR CONTINUING TO EAT HEALTHY FOODS

- Use your crisis management plan in case you start eating fatty foods again
- Top your favourite cereal with apples or bananas
- Chew food slowly, and enjoy its flavours and textures
- Carry a healthy, low calorie lunch to work
- Try to have legumes more often as salad, soup, main meal or accompaniment
- Cut raw vegetables such as celery or carrots and keep them ready to be eaten in case you are hungry
- Try a green salad instead of fries
- Drink plenty of water
- Stay motivated
- Refrain from eating high fat foods
- Don't skip breakfast
- Snack on fruits and vegetables
- Eat before grocery shopping
- Make a grocery list before you shop
- When you get home from work and are hungry eat a piece of fresh fruit

DOES EATING LESS FAT COST MORE

- Fresh produce cost less
- Lean meats cost more but there is less wastage and therefore better value for money

Fat content of some common foods
(Compare the total fat of the following foods to a golf ball which weighs approximately 45 grams)

<table>
<thead>
<tr>
<th>Food</th>
<th>Fat (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Big Mac</td>
<td>24.9</td>
</tr>
<tr>
<td>Cheese burger</td>
<td>12.1</td>
</tr>
<tr>
<td>Large fries</td>
<td>23.3</td>
</tr>
<tr>
<td>6 chicken nuggets</td>
<td>19.8</td>
</tr>
<tr>
<td>Quarter pounder with cheese</td>
<td>28.5</td>
</tr>
<tr>
<td>KFC large popcorn chicken</td>
<td>31</td>
</tr>
<tr>
<td>Regular pies</td>
<td>15.35</td>
</tr>
<tr>
<td>Small serve cheesecake</td>
<td>23</td>
</tr>
<tr>
<td>Full Cream Milk</td>
<td>9</td>
</tr>
</tbody>
</table>

BARRIERS TO HEALTHY EATING

- Inconvenient in the beginning
- Have to plan meals ahead of time
- Have to concentrate more on what you eat through out the day
- Having to deal with family members

MAKE A LIST OF SOME OF THE PROBLEMS YOU THINK YOU MIGHT HAVE TO OVERCOME:

________________________________________________________________________
________________________________________________________________________
Important Resources

NSW Quitline............................................Contact 13 1848 or www.quit.org.au

The National Heart Foundation of Australia...Contact 1300362787 or www.heartfoundation.com.au

Dietitians Association of Australia...........Contact (02) 6282 9555 www.daa.asn.au

Nutrition Australia............................................Contact 4221 5346 www.nutritionaustralia.org

Diabetes Australia............................................Contact 1300136588 www.diabetesaustralia.com.au

Cardiac Rehabilitation Centres
Liverpool (02) 9828 3000
Campbelltown (02) 4634 3000
Bankstown (02) 9722 7963
Fairfield (02) 9616 8153
Bowral (02) 4861 0290

This booklet has been prepared by Ms Ritin Fernandez from the South Western Sydney Centre for Applied Nursing Research as a requirement for the completion of the PhD and is based on the best available evidence at the time of publication.

© Ritin Fernandez 2006.
## Appendix 25  Personalised risk factor card

### PERSONAL RISK FACTOR CARD

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Normal level</th>
<th>Your level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family History of heart disease</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>Non smoking</td>
<td>Never smoked</td>
</tr>
<tr>
<td>Physical activity</td>
<td>150 minutes/week</td>
<td>200 minutes/week</td>
</tr>
<tr>
<td>Body Mass Index (BMI) which indicates your weight status (Calculated from weight and height)</td>
<td>Between 18.5 and 24.9 kg/m²</td>
<td>24.7 kg/m²</td>
</tr>
<tr>
<td>Lipids</td>
<td>Normal values</td>
<td></td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>Less than 4.0 mmol/L</td>
<td>6.2 mmol/L</td>
</tr>
<tr>
<td>LDL-C</td>
<td>Less than 2.5 mmol/L</td>
<td></td>
</tr>
<tr>
<td>HDL-C</td>
<td>More than 1.0 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Less than 2.0 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Diabetes (blood sugar)</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Normal values</td>
<td>Your values</td>
</tr>
<tr>
<td>Systolic (upper)</td>
<td>Less than 140</td>
<td>100</td>
</tr>
<tr>
<td>Diastolic (lower)</td>
<td>Less than 90</td>
<td>72</td>
</tr>
<tr>
<td>Current history of heart disease</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

According to the guidelines used by the National Heart Foundation of Australia\(^1\), as you were admitted to hospital with a cardiac event, your chance of having further heart disease in the next 5 years is more than 20%.

This risk level is considered to be **HIGH**.

From the information that you have given us, and your blood test results, you have 1 risk factor which you can modify to reduce your chance of having a further heart event.

It is now your decision to change these to prevent you from having further heart problems.

As you have never smoked, you have reduced your risk of heart disease considerably.

The “HeLM” booklet will provide you with strategies to modify these risk factors.

---

Appendix 26  Patient feedback form

South Western Sydney
Centre for Applied Nursing Research
(A joint initiative between the University of Western Sydney and Sydney South West Area Health Service)

Date

Dear (Name of participant)

While in hospital you would have been informed that you have coronary heart disease and would have received information about heart disease. As you are aware the risk factors that caused your event still exists and you need to take measures to prevent further occurrences by changing these.

Your risk factor status is listed below

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Normal level</th>
<th>Your level</th>
<th>Do I need to do something about it</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipids</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>Less than 4.0 mmol/L</td>
<td>8 mmol/L</td>
<td>Definitely</td>
</tr>
<tr>
<td>LDL-C</td>
<td>Less than 2.5 mmol/L</td>
<td>2.5 mmol/L</td>
<td></td>
</tr>
<tr>
<td>HDL-C</td>
<td>More than 1.0 mmol/L</td>
<td>2.2 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Less than 2.0 mmol/L</td>
<td>1.5 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Less than 140/90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td>150 minutes /week</td>
<td>None</td>
<td>Definitely</td>
</tr>
<tr>
<td>Blood glucose</td>
<td>HbA1c&lt;= 7%</td>
<td>12</td>
<td>Definitely</td>
</tr>
<tr>
<td>Weight</td>
<td>BMI less than 25 kg/m2</td>
<td>28</td>
<td>Definitely</td>
</tr>
</tbody>
</table>

You also indicated that

- Smoking
  - [ ] You are not yet consciously considering the possibility of changing your diet habits (precontemplation)
  - [ ] Thinking about the pros and cons of making or rejecting a change relating to smoking. (contemplation)
  - [ ] Preparing yourself for change (preparation )
  - [ ] Determined to change and are doing something. (Action )
  - [ ] You have maintained this change for at least 6 months (maintenance )

- Physical Activity
  - [ ] You are not yet consciously considering the possibility of changing your diet habits (precontemplation)
  - [ ] Thinking about the pros and cons of making or rejecting a change relating to smoking. (contemplation)
  - [ ] Preparing yourself for change (preparation )
  - [ ] Determined to change and are doing something. (Action )
  - [ ] You have maintained this change for at least 6 months (maintenance )
Healthy eating

- You are not yet consciously considering the possibility of changing your diet habits (precontemplation)
- Thinking about the pros and cons of making or rejecting a change relating to smoking. (contemplation)
- Preparing yourself for change (preparation)
- Determined to change and are doing something. (Action)
- You have maintained this change for at least 6 months (maintenance)

Please find enclosed a booklet that will provide you with information about how to make changes and reduce your risk of further cardiac events.

This information is provided to you so that you are aware of your risk factors and can make the necessary changes. A health professional will contact you within 2 weeks if you require assistance with the booklet. He/she will also contact you after 1 month, 2 months and 3 months to see how you are managing. If you need any additional information please do not hesitate to ring us on 98286589

Good luck
Dr (Name),
60 Smart St,
Fairfield NSW 2165

Dear Doctor Name,

Mr (Patients Name) was recently admitted to Liverpool Hospital for an elective PCI under the care of Dr (Dr’s Name). Mr (patient’s name) informs us that he attends your General Practice at (address).

The Liverpool Health Service, in conjunction with the South Western Sydney Centre for Applied Nursing Research (CANR), is presently conducting a clinical trial: “Health related lifestyle management in patients with Acute Coronary Syndrome”. (“HeLM”). The aim of this randomised controlled trial is to investigate the effects on patients with coronary artery disease of a brief lifestyle self-management intervention, as compared to usual care, on behavioural change in relation to their smoking, fat intake, attendance at cardiac rehabilitation, and physical activity.

As (patient’s name) meets the inclusion criteria for this trial, a representative of CANR asked him/her, during his stay in the Hospital’s Coronary care Unit, if he/she would consent to participate in this clinical trial. (patient’s name) has agreed to be a participant in this trial.

The trial protocol includes feedback, telephone support, and a follow-up personal interview by a health professional with your patient at Liverpool Hospital at the end of six weeks. This assessment includes a questionnaire and a blood pressure measurement. No invasive procedures will be performed. This trial has been approved by the SWSAHS Human Research Ethics Committee and by the University of Western Sydney Ethics Review Committee (Human Subjects).

If you would like to know more about this clinical trial, please do not hesitate to contact Ms Ritin Fernandez or Mr Bruce Stafford at the Centre for Applied Nursing Research, telephone 9828-6587. For the purposes of this trial, however, the Centre cannot disclose to you whether (patient’s name) is in the control group or the intervention group.

Yours faithfully,

Bruce Stafford
Senior Research Officer
Telephone 9828-6588
Appendix 28  Interviewer guide for motivation support

Questions to be asked according to each stage of change

PRE CONTEMPLATION STAGE

Goal: Client will begin thinking about change.

QUESTIONS
1. What would have to happen for you to know that this is a problem?
2. What warning signs would let you know that this is a problem?
3. Have you tried to change in the past?

CONTEMPLATION STAGE

Goal: Client will examine benefits and barriers to change.

QUESTIONS
1. Why do you want to change at this time?
2. What were the reasons for not changing?
3. What would keep you from changing at this time?
4. What are the barriers today that keep you from change?
5. What might help you with that aspect?
6. What things (people, programs and behaviours) have helped in the past?
7. What would help you at this time?
8. What do you think you need to learn about changing?

PREPARATION STAGE

Goal: Intending to start positive behaviour in the next month or has tried previously

QUESTIONS
1. What are the good things about the way you're currently trying to change? What are the not-so-good things?
2. What would be the good result of changing?
3. What are the barriers to changing?
4. Pick one of the barriers to change and list some things that could help you overcome this barrier.
5. Pick one of those things that could help and decide to do it by
6. If you've taken a serious step in making a change:

**ACTION STAGE**

*Goal: Successfully maintained positive behaviour from 1 day to 6 months*

**QUESTIONS**

1. What made you decide on that particular step?
2. What has worked in taking this step?
3. What helped it work?
4. What could help it work even better?
5. What else would help?

**MAINTENANCE STAGE**

*Goal: Maintaining the positive behaviour pattern for more than 6 months*

**QUESTIONS**

1. If you're changing and trying to maintain that change: Congratulations! What's helping you?
2. What else would help?
3. What are your high-risk situations?
4. If you've gone back to your old ways: What worked for a while? Don't kick yourself--long-term change almost always takes a few cycles.
5. What did you learn from the experience that will help you?
**Stage of Change: CONTEMPLATION**

*Outcome:* The client is making change statements and is thinking towards making a commitment to changing the behaviour.

<table>
<thead>
<tr>
<th>Things to Consider</th>
<th>Therapist Tasks</th>
<th>Strategies</th>
</tr>
</thead>
</table>
| ▶ Individuals in this stage of change are inconsistent.  
▶ They are keen to consider the problem and possibility of change.  
▶ They are quite open to information and yet wait for the one final piece of information that will compel them to change. (magic moment or an overwhelming piece of information that will make the decision for them.  
▶ This is a particularly opportune time for motivational interviewing strategies.  
▶ Contemplation and interest in change are not commitment. Information and incentives to change are important elements for assisting contemplators. Personally relevant information can have a strong impact at this stage. | 1. Consider the pros and cons (from the clients perspective) of the problem behavior, as well as the pros and cons of change.  
2. Gather information about past change attempts. Frame these in terms of some success rather than change failures.  
3. Explore options the client has considered for the change process and offer additional options where indicated and if the client is interested. Remember that our clients are rarely novices to the change process.  
4. Elicit change statements. | 1. Inquire about the good and less good things of the problem behaviour.  
2. Explore concerns.  
3. Help identify resources/support |
### Stage of Change: PREPARATION

**Outcome:** The client is making clear change statements and has an action plan in place.

<table>
<thead>
<tr>
<th>Things to Consider</th>
<th>Therapist Tasks</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>► Despite making a decision to alter behavior, change is not automatic. Ambivalence, though diminishing, is still present. The decision-making process is still occurring and ► pros and cons are still being weighed.</td>
<td>1. Assess strength of commitment. Strong verbal statements may be a sign of weak commitment. Calm dedication to making this a top priority is a good sign 2. Examine barriers and elicit solutions 3. Build coping behaviors 4. Reinforce commitment but provide words of caution</td>
<td>1. Determine why client continues the risk related behaviours. Assist client in building an action plan and removing barriers. Set a date for change behaviour. 2. Examples of key questions are: What do you think you will do? What's the next step? It sounds like things can't stay how they are now. What are you going to do? 3. Specific statement of changes to be made Why these changes are important? 4. Steps in making these changes 5. Inclusion of others in the plan 6. A method for evaluating the plan 7. Identify possible barriers to the plan</td>
</tr>
</tbody>
</table>
## Stage of Change: ACTION

**Outcome:** Changes in behaviour are clearly visible

<table>
<thead>
<tr>
<th>Things to Consider</th>
<th>Therapist Tasks</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>▶ This stage involves a continuous effort towards making positive changes. ▶ Clients have made a plan and have started implementing it. ▶ Issues of ambivalence and commitment remain. ▶ Often individual do not go back and re-assess their change plan. Where is it working? Where did it not? Is there a procedure for re-evaluating the plan? Has there been any planning for handling little slips?</td>
<td>1. Increase client's self-efficacy by: 2. Focusing on successful activity 3. Reaffirming commitment 4. Acknowledge the success 5. Refer them to the HeLM Booklet.</td>
<td>1. Use interventions that therapist has experienced in providing (e.g. skill building, active problem solving), 2. Refer individual to HeLM manual</td>
</tr>
</tbody>
</table>
**Stage of Change: MAINTENANCE**

*Outcome: Client is maintaining the positive behaviour*

<table>
<thead>
<tr>
<th>Things to Consider</th>
<th>Therapist Tasks</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>▶ Maintenance is also a crucial stage as relapse is possible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▶ Relapse may occur due an initial slip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▶ During these times the client is frightened and has low self-efficacy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▶ Clients seek reassurance from therapists while trying to make sense of the crisis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Review the action plan and a strategy for periodic review of the plan should be stated.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. If a client has relapsed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Explore factors precipitating and maintaining the crisis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Provide information and feed back</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Provide empathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Explore what succeeded, as well as what is causing their current concerns.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Identify possible triggers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Offer models of success while normalizing relapse in situations where change is not easily accomplished.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Reinforce and support their active efforts in making change possible and their commitment to change.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Review the Stages of Change model and explain that relapse is part of the change process</td>
<td></td>
</tr>
</tbody>
</table>


# Appendix 29  Health Diary

**Contents**

- Personal data 2
- Insurance information 3
- Emergency medical information 4
- Family medical history 5
- Doctors’ contact details 8
- Allergies, immunisations 10
- Medical history 12
- Fractures, x-rays, surgeries 14
- Physical examinations, illness and injury 16
- Medicines 18
- Cholesterol 20
- Blood pressure 22
- Weight 23
- HbA1C 24
- Urine microalbumin 25
- Foot care 26
- Eye examination 27
- Notes 28
Appendix 30  Ethics approval for the HeLM study (SSWAHS western zone)

Ms Ritin Fernandez
CANRE
Liverpool Hospital
Locked Bag 7103
LIVERPOOL BC  1871

Dear Ms Fernandez,

Project No 2006/043 - Randomised Controlled Trial (RCT) of a Multifaceted Intervention to Promote Behavioural Changes Related to Risk Factors in Patients with Coronary Artery Disease – A Pilot Study

The SSWAHS Human Research Ethics Committee wishes to acknowledge receipt of your correspondence with regards to the above project.

As all of the issues raised by the Committee have now been satisfactorily addressed, formal approval is hereby granted for this study to proceed as a Category A Project.

Ethics clearance is granted for periods of up to twelve months. This project will be due for renewal on 30th April, 2007 and you must provide a Progress Report (attached) or final report by this date. If no report is supplied, ethics clearance for this project may be cancelled.

Your attention is drawn to the attached document Guidelines for Investigators which sets out not only the principles under which research should be conducted, but also the conditions under which Ethics approval is granted by the Committee. Also enclosed for your information, is a copy of the document Guidelines for Responsible Practice in Research and Dealing with Problems of Research Misconduct.

Please note that the Committee must be notified IMMEDIATELY of any untoward or unexpected complications or side affects arising during the project or of any ethical or medico-legal problems that may arise. Also, any changes to the original protocol must be submitted to the Committee for approval.

Would you please quote the above project number in all future correspondence relating to this project.

Yours sincerely,

PROFESSOR HUGH DICKSON
Chairperson
SSWAHS Human Research Ethics Committee

For:   Mr Mike Wallace
       Chief Executive, SSWAHS

Category A: Projects with limited risk potential, including quality assurance surveys.
Category B: Projects with significant patient risks.
Category C: Drug trials (international/national) sponsored by drug companies and already covered for risk evaluation and monitoring of adverse reactions.
Appendix 31  Ethics approval for the HeLM study (UWS)

30 August 2006

Locked Bag 1797
Penrith South DC NSW 1797 Australia

Ms Ritin Fernandez
South Western Sydney Centre for Applied Nursing Research
Liverpool Hospital
Locked Bag 7103
Liverpool BC 1871

Dear Ritin,

HREC 06/117 The Health related lifestyle management (HeLM) in patients with acute coronary syndrome study

The Committee reviewed your application that was submitted to Human Research Ethics Committee (Western Zone). The UWS HREC has agreed to endorse the approval granted by this Committee.

You are advised that the Committee should be notified of any further change/s to the research methodology should there be any in the future. You will be required to provide a report on the ethical aspects of your project at the completion of this project. The form is located on the Research Services Ethics Web Page.

The Protocol Number HREC 06/117 should be quoted in all future correspondence about this project. Your approval will expire 30 June 2007. Please contact the Human Ethics Officer, Kay Buckley on tel: 02 47 360 883 if you require any further information.

The Committee wishes you well with your research.

Yours sincerely,

[Signature]

Associate Professor Louise O’Brien
Acting Chairperson & Deputy Chairperson
UWS Human Research Ethics Committee