ACUPUNCTURE TREATMENT IN THREATENED MISCARRIAGE: A MIXED METHODS STUDY

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A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy, Centre for Complementary Medicine Research, School of Science and Health, University of Western Sydney.

August 2013
Statement of Authentication

I declare that this thesis does not incorporate without acknowledgement any material previously submitted for a diploma or degree in any university, and that to the best of my knowledge it is original and does not contain any materials previously published or written by another person except where due reference is made in the text.

Debra Betts
August 2013
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<table>
<thead>
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<th>Description</th>
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<tbody>
<tr>
<td>APH</td>
<td>Antepartum haemorrhage</td>
</tr>
<tr>
<td>APS</td>
<td>Antiphospholipid syndrome</td>
</tr>
<tr>
<td>ßhCG</td>
<td>Beta human chorionic gonadotropins</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CAM</td>
<td>Complementary and Alternative therapies</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
</tr>
<tr>
<td>CNKI</td>
<td>China National Knowledge Infrastructure</td>
</tr>
<tr>
<td>CRL</td>
<td>Embryo Crown Rump Length</td>
</tr>
<tr>
<td>CV-I</td>
<td>Content Validity Index</td>
</tr>
<tr>
<td>ED</td>
<td>Emergency Department</td>
</tr>
<tr>
<td>ESFRE</td>
<td>European Society of Human Reproduction and Embryology</td>
</tr>
<tr>
<td>FPI</td>
<td>Fertility Problem Inventory</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>hCG</td>
<td>Human chorionic gonadotropins</td>
</tr>
<tr>
<td>IVF</td>
<td>In vitro Fertilisation</td>
</tr>
<tr>
<td>LMC</td>
<td>Lead Maternity Caregiver</td>
</tr>
<tr>
<td>MAU</td>
<td>Maternity Assessment Unit</td>
</tr>
<tr>
<td>MMR</td>
<td>Mixed Methods Research</td>
</tr>
<tr>
<td>MSD</td>
<td>Mean Gestation Sac Diameter</td>
</tr>
<tr>
<td>MYMOP</td>
<td>Measure Yourself Medical Outcome Profile</td>
</tr>
<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>PRF</td>
<td>pregnancy-related fear</td>
</tr>
<tr>
<td>PROM</td>
<td>Premature Rupture of the Membranes</td>
</tr>
<tr>
<td>PPROM</td>
<td>Preterm Premature Rupture of Membranes</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>RR</td>
<td>Relative Risk</td>
</tr>
<tr>
<td>SIGP</td>
<td>Special Interest Group Early Pregnancy</td>
</tr>
<tr>
<td>STRICTA</td>
<td>STandards for Reporting Interventions in Clinical Trials of Acupuncture</td>
</tr>
<tr>
<td>TLC</td>
<td>Tender Loving Care</td>
</tr>
<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
</tr>
<tr>
<td>NZQA</td>
<td>New Zealand Qualification Association</td>
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<tr>
<td>NZRA</td>
<td>New Zealand Register of Acupuncturists</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Abstract

Threatened miscarriage is a common complication of early pregnancy, with risk factors for miscarriage or pregnancy complications that may include premature delivery. Currently, no Western medical pharmacological or non-pharmacological management is strongly recommended, resulting in medical monitoring with a ‘watchful waiting’ approach. While it is known that chromosomal abnormalities are responsible for approximately 50% of miscarriages, treatment options may be available for women where these factors are absent. The overarching aim of this study is to explore supportive care with a focus on the role of acupuncture in the treatment of threatened miscarriage. The following research questions are addressed:

1. What is the current interest and use of acupuncture among acupuncturists, and what are their considerations for clinical practice compared to textbook recommendations?
2. Is acupuncture a feasible intervention to deliver, and what effect does acupuncture have on quality-of-life and pregnancy outcomes for women with threatened miscarriage compared to women receiving supportive care?
3. What do Western-trained health practitioners consider optimal clinical practice for the treatment of threatened miscarriage?
4. What are women’s experiences of threatened miscarriage and the care they receive?

A mixed methods research (MMR) approach is used with quantitative methods for a survey and a pilot randomised controlled trial (RCT), and qualitative methods are used for semi-structured interviews and Internet-based data collection. Four studies are undertaken, including an online survey of acupuncturists in Australia and New Zealand in which practitioners have been purposely selected for an interview. A pilot RCT is undertaken, which involves 39 women who have received acupuncture or an active control of touch, with women interviewed as they exited the RCT. Western health practitioners who treat women with threatened miscarriage are also interviewed, and data are collected from threatened miscarriage discussion forums on the Internet. Thematic analysis is used to code and analyse the data from the interviews and Internet
forums. A ‘following-a-thread’ technique and dialectic approach is used to integrate the data sets.

Women express dissatisfaction with the care they receive from their Western health practitioners, and challenge medical authority when this support is not received. The value of hope emerges as a key theme, with women demonstrating a need for emotional support in addition to medical monitoring. This support involves offering the possibility of hope for a viable pregnancy, offering hope by doing everything possible and providing access to information by talking to a knowledgeable person.

Western health practitioners and acupuncturists have different approaches to the care they offer women, as well as different perceptions on acupuncture as a treatment for threatened miscarriage. Western health practitioners offer medical monitoring and maintain a professional responsibility not to give ‘false hope’ by using the results of medical diagnostic tests and preparing women for potential pregnancy loss. These practitioners see acupuncture as one of many complementary alternative medicine (CAM) therapies that have the potential to provide relaxation, but not as a treatment that can influence pregnancy outcomes. In contrast, acupuncturists see themselves as offering a treatment to stimulate positive qi responses in early pregnancy through acupuncture, diet and lifestyle advice, and therapeutic support. Acupuncturists also express concern about the safety of treatment if used incorrectly, and they describe using diverse treatment modalities for acupuncture and moxibustion in clinical practices to treat threatened miscarriage.

The RCT demonstrates that acupuncture is a feasible treatment to offer in a Western clinical setting, and it demonstrates a statistically significant improvement for threatened miscarriage symptoms such as anxiety due to vaginal bleeding, abdominal cramping and back ache (MD 1.36; 95% CI, 0.07, 2.66, p=0.04).

In conclusion, women presenting with threatened miscarriage seek care beyond medical monitoring from Western health practitioners. In addition, they actively seek hope for a viable pregnancy, with medical expertise challenged when this is not provided. This study demonstrates how acupuncture treatment meets women’s emotional needs for support, including hope, and how it significantly reduces symptoms related to
threatened miscarriage. This study provides clinical guidance for acupuncturists treating women with threatened miscarriage, as well as information for Western health practitioners wanting to offer these women support. This thesis also provides knowledge for future research to investigate what types of care women view as supportive, as well as the potential of acupuncture as a treatment for women presenting with this common complication of early pregnancy.
Chapter 1: Introduction and Background

1.1 Introduction

This chapter begins by presenting the Western medical background for threatened miscarriage. This includes the definition of threatened miscarriage and a discussion on the incidence, aetiology and pregnancy and birthing outcomes, followed by a description of the incidence and aetiology of miscarriage and Western medical treatment considerations. The concept of acupuncture as a practice in traditional Chinese medicine (TCM) is then introduced, followed by a discussion of the historical and current use of acupuncture in the treatment of threatened miscarriage. A literature review of the current evidence for the treatment of threatened miscarriage follows, which includes both Western medical and acupuncture treatment approaches. Finally, this chapter concludes with the rationale and aim for this study and the chapter structure of this thesis.

1.2 Miscarriage

Miscarriage refers to a spontaneous pregnancy loss prior to the embryo or foetus being sufficiently developed to survive. This has been defined by the World Health Organization (WHO) as a gestation of 20 weeks or a foetal weight of less than 400 grams (Zegers-Hochschild et al. 2009) and this is the definition used in New Zealand. In the United Kingdom (UK), this viability limit is extended to a gestation of 24 weeks (Swer & Jurkavic 2011). A pregnancy loss that occurs after these viability criteria have been reached is termed as a stillbirth if there are no signs of life or a neonatal death if there are signs of life.

Miscarriage is a common complication of early pregnancy, with an estimated 10–20% of all clinically recognised pregnancies ending in miscarriage (Royal College of Obstetricians and Gynaecologists 2006). Although a miscarriage can occur in either the first or second trimester of a pregnancy, the majority occur in the first trimester, with an
estimated 1–2% of pregnancy losses occurring in the second trimester (Royal College of Obstetricians and Gynaecologists 2011a). Recurrent miscarriage is a term that describes reoccurring pregnancy loss. The incidence of recurrent miscarriage has been estimated to be 1–2% of women trying to conceive when defined as three or more consecutive pregnancies in the first trimester (Royal College of Obstetricians and Gynaecologists 2011a). When this definition is expanded to include women who have experienced two or more consecutive pregnancy losses, this incidence increases to at least 3% of all couples trying to conceive (Regan & Rai 2000).

1.2.1 Defining Threatened Miscarriage

Threatened miscarriage involves a history of vaginal bleeding (with or without abdominal pain), a cervical os that remains closed and a presumed viable pregnancy (Swer & Jurkavic 2011). The presence of a viable foetus differentiates threatened miscarriage from inevitable, incomplete or missed miscarriage, where there is no possibility of a pregnancy continuing. Although threatened miscarriage differs from miscarriage at the time of assessment due to this potential for the pregnancy to continue, there are increased risk factors for subsequent pregnancy loss. In this chapter, threatened miscarriage is first defined with the incidence, possible causes for vaginal bleeding and pregnancy outcomes before proceeding to discuss the aetiology of miscarriage in general.

The most accurate method for determining the viability of a pregnancy is ultrasound scanning (Swer & Jurkavic 2011). While advances in ultrasound scanning technology mean that it is now possible to identify a pregnancy through a gestational sac at four and a half gestational weeks and a yolk sac at five gestational weeks, the presence of cardiac activity at six gestational weeks is recommended to confirm viability (Obstetricians and Gynaecologists Royal College of Physicians of Ireland 2010). This definition of foetal viability is used in this study in accordance with the recommendations in the threatened miscarriage literature (Saraswat et al. 2010).
1.2.2 Incidence and Pregnancy Outcomes of Threatened Miscarriage

It is difficult to accurately assess the incidence and pregnancy outcomes for threatened miscarriage in the general population. Underreporting may occur due to women initially being unaware they are pregnant and assuming that any subsequent bleeding is related to menstruation, or they may not seek medical attention because family, friends and Internet information sites may reassure them that some early bleeding in pregnancy is normal and can be viewed as harmless ‘spotting’ or ‘implantation bleeding’.

When reports of vaginal bleeding during pregnancy were assessed in the community, it was reported as a common complication of early pregnancy. A prospective community study from the UK that involved pregnant women seeking care from their general practitioner (GP) reported that bleeding occurred in 21% of recognised pregnancies before the 20th gestational week. Of the women who experienced bleeding, nearly half (42.7%) continued to have a viable pregnancy at 20 gestational weeks (Everett 1997).

When threatened miscarriage was examined in hospital clinics, there was a range of reported pregnancy loss outcomes. In prospective cohort studies where establishing cardiac activity was defined as the entry criteria, pregnancy losses until 14 gestational weeks were reported at 6.6–21% (Adam et al. 2011; Johns & Jauniaux 2006; Johns et al. 2007; Mukri et al. 2008). When the pregnancy loss was extended to 20–24 gestational weeks, this was reported as 5.5–26.6% (Basama & Crosfill 2004; Calleja-Agius et al. 2010; Dongol et al. 2011; Falco et al. 1996; Makrydimas et al. 2003; Özkaya et al. 2011; Poulse et al. 2006; Tongsong et al. 1995).

Although retrospective cohort studies have limitations due to the potential for inaccurate record keeping and missing data, these studies reported miscarriage rates following a diagnosis of threatened miscarriage that was in the range of prospective cohort studies. When hospital records for women presenting to hospital clinics for threatened miscarriage were analysed for subsequent miscarriage rates, they were reported as 9.3–19% (Bennett et al. 1996; Juliano et al. 2008; Papaioannou et al. 2011).
1.2.3 Risk Factors for Threatened Miscarriage

1.2.3.1 Gestational age and effect

Pregnancy loss in the first trimester is known to reduce with increasing gestational age (Bottomley 2011). A higher mean gestational age at recruitment may account for some of the variation in pregnancy loss in these studies. Pregnancy loss was lowest in prospective cohort studies that recruited women with a mean gestational age of eight and nine weeks, with pregnancy losses of 5% (Tongsong et al. 1995), 6.6% (Johns et al. 2007), 9.3% (Johns & Jauniaux 2006) and 11.1% (Poulose et al. 2006). Authors reporting a mean gestational age of seven weeks reported pregnancy losses of 16% (Makrydimas et al. 2003) and 22% (Mukri et al. 2008). This range of pregnancy loss according to gestational age was also reported by Basama and Crosfill (2004), with a 29% miscarriage rate for women recruited at 5–6 gestational weeks compared to 8.2% for women recruited at 7–12 gestational weeks.

When the risk of a subsequent miscarriage for women presenting with threatened miscarriage was compared to women at a similar gestational age that did not experience vaginal bleeding, two prospective cohort studies demonstrated an increased risk of early pregnancy loss. Women presenting with threatened miscarriage were at twice the risk for a subsequent pregnancy loss according to Tongsong et al. (1995) (relative risk (RR), 2.9; 95% confidence interval (CI), 1.06, 7.96, p<0.05) and Makrydimas et al. (2003) (RR, 2.6; 95% CI, 1.27, 5.03, p=0.008).

1.2.3.2 Vaginal bleeding and effect

In addition to gestational age, a further consideration with threatened miscarriage is the nature of the vaginal bleeding reported. The bleeding that women experience in early pregnancy may range from light occasional spotting to bleeding that is similar to, or heavier than, menstruation. The timing of vaginal bleeding may also be relevant; following sexual intercourse, bleeding may occur due to local irritation of the cervix. While there is often a perception that light, inconsistent bleeding—frequently termed ‘spotting’—may be normal or harmless in early pregnancy, this perception has not been confirmed by research.
It is difficult to assess whether women with light bleeding are included in the research, as the majority of prospective studies to date fail to report their entry criteria for the type or amount of vaginal bleeding (Adam et al. 2011; Calleja-Agius et al. 2010; Falco et al. 1996; Makrydimas et al. 2003; Mukri et al. 2008; Özkaya et al. 2011; Tongsong et al. 1995). When light bleeding has been mentioned, it has been as an exclusion criterion (Johns et al. 2007), or the type of bleeding is poorly defined (Basama & Crosfill 2004). The exception to this reporting is a study by Poulase et al. (2006), who defined light bleeding as bleeding that is lighter than a period.

When compared to women with no reported bleeding, light bleeding that is defined as ‘spotting’ or bleeding that is lighter than a period indicates that women are at risk for pregnancy complications. In a prospective multicentre investigation (Weiss et al. 2004), 16,506 women were enrolled at 10–14 gestational weeks to examine subsequent pregnancy loss, pregnancy complications and birthing outcomes until 24 gestational weeks. While the overall pregnancy loss was 0.5% for all women in this study, there were statistically significant differences for women experiencing a pregnancy loss who had experienced bleeding prior to study entry, both when the bleeding was defined as light (spotting only) and experienced by 13% of women (odds ratio (OR), 2.5; 95% CI, 1.5, 4.3) and when bleeding was described as heavy (similar to menstruation) and experienced by 1% of women (OR, 4.2; 95% CI, 1.6, 10.9).

It is possible that by failing to define the nature of bleeding in studies, women with light ‘spotting’ have not been fully accounted for in the research. Although asking women to report their vaginal bleeding does have limitations in terms of subjectivity, if asked at the time of bleeding or with recall bias if asked at a later date, this method has been shown to be reliable. In a study examining bleeding characteristics such as spotting among 153 women, a high level of agreement was found with reporting in a web-based diary kept by women and their later recall at a first-trimester interview (Hasan et al. 2009). Although the authors acknowledged that women in this study came from a motivated, educated group and the act of keeping a diary may have assisted with later recall, they suggested that the presence of spotting or bleeding in early pregnancy may be a noteworthy event for many women, thus reducing recall bias, and that this information was relevant to further studies when examining the incidence and extent of potential pregnancy loss for women presenting with bleeding in early pregnancy.
For some women, the onset of bleeding in threatened miscarriage may result from intrauterine bleeding between the chorion and the uterine wall—a subchorionic hematoma. These hematomas can be identified on ultrasounds, but the clinical relevance of being able to identify their presence and size remains uncertain. In an attempt to assess independent risk factors associated with the presence of a hematoma, a retrospective case-controlled study (Ball et al. 1996) compared two subgroups of women matched for maternal and gestational age. One group comprised women with a subchorionic haemorrhage and vaginal bleeding (n=166) and the other group comprised women with a subchorionic haemorrhage and no vaginal bleeding (n=72). The authors reported that there was no statistical significance for adverse pregnancy outcomes between these two groups. However, when women with a subchorionic haemorrhage and vaginal bleeding were case-matched with women who had bleeding but no subchorionic haemorrhage (n=167), there was an increased number of spontaneous miscarriages for women with a subchorionic haemorrhage that approached statistical significance (p=0.057). Although further evidence of statistical and clinical significance is required, the authors suggested that this indicated the possibility that the presence of a subchorionic haemorrhage without vaginal bleeding posed no additional risk factors for subsequent miscarriage, but that for women with a subchorionic haemorrhage and vaginal bleeding, there may be an increased risk for subsequent miscarriage.

It remains uncertain whether the physical size of a hematoma is relevant to the prognosis of a subsequent miscarriage. While increased risk factors for adverse pregnancy outcomes have been reported for women with threatened miscarriage where the hematoma has been defined as large (Dongol et al. 2011; Maso et al. 2005; Özkaya et al. 2011; Poulse et al. 2006), other authors have found no link to the size of the bleeding as seen on an ultrasound (Falco et al. 1996; Jouppila 1985). As ultrasound technology continues to improve, a clearer understanding may develop to explain the clinical implications of the presence of subchorionic bleeding for the prognosis of women presenting with threatened miscarriage. However, there is also a possibility that ultrasound scanning as a diagnostic tool will never provide the complete answer. Ball et al. (1996) suggested that the total effect of a subchorionic hematoma on a pregnancy may involve not only the blood collecting in the hematoma, but also the amount of
blood reabsorbed in the uterus and the amount of blood lost through the cervix as vaginal bleeding. Therefore, the visualisation of a hematoma on an ultrasound in isolation may never be the most reliable way of measuring the total effect of a subchorionic hematoma on pregnancy outcomes.

1.2.3.4 Uterine fibroids as a possible cause for vaginal bleeding

At present, the possible effects of uterine fibroids (leiomyomas) on women presenting with threatened miscarriage is undetermined. While vaginal bleeding in the first trimester may be more common in women who have uterine fibroids, it may not be the presence of vaginal bleeding, but rather the location of the fibroid in relation to embryo implantation and the developing placenta that determines the potential for subsequent pregnancy loss (Ouyang et al. 2006).

1.2.4 Pregnancy Complications and Birthing Outcomes of Threatened Miscarriage

In addition to subsequent pregnancy loss, women presenting with threatened miscarriage may remain at risk for adverse maternal and perinatal outcomes. These potential risks were examined in a systematic review of threatened miscarriage outcomes (Saraswat et al. 2010). This review of 14 studies, which was the first systematic review to examine both maternal and perinatal outcomes, reported increased maternal and perinatal risks for women presenting with threatened miscarriage. Increased maternal risks for antepartum haemorrhage (APH) and preterm premature rupture of membranes (PPROM) were found for women with first-trimester vaginal bleeding. The risks for APH include those attributed to placenta praevia (OR, 1.62; 95% CI, 1.19, 2.22, p=0.002) and of unknown origin (OR, 2.47; 95% CI, 1.52, 4.02, p=0.0003) with risk factors for PPROM (OR, 1.78; 95% CI, 1.28, 2.48, p=0.00007). In terms of perinatal outcomes, there were increased risk factors for preterm delivery (before 37 completed weeks) (OR, 2.05; 95% CI, 1.76, 2.4, p< 0.00001), for babies with intrauterine growth restriction (OR, 1.54; 95% CI, 1.18, 2.00 p=0.001), low birth weight (≤2500 g) (OR, 1.83; 95% CI, 1.48, 2.28 p<0.00001) and for increased perinatal mortality (OR, 2.15; 95% CI, 1.41, 3.27, p=0.0004).
Saraswat et al. (2010) also reported risks that were statistically significant but with lower odds ratios that were not seen as having clinical relevance. These included women with a history of early pregnancy bleeding being more likely to deliver babies with an Apgar score of <7 five minutes after birth (OR, 1.2; 95% CI, 1.03, 1.4, p=0.02) and to have their babies admitted to the neonatal unit (OR, 1.13; 95% CI, 1.03, 1.23, p=0.009). The authors concluded that women with first-trimester bleeding had an increased risk factor for APH, PPROM and preterm delivery, and that their babies had an increased risk factor for intrauterine growth restriction, low birth weight and increased perinatal mortality. Although these risk factors are low (OR ≤ 2) for the majority of women and their babies, Saraswat et al. (2010) recommended that their findings be used to alert health practitioners to these risk factors.

A literature review that examined the effects of a range of first-trimester complications on maternal and perinatal outcomes included four studies involving threatened miscarriage (van Oppenraaij et al. 2009). The authors used levels of evidence and an OR>2 to determine clinically relevant associations for the risk of low birth weight (RR, 2.3; 95% CI, 1.9, 2.7) and very low birth weight (<1500 g) (RR, 2.2; 95% CI, 1.3, 3.5) for women who presented with a threatened miscarriage. Additional increased risk factors were found for APH, placental abruption, placenta praevia, PPROM and preterm delivery; however, these associations were viewed by the authors as questionable in terms of clinical relevance.

These risk factors for threatened miscarriage continue to be reported. In the most recent study (Dadkhah et al. 2010), the pregnancy outcomes for 500 women reporting bleeding before 20 gestational weeks were compared to 500 women with no episodes of bleeding. Women were then monitored from 20 gestational weeks until delivery. While there were no statistically significant differences found for age, parity and body mass index (BMI) between the two groups, the authors reported an increased risk of poorer pregnancy outcomes for all women with bleeding (which included episodes of spotting, which were termed mild, as well as bleeding that was similar to, or heavier than, menstruation, which was termed severe). Increased risks were found for spontaneous preterm labour (RR, 1.4; 95% CI, 1.2, 1.5, p=0.001), premature rupture of membranes (PROM) (RR, 2.1; 95% CI, 1.2, 2.3, p=0.02) and placental abruption (RR, 1.1; 95% CI, 1.01, 1.2, p=0.01). The mean birth weight of the babies born at term to women reporting
bleeding was also less than those reporting no vaginal bleeding \((p=0.001)\). For women presenting with threatened miscarriage, there were no risk factors for preeclampsia or caesarean section deliveries (Dadkhah et al. 2010; Saraswat et al. 2010; van Oppenraaij et al. 2009). However, the reported risk factors for clinically relevant associations including APH, preterm delivery, increased perinatal mortality (Saraswat et al. 2010), low and very low birth weight (van Oppenraaij et al. 2009) and PROM (Dadkhah et al. 2010) suggest that women presenting with threatened miscarriage may be at risk for adverse maternal and perinatal outcomes beyond that of a subsequent miscarriage.

1.2.5 General Causative Factors Involved in Miscarriage

A variety of underlying mechanisms may be responsible for early miscarriage. These involve chromosomal abnormalities, teratogenic drugs, maternal medical conditions and maternal uterine abnormalities (Swer & Jurkavic 2011).

For first-trimester miscarriages, chromosomal abnormalities are reported to be responsible for approximately 50% of spontaneous miscarriages that occur. While single studies have reported rates as high as 70% (Ogasawara et al. 2000; Saraswat et al. 2010), a pooled analysis of 11 studies involving 4,696 spontaneous miscarriages using the methods of cytogenetic evaluation currently available (tissue sampling, culture technique and direct preparation of chorionic villi) reported 49% as chromosomally abnormal (Goddijn & Leschot 2000). Genetic analysis is costly at present, with practical difficulties involved in obtaining the embryonic or foetal tissue for testing. This may limit women seeking cytogenetic evaluation to those already concerned about their fertility or those receiving fertility treatment. There is also potential for inaccuracies, as both the standard methods of testing—metaphase karyotyping and the recent development of comparative genomic hybridisation—have limitations due to the possibility of maternal cell contamination (Lathi et al. 2011). However, the extent of chromosomal abnormalities occurring in spontaneous miscarriages may become more accurate as this technology develops. The majority of chromosomal abnormalities are trisomies, with the risk increasing for women aged 35 years and over. An estimated 20% of pregnancies in women aged 35 years and over result in miscarriage, while for women aged 45 years and over, this figure is 74.7% (Swer & Jurkavic 2011).
Further aetiological factors associated with first-trimester miscarriage include teratogenic drugs (including cigarette smoking, consuming over four cups of coffee per day, consuming three or more units of alcohol per week and taking illicit drugs), maternal medical conditions such as uncontrolled diabetes and undiagnosed thyroid disorders, and maternal uterine anatomical abnormalities (Regan & Rai 2000).

The extent to which thrombosis is involved in first-trimester miscarriage remains uncertain. It had previously been suggested that inherited thrombophilias such as factor V Leiden, as well as acquired thrombophilias such as antiphospholipid syndrome (APS), may contribute through placental infarction; however, in early miscarriage, this has not been convincingly demonstrated. Pregnancy loss before 10 gestation weeks is now thought to be due to abnormal trophoblastic invasion and inflammation rather than thrombosis (Bennett et al. 2012; Check 2012; Danza et al. 2012). The extent to which thrombophilias may be causative factors in miscarriage following the first trimester, as well as in recurrent miscarriage, remains under investigation (Danza et al. 2012; McNamee et al. 2012a; McNamee et al. 2012b).

Second-trimester miscarriages are associated with a lower rate of chromosomal abnormalities, reducing to an estimated 15%, with other possible causes including infection, cervical weakness, structural uterine abnormalities or thrombophilia (Bottomley & Bourne 2009).

1.2.6 Current Treatment Considerations for Threatened Miscarriage

Currently, there are no strongly recommended medical pharmaceutical or therapeutic treatment options for women presenting with threatened miscarriage. Rather, a ‘wait and see’ approach is taken, with the recommendation to wait until three concurrent miscarriages have occurred before investigating possible causative factors (Jauniaux et al. 2006). While there has been research into the use of medications such as progesterone, anti-coagulant therapies and human chorionic gonadotropins (hCG), as well as the use of bed rest as a lifestyle intervention, the evidence to date does not support their use in clinical practice (Aleman et al. 2005; Devaseelan et al. 2010; Empson et al. 2005; Wahabi et al. 2011).
The cause of a woman miscarrying in either the first or second trimester is not always known, and causative factors are never identified for the majority of women who experience a miscarriage where chromosomal abnormalities are not detected (Bulletti et al. 1996). While the onset of bleeding in early pregnancy may be due to the aetiological factors associated with miscarriage, it may also be possible that the bleeding seen in threatened miscarriage has intrauterine causes such as subchorionic hematoma or early pregnancy hormonal responses, which are specific to threatened miscarriage. While there remains potential for an early pregnancy in this case to progress to a miscarriage, there is also a possibility that if these specific factors resolve, the pregnancy will continue. In cases where there are specific causes unrelated to miscarriage factors such as chromosomal abnormalities and teratogenic drugs, there exists a possibility that rather than wait for three miscarriages to occur before investigating treatment possibilities, there may be therapeutic interventions that have yet to be examined in the research. These therapeutic interventions relate to early pregnancy physiology and maternal stress responses, and they are discussed below.

1.2.7 Early Pregnancy Physiology and Stress Responses

In early pregnancy, progesterone levels are dependent on ovarian production until the placenta takes over production at 10–12 weeks (Stables 2005). While the immune responses to implantation and early embryo development are not yet fully understood, it is thought that immune and inflammatory responses capable of destroying the developing embryo are selectively compromised by progesterone (McNabb 2004). It is therefore theoretically possible that factors compromising the hormonal production of progesterone may negatively affect the developing pregnancy. It has been suggested that maternal stress in early pregnancy may promote overstimulation of the hypothalamic–pituitary–adrenal axis, resulting in decreased progesterone production and/or altered immune responses, therefore creating an unfavourable environment for maintaining a pregnancy (Nakamura et al. 2008).
1.2.7.1 Stress and chromosomally normal pregnancy loss

An association with recent negative life events and the risk of chromosomally normal pregnancy loss events has been reported (Neugebauer et al. 1996). In the study, 192 women were interviewed following early pregnancy loss for positive and negative life events, with chromosomally normal and abnormal loss identified post-interview through karyotyping. While no association was found for positive life events, there was an association between post-conception negative life events and chromosomally normal pregnancy loss (adjusted OR, 2.6; 95% CI, 1.3, 5.2). This association was unaltered by adjustments for smoking, caffeine intake and alcohol consumption. The authors concluded that early pregnancy loss following the physiological disruption caused by stressful life events was theoretically plausible, but that further research was required.

1.2.7.2 Emotional responses following previous pregnancy loss

It has also been reported that women with a history of prior miscarriages had higher levels of pregnancy-related fear during the first trimester of a subsequent pregnancy and that this early pregnancy-related fear (PRF) significantly correlated with complications during pregnancy, including that of threatened miscarriage (Fertl et al. 2009). In this prospective longitudinal study, 143 women with a history of a previous miscarriage were assessed for PRF and general anxiety during a subsequent pregnancy. PRF was evaluated using a pregnancy fear questionnaire that examined attitudes on pregnancy, sexuality and delivery, while anxiety was assessed using a State–Trait Anxiety Inventory that examined feelings of apprehension, tension, nervousness and worry. At each of the four assessment points, a control group was created using a sample of pregnant women without a history of miscarriage who were matched according to gestational weeks.

During the first trimester, PRF was significantly higher in pregnant women with a history of miscarriage than in the control group (p=0.001). When examining pregnancy complications, elevated PRF was associated with significantly more vaginal bleeding (p=0.01), although there was no association for elevated anxiety (p=0.40). In comparison, elevated anxiety in early pregnancy was associated with vertigo or low blood pressure (p=0.03). PRF and its association to vaginal bleeding in this study may
be an important consideration, with the authors suggesting that maternal stress may lead to increased production of stress hormones and may negatively influence the developing pregnancy.

In summary, the current research on a possible association between women’s stress responses in early pregnancy and their physiological effects on a pregnancy is limited. However, Nakamura et al. (2008) suggested that maternal stress responses have the potential to disrupt beneficial biological responses in early pregnancy; therefore, for women not miscarrying due to chromosomal abnormalities, interventions assisting them to moderate stress responses may be beneficial to promoting positive pregnancy outcomes. At present, interventions have not been examined that help women with threatened miscarriage to moderate their stress responses. However, research has examined the effectiveness of these interventions for women with a history of three or more unexplained recurrent miscarriages, and this research is discussed below.

1.2.8 Supportive Care as a Treatment Modality

Early pregnancy stress responses have been explored in unexplained recurrent miscarriage, with studies reporting that when these women receive medical monitoring and additional care—termed ‘supportive care’—this intervention increased live birth rates compared to women receiving standard antenatal care (Clifford et al. 1997; Liddell et al. 1991; Stray-Pedersen & Stray-Pedersen 1984). While it is unknown why supportive treatment reduces miscarriage rates among women with recurrent miscarriage (Clifford et al. 1997), two of the authors of the supportive care studies have suggested that the provision of regular medical monitoring and reassurance may reduce stress for these women, which will in turn positively affect pregnancy outcomes (Brigham et al. 1999; Liddell et al. 1991).

The findings on the use of supportive care for unexplained recurrent miscarriage may be relevant to women with threatened miscarriage. Liddell et al. (1991) reported that 40% of the women in their research who received supportive care experienced symptoms of threatened miscarriage, often bleeding for several weeks. The increased incidence of successful live-birthing outcomes for women receiving supportive care when
experiencing vaginal bleeding raises interesting possibilities that this care may play a role in treatment in threatened miscarriage.

However, the concept of providing supportive care remains ill-defined, as the care described by the authors used a variety of terminologies without specifying details of the care that women received. This terminology includes antenatal counselling, emotional support, psychological support, supportive care and tender loving care (TLC) and health advice. While the care provided in all studies included regular contact for medical monitoring, different diet and lifestyle advice was given in the studies. This was reported using the general term of emotional support (Brigham et al. 1999; Clifford et al. 1997) through to specific advice involving relaxation techniques, bed rest and avoiding sexual intercourse (Liddell et al. 1991; Stray-Pedersen & Stray-Pedersen 1984).

1.2.9 Women’s Experiences of Threatened Miscarriage

There is a lack of research that specifically examines women’s experience of threatened miscarriage, including their expectations of care or their experience of the care they receive from health professionals. Issues relating to miscarriage have been explored in the nursing and medical literature, including potential emotional effects for women (Brier 2004, 2008; Beutel et al. 1995; Geller et al. 2004; Lok & Neugebauer 2007; Mann et al. 2008), the effect on a couple’s relationship (Beutel et al. 1996; Kong et al. 2010a), the effect of a previous miscarriage on a subsequent pregnancy (Bergner et al. 2008; Fertl et al. 2009; Franche & Mikail 1999; Theut et al. 1988), women’s experience of the care they receive from health professionals (Evans et al. 2002; Rowlands & Lee 2010), the support women receive from Internet forums (Gold et al. 2012) and health professionals’ perceptions of the emotional effects of miscarriage compared to the perceptions of women and their partners (Kong et al. 2010b). However, these aspects have not been specifically explored for women presenting with threatened miscarriage. As women with threatened miscarriage are informed that they have a viable baby, it is likely that their experiences and interactions with health professionals will be different compared to those experiencing a known pregnancy loss.
Health professionals may not have adequately identified specific considerations that are important to women relating to the experience of bleeding in early pregnancy. Although a qualitative study identified this knowledge gap and aimed to explore the experiences of women presenting in hospital emergency departments for a variety of early pregnancy problems (Warner et al. 2012), the extent to which this study explores women’s experiences with threatened miscarriage is unclear. Although two of the 16 women were identified in the article as having gone to term and given birth at the time of their interviews, it is unknown whether they initially presented with threatened miscarriage or with other early pregnancy problems. As the remaining women had experienced pregnancy loss at the time of their interviews, issues concerning pregnancy loss were specifically identified and commented on in each of the reported themes. The women discussed their experiences of staff acknowledging their pregnancy loss, their experience of miscarrying while in hospital and the assistance they were offered following their pregnancy loss. Although some women may have initially presented for threatened miscarriage, as they were interviewed a considerable time after they initially presented to hospital, their eventual interviews may have dealt with their experiences from the perspective of a subsequent miscarriage. The identified themes are relevant to women presenting to health practitioners with threatened miscarriage, and they include privacy, dignity, compassion and respect. However, there may be further issues for women presenting when a pregnancy is identified as viable.

Although no research specifically examines the experiences of women with threatened miscarriage, it is known that women share experiences through Internet forums that have discussion sites for threatened miscarriage. These online forums consist of women placing postings to share their experiences and ask others for advice. While someone may moderate these to ensure that the content stays within the rules set by the individual forums, these moderators do not usually offer medical advice. These forums are free to access and easy to locate through Internet search engines such as Google. While women and their partners can join as members and carry out private conversations, many forums are open for public discussion and viewing. While these Internet sites are used by women to specifically discuss their experience of receiving a diagnosis of threatened miscarriage, these experiences have not yet been documented in nursing, midwifery and medical literature.
1.2.10 Western Health Practitioners’ Perceptions of Providing Optimal Care

It is known anecdotally that Western health practitioners offer women supportive care when they present with threatened miscarriage, and that this care may involve extra medical monitoring as well as dietary and lifestyle advice such as bed rest and limited physical or sexual activities. However, it is not known how practitioners perceive this care or how they decide what support to recommend. While practitioners may also refer women for complementary and alternative therapies when they present with threatened miscarriage, it is not known whether they perceive this as valuable. To date, there is no quality research in this area regarding the specific advice they offer or their perceptions of optimal practice when treating women with threatened miscarriage.

The first part of this introduction discussed the background information for threatened miscarriage, as well as Western medical treatment considerations. The second part of this background information section introduces acupuncture as a treatment modality.

1.3 Acupuncture as a Treatment Modality

Acupuncture is a treatment modality that belongs to the wider scope of practice in TCM, and it also includes the use of herbal medicine, massage and manipulation techniques. Acupuncture involves the insertion of fine needles into specific body points to stimulate an energetic response involving qi, which is also termed energy or the body’s life force. The aim is to initiate therapeutic responses by promoting the smooth flow of qi in defined pathways known as meridians. Qi is a concept that can be difficult to translate. The Chinese character depicts ‘uncooked rice’ sitting below what can be translated as vapour, steam or gas (Maciocia 1989). From this depiction, it is possible to interpret qi as something that has substance, such as rice, and something that is immaterial, such as the steam arising from a pot where rice is being cooked. The image used here to explain qi is that although it may not be possible to see the steam, it is possible to feel the effects, such as the heat or force produced to lift the lid off a cooking pot. Although related to functions in the body, these qi effects are also described as being more than physical, including emotional, mental and spiritual aspects (Birch & Lewith 2008).
Although qi flows in set pathways where it can be influenced through acupuncture techniques, these pathways branch off into networks of smaller and smaller pathways to eventually spread qi through the entire body and therefore influence all bodily functions. The underlying concepts of TCM involve theories on how qi interacts within the body and how it is influenced by interactions with the external environment. When the qi of the body is unable to flow smoothly, it is more difficult for a person to maintain a healthy responsive balance, both for maintaining optimal body functions internally and responding to external environment stimuli.

Acupuncture treatment has historically developed from practitioners documenting their own treatment experiences, framing treatment protocols and results in specific theoretical models, and passing these on as lessons for future practitioners. In this context, acupuncture can be viewed as an ‘experience-based medicine’ (Birch and Lewith 2008, p. 17). Although the initial concepts of TCM date back to writings compiled between 500 and 300 BC, they continue to be interpreted and developed in textbooks published today (Deadman et al. 2001).

To make a diagnostic decision, information is gathered in a framework that considers the qi interactions occurring in the body at the time of consultation, as well the person’s underlying individual characteristics. This involves asking specific questions and making specific observations of the person, which may include their tongue, pulse and abdomen. This information is woven into a ‘pattern of disharmony’ (Kaptchuk 1983). Decisions are then made regarding the appropriate treatment, which may include diet and lifestyle advice, with the aim of assisting the body to respond in a beneficial way. Although the focus of acupuncture treatment is often regarded as being the point selection and method for needling acupuncture points, in clinical practice, acupuncture treatment can be viewed as a complex treatment intervention in which the effects are not only derived from the use of needles, but also through dietary and lifestyle advice specifically tailored to meet diagnostic criteria (Schneyer et al. 2008).

This diagnostic criterion used in TCM is then continually reassessed at subsequent consultations in order to adapt treatment according to the changes seen by the practitioner. While this diagnostic assessment involves a subjective assessment in terms of collecting the patients’ ‘lived’ subjective symptoms to formulate a diagnosis, the
diagnosis itself is based on set criteria for the different diagnostic patterns. These criteria are documented according to the TCM theories utilised and can therefore be validated by other practitioners using an objective rationale for diagnosis. However, in clinical practice, where multiple patterns are often diagnosed, individual practitioners may select a different pattern as the primary pattern to initially address, allowing for a range of acceptable diagnoses rather than one optimal diagnosis that would be agreed upon by a group of practitioners.

1.3.1 Acupuncture as a Treatment Modality for Pregnancy

Acupuncture has a treatment advantage in pregnancy, as it does not involve the ingestion of any medicinal substances. Currently, women can receive treatment during pregnancy from a variety of practitioners, including acupuncturists working in private practice, midwives who have completed training courses for specific pregnancy conditions and physiotherapists treating muscular skeletal pain. While acupuncture is usually offered as a treatment option for women to access through acupuncturists practicing privatively, treatment is also offered in specialised hospital clinics in Germany, the UK and the United States (US) (Budd et al. 1998; Citkovitz et al. 2009; Roemer 2005).

A recent survey of UK practitioners (Hopton et al. 2012) identified that for acupuncturists in private practice, pregnancy-related conditions were listed among the conditions they frequently treated. In this survey, acupuncturists were asked to detail the previous 10 consecutive treatments they had provided. Acupuncturists who were traditionally trained submitted details for 946 patients, of which pregnancy-related conditions accounted for 13% of treatments. This was equal with the category for psychological-related conditions, with musculoskeletal treatments being the most frequent category of delivered treatment at 32%.

For midwives, specific acupuncture training courses exist in Denmark, Germany, Norway and Switzerland, and treatment is currently available through specialised National Health antenatal clinics in the UK. Acupuncture is recommended by midwives for specific pregnancy-related conditions such as nausea, constipation, heartburn, back pain, sciatica and insomnia, as well as for its effects in reducing stress responses in

In New Zealand, midwives are using acupuncture after completing a certificate in obstetric acupuncture, which is provided by the New Zealand School of Acupuncture and Traditional Chinese Medicine. This course is endorsed by the New Zealand Qualification Association (NZQA) and has been awarded education points by the New Zealand Midwifery Council. While there are no accurate figures regarding the number of midwives currently practicing acupuncture or referring women for acupuncture treatment privately in New Zealand, a postal survey of 171 New Zealand midwives found that 55% of respondents referred women for acupuncture treatment (Harding & Foureur 2009).

With midwives using acupuncture as part of their midwifery practices in New Zealand since 1997, awareness of acupuncture as a treatment modality in pregnancy has increased. In 2008, midwifery support for antenatal acupuncture resulted in a hospital-based clinic opening in the Hutt Valley Hospital—the first of its kind in New Zealand. Due to the positive feedback received from women receiving treatment and the demand from continuing midwifery and medical referral, the clinic continues to operate, providing acupuncture treatment for a wide range of conditions for women during pregnancy and postpartum.

1.3.2 Historical References on Using Acupuncture for Threatened Miscarriage

Although texts detailing the use of acupuncture treatment date from 500 to 300 BCE, texts did not specifically address women’s health issues until the Song Dynasty, when the writings of scholars and physicians identified disorders specifically related to women’s fertility, pregnancy and postpartum (Furth 1999). In particular, there was an emphasis on blood production and movement in women’s bodies that underpinned diagnosis and treatment, resulting in careful observation and documentation for uterine bleeding as part of menstrual cycles, during pregnancy and postpartum.
Sun Simiao (581–682 CE) was an early writer who stressed the importance of female health for successful reproduction, with TCM advice both for successfully maintaining a pregnancy and for treatment when there was vaginal bleeding in early pregnancy (Wilms 2002).

The historical concepts of treating women for vaginal bleeding in pregnancy—acknowledged as a potential miscarriage—continued to be explored throughout the development of TCM, forming the basis for acupuncture treatment protocols given in acupuncture textbooks published today.

### 1.3.3 Acupuncture as a Treatment Modality for Threatened Miscarriage

Acupuncture is a recommended treatment modality for threatened miscarriage in textbooks that specifically detail pregnancy-related care (Betts 2006; Low 1990; Lyttleton 2004; Maciocia 1998; Marchment 2007; West 2001). Several texts also contain case histories that illustrate clinical experiences in treating threatened miscarriage (Betts 2006; Lyttleton 2004; West 2001). The treatment recommendations made in these texts are based on specific symptoms related to threatened miscarriage, such as the amount, colour and flow of the vaginal bleeding, as well as the nature of any pain due to uterine cramping or back pain. In addition, in the context of a TCM diagnosis, pre-existing health problems, emotional responses such as anxiety or depression, physical symptoms such as problems sleeping, and diet and lifestyle factors are also taken into consideration.

Textbooks provide evidence that acupuncture has been used historically to treat threatened miscarriage, and this is reinforced through midwifery and practitioners’ clinical experiences. However, at present, these treatment recommendations are based on anecdotal evidence.
1.3.4 Acupuncture Practitioners’ Perceptions of Providing Optimal Care

As discussed above, acupuncture is presented as a treatment option for threatened miscarriage in fertility and obstetric acupuncture texts; however, there are differing recommendations regarding acupuncture points that may be used safely and different modalities recommended for delivering treatment. These conflicts concern acupuncture points that are to be avoided in pregnancy, the use of abdominal points, acupuncture points with blood-moving functions and the use of moxibustion on specific points when treating threatened miscarriage, which are discussed below.

Acupuncture points that are termed as contradicted or forbidden in pregnancy can be viewed as belonging to two distinct groups. The first group is acupuncture points that are documented in historical texts for a ‘difficult labour’ and that are now recommended to promote an efficient labour, including the induction of labour. These points are not recommended in acupuncture texts for use in pregnancy due to concerns that their use may stimulate the onset of contractions and subsequently miscarriage or early labour. However, there are medical acupuncture texts that do not view any acupuncture points as contraindicated in pregnancy (Roemer 2005). There is also another list of acupuncture points that are listed in certain acupuncture texts as contraindicated in pregnancy; however, no acupuncture points are specifically indicated for problems in labour or to induce labour. For these points, the rationale behind why they are contraindicated is often unclear, with some authors stating personal preference as an explanation.

There are conflicting recommendations in pregnancy texts concerning the use of abdominal points for the treatment of threatened miscarriage. These recommendations include avoiding their use completely (West 2001; Maciocia 1998), using these points but only with acupuncture (Betts 2006) or recommending these points only through using moxibustion (Lyttleton 2004).

Acupuncture points that have energetics functions related to their actions of moving or invigorating blood are generally also avoided during pregnancy-related treatments, although in the case of threatened miscarriage, they may have indications where bleeding is related to blood accumulation in the uterus. Although the use of these points
is recommend in textbooks for a diagnosis of threatened miscarriage related to falls and trauma (Lyttleton 2004; Maciocia 1998), they may also be appropriate for women presenting with a subchorionic hematoma.

Finally, a specific acupuncture point (SP 1) is recommended in acupuncture textbooks due to its historical use in treating uterine bleeding. However, this point is recommended with the use of moxibustion or needling for threatened miscarriage in certain texts (West 2001) and with only needling in other texts (Lyttleton 2004; Maciocia 1998).

To date, although there are textbook recommendations detailing the use of acupuncture, its use as a treatment for threatened miscarriage among acupuncturists is unknown. It is also unknown how acupuncturists use these diverse and conflicting textbook recommendations in their clinical practice and to what extent they use other TCM treatment modalities, including herbal medicine and dietary and lifestyle advice.

**1.3.5 Herbal Medicine for Threatened Miscarriage**

Although the use of acupuncture is examined in this thesis, Chinese herbal medicine is also recommended as a treatment for the use of threatened miscarriage in TCM textbooks (Lyttleton 2004, Maciocia 1998, Marchment 2007, Flaws 2002). However, concerns have been raised over the safety of using Chinese herbs for the treatment of threatened miscarriage (Li et al. 2011, Li et al. 2012a, Wang et al. 2012).

A Cochrane review on Chinese herbal medicine examined 44 randomised control trials (RCTs) where Chinese herbal medicines were used to treat women presenting with threatened miscarriage (Li et al. 2012b). All of these trials were from within China and compared the use of Chinese herbal medicine to Western medicines alone or Chinese herbal medicine in combination with Western medicines to Western medicines alone. There were no trials comparing Chinese herbal medicine to a placebo or to bed rest or supportive care. There were no significant differences in pregnancy loss between women receiving Chinese herbal medicines alone to those receiving Western medicines alone (RR, 1.23; 95% CI, 0.96, 1.57). A beneficial reduction was statistically significant for women receiving Chinese herbal medicines combined with Western medicines.
compared to those receiving Western medicines alone (RR, 1.28; 95% CI, 1.18, 1.38). However, due to the poor methodology used for all of these trials, the authors concluded that there was a lack of evidence to determine whether Chinese herbal medicine was beneficial in the treatment of threatened miscarriage. Of concern was the inadequate reporting of any side effects experienced during these studies, as well as inadequate follow-up through pregnancy to birth and the new-born to assess the safety of treatment. This lack of research accountability on reporting on the adverse effects for women raises questions regarding the assumed safety of Chinese herbal medicine to treat threatened miscarriage, with further research and monitoring required to confirm the safety of using herbal medicines during early pregnancy.

This concludes the background information on the use of acupuncture for threatened miscarriage. The following section examines the literature for both Western medical and acupuncture treatment for threatened miscarriage.

1.3.6 Literature Review of Treatment Options for Threatened Miscarriage

The aim of this narrative review is to examine the use of Western medical and acupuncture treatment for threatened miscarriage. This literature review comprises two sections: the first section examines Western medical treatment options, while the second section examines the use of acupuncture for the treatment of threatened miscarriage. Due to the minimal literature found for both Western medical and acupuncture treatment, both sections include relevant literature from related treatments. In the case of Western medicine, this includes the use of supportive care for unexplained recurrent miscarriage and the use of acupuncture in fertility treatment.

1.3.6.1 Search Strategies

To review the current evidence on the use of Western medical and acupuncture treatment for threatened miscarriage, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane, Proquest, PsycINFO, Medline, and the Chinese-language China National Knowledge Infrastructure (CNKI) and Chongqing VIP Information Co., Ltd databases on the Internet were searched for papers on this topic from inception until October 2012.
1.3.7 Western Medical Treatment Options for Threatened Miscarriage

The search terms for this Western medical treatment literature review were ‘medical treatment’, ‘medication’ or ‘care’ with ‘threatened miscarriage’, ‘threatened abortion’ or ‘early pregnancy loss’.

Six Cochrane systematic reviews were found that were relevant to the treatment of threatened miscarriage. In addition to the 23 studies in these systematic reviews, two additional studies were located on the use of bed rest and a review of oral progesterone that included three studies that were not included in the Cochrane review on this topic. Animal studies were excluded from this review. The research to date evaluates the use of progesterone supplementation, anti-coagulant therapies, hCG, oestrogen derivatives, uterine muscle relaxants and bed rest, and these are discussed below.

1.3.7.1 Progesterone supplementation

Progestational agents have been prescribed since the 1950s, with the rationale that, due to progesterone’s beneficial physiological action in early pregnancy, supplementation may be useful in preventing miscarriage (Carp 2012). However, early studies without access to ultrasound technology were not always able to distinguish between women presenting with viable and non-viable pregnancies. This has the potential to affect reported outcomes, as not all women entering these trials may have done so with a viable pregnancy. The most recent Cochrane systematic review (Wahabi et al. 2011) included only those trials with a viable pregnancy. It examined two trials of oral progesterone compared to no treatment and two trials of vaginal progesterone (suppository or gel) compared to a placebo. While evidence was found of reduced miscarriage rates for women using progesterone supplementation (RR, 0.53; 95% CI, 0.35, 0.79), the authors concluded that due to the small number of participants (421) and the poor methodological quality of four eligible studies, there was insufficient evidence to support the routine use of progestogens for the treatment of threatened miscarriage.

These poor methodological qualities indicated that selection bias was a possibility in three trials due to unclear or inadequate randomisation procedures (Gerhard et al. 1987; Palagaino et al. 2004). In addition, there was a possibility of attrition bias due to a lack
of information if participants left one study (Gerhard et al. 1987), and further bias was a possibility because the number of participants who left a trial was not specified (Palagiano et al. 2004). Therefore, the data to use intention-to-treat analysis were only available for one study (El-Zibdeh & Yousef 2009). As these poor methodological factors could influence the findings, the authors recommended that further ‘methodologically sound’ RCTs examine the safety of using the treatment during early pregnancy.

A review of five randomised studies with 660 participants taking oral progesterone (Carp 2012) reported a 13% miscarriage rate in those taking supplementation compared to 24% in the control groups receiving placebo or standard supportive care, with a decreased risk for miscarriage (OR, 0.47; 95% CI, 0.31, 0.7). However, not all of the studies reviewed may be considered relevant. Of the five studies, only two were evaluated as part of the Cochrane systematic review discussed above (El-Zibdeh & Yousef 2009; Pandian 2009). The others were not included in the Cochrane systematic review because they did not specify a viable heartbeat as inclusion criteria, and therefore may not provide accurate information for threatened miscarriage due to women entering the study with bleeding but a non-viable pregnancy. In addition, two of the studies dated from 1967, a time when diagnostic criteria were different and the methodology employed was less structured; as such, they may no longer be considered relevant for consideration. Although the author of this review concluded that oral progesterone was associated with a reduction in the odds for miscarriage, this conclusion was due to the inclusion of studies from 1967, as well as studies that did not ensure a viable pregnancy through determining a foetal heartbeat as entry criteria, therefore diminishing the validity of this conclusion.

1.3.7.2 Anti-coagulant therapies

In a Cochrane review of anti-coagulant therapies for women with antiphospholipid antibodies, 13 trials involving 849 participants were examined (Empson et al. 2005). Of the interventions examined using heparin and aspirin, only unfractionated heparin combined with aspirin reduced the incidence of pregnancy loss (RR, 0.46; 95% CI, 0.29, 0.71) when compared with aspirin alone. However, the benefits of this therapy
were limited to women with antiphospholipid antibodies who had a history of recurrent miscarriage. Treatment was not recommended for women with antiphospholipid antibodies who did not have this history, as the benefits were not thought to be sufficient. In addition, the review cautioned the use of prednisone for all pregnant women, with adverse effects including premature delivery and gestational diabetes.

1.3.7.3 Human chorionic gonadotropins (hCG)

Due to the physiological benefits in early pregnancy, hCG can be used to treat threatened miscarriage; however, to date, their safety and efficacy have not been demonstrated in the research. The latest Cochrane review (Devaseelan et al. 2010) examined three RCTs involving 312 participants. Their meta-analysis found no statistically significant difference for the incidence of miscarriage for women receiving hCG injections compared to women receiving placebo injections or no treatment (RR, 0.66; 95% CI, 0.42, 1.05). While they reported that hCG treatment demonstrated a significant reduction in the risk of miscarriage (RR, 0.47; 95% CI, 0.27, 0.82) when compared to bed rest, this result needs to be interpreted with caution due to the poor methodological qualities of one study. This trial (Suvonnakote 1986) had potential bias because group allocation was not reported and participants and caregivers were aware of treatment allocations. The benefits of hCG treatment were no longer demonstrated when only two trials were considered high quality, and the authors concluded that current evidence did not support the routine use of hCG in the treatment of threatened miscarriage, and that further quality RCTs were required.

1.3.7.4 Oestrogen derivatives and uterine muscle relaxants

Diethylstilbestrol, an oestrogen derivative, is no longer used in modern obstetric practice for miscarriage prevention. This is due to research in the 1970s demonstrating that use in pregnancy led to an increased rate of miscarriage, preterm birth, an association to a rare vaginal cancer in women taking this medication and a statistically significant increase in primary infertility, adenosis of the vagina/cervix in female babies and testicular abnormality in male babies (Bamigboye & Morris 2003). Although medications that relax the uterus have been used historically to treat threatened
miscarriage, studies evaluating their use were conducted over 20 years ago with insufficient evidence to support the use of uterine muscle relaxant drugs for women with threatened miscarriage (Lede & Duley 2010).

1.3.7.5 Bed Rest

Bed rest has also been examined as a treatment intervention, with a Cochrane systematic review examining two small studies involving a total of 84 women (Aleman et al. 2005). There was no reduction in the risk of miscarriage in the bed rest group (hospital or home) compared to a no-bed-rest group (RR, 1.54; 95% CI, 0.92, 2.58). However, there was a possible selection bias because the randomisation procedures were not reported in either trial (Hamilton et al. 1991; Harrison 1993). Nine women were also excluded post-randomisation from one study when foetal cardiac activity could not be confirmed (Hamilton et al. 1991). Due to the potential bias and the small number of women involved in these studies, the authors concluded that there was insufficient evidence to recommend bed rest as a treatment option.

Further to this review, a retrospective analysis was carried out of 230 women presenting with threatened miscarriage and the presence of a subchorionic hematoma (Ben-Haroush et al. 2003). In this non-randomised study, women who complied with bed rest advice and remained at home (n=200) were compared to women who failed to maintain bed rest and continued working (n=30). Overall, there were 20 early pregnancy losses (8.7%). Although compliance with bed rest demonstrated a reduced miscarriage rate (9.9% vs. 23.3%, p=0.004), this comparison was non-randomised, with potential selection bias between those prepared to comply with medical advice and those who were not introducing additional unknown prognostic factors that may have affected reported outcomes. In addition, the disparity in the numbers in the two groups and the retrospective design of the outcome data collection make it difficult to draw meaningful conclusions from this study.

The use of bed rest and medications for the treatment of threatened miscarriage continues to be explored in the research. The most recent of these studies (Dongol et al. 2011) involved 70 women presenting to a hospital department in Nepal with threatened miscarriage. They received bed rest in the hospital until bleeding had ceased for 48
hours, and they received folic acid supplementation, a uterine sedative (phenobarbitone) and hormonal treatment involving hCG for up to 12 weeks, followed with progesterone after 12 weeks until 28 weeks of gestation. Although the authors concluded that pregnancy outcomes were improved following this treatment, it is difficult to have confidence in this conclusion because this was a small prospective study with no control group. The pregnancy loss for women in this study was reported as 24.2% (n=17). This does not demonstrate a reduced pregnancy loss when compared to other cohort studies where no treatment, including bed rest, was administered. These studies reported pregnancy losses until 20–24 gestational weeks of 5.5–26.6% (Basama & Crosfill 2004; Calleja-Agius et al. 2010; Dongol et al. 2011; Falco et al. 1996; Makrydimas et al. 2003; Özkaya et al. 2011; Poulose et al. 2006; Tongsong et al. 1995).

1.3.8 Supportive Care as Treatment for Unexplained Recurrent Miscarriage

When supportive care was provided for women with unexplained recurrent miscarriage, this care had beneficial outcomes, with research demonstrating increased live births for woman when compared to a control group receiving standard antenatal care (see Table 1.1). Of the four studies, three were controlled trials, with two demonstrating a live birth rate of 86% compared to 33% for women receiving standard antenatal care (p<0.05) (Liddell et al. 1991; Stray-Pedersen & Stray-Pedersen 1984). The third study reported a 26% miscarriage rate in the intervention group compared to 51% in the control group (p<0.002) (Clifford et al. 1997). The fourth study was a prospective cohort study and reported a 75% pregnancy rate beyond 24 gestational weeks (Brigham et al. 1999).

These women all presented with a pregnancy following three or more miscarriages and had undertaken previous medical investigations where no cause had been found for their previous pregnancy losses. The support provided for these women included a range of care such as medical monitoring and lifestyle advice. The specific support varied between studies and was not always reported in detail. The care reported in the research papers is outlined in Table 1.1.
Table 1.1: Supportive care use in recurrent miscarriage studies 1984–1999

<table>
<thead>
<tr>
<th>Author</th>
<th>Trial design</th>
<th>Supportive care</th>
<th>Control group</th>
<th>Supportive care outcomes</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stray-Pederson (1984)</td>
<td>Non-RCT</td>
<td>N=37</td>
<td>N=24</td>
<td>Advice: rest, avoid heavy lifting, travelling, refrain from sexual intercourse. Bed rest for two weeks at the gestational age they had previously miscarried.</td>
<td>Reported as live births at term. Supportive care 32 (86%). Routine antenatal care 8 (33%) (p&lt;0.001).</td>
</tr>
<tr>
<td>Liddell (1991)</td>
<td>RCT</td>
<td>N=42 (44 pregnancies)</td>
<td>N=9</td>
<td>Weekly visits until 13 gestational weeks. Consistent medical personnel, weekly medical monitoring (ultrasound, serum hCG, progesterone tests), weekly stress reduction session with a physiotherapist, relaxation tape for home use, access to early pregnancy clinic for additional reassurance.</td>
<td>Reported as live births at term. Supportive care 38 (86%). Routine antenatal care 3 (33%) (p=0.005).</td>
</tr>
<tr>
<td>Clifford (1997)</td>
<td>Non-RCT</td>
<td>N=160</td>
<td>N=41</td>
<td>Weekly ultrasound until 12 weeks at a specialised early pregnancy clinic.</td>
<td>Reported as miscarriage rates. 42 (26%) supportive care group. 21 women (51%) routine antenatal care (p=0.002).</td>
</tr>
<tr>
<td>Brigham (1999)</td>
<td>Prospective longitudinal observational study</td>
<td>N=226</td>
<td>N/A</td>
<td>Supportive care protocol that included a fortnightly ultrasound for foetal viability until 12 gestation weeks.</td>
<td>Reported as pregnancy rates. 75% beyond 24 weeks.</td>
</tr>
</tbody>
</table>

Of the three controlled studies, only one attempted to randomise women to a non-treatment group (Liddell et al. 1991), although the authors reported that they were unable to continue this randomisation because women refused to be randomised when they became aware of the treatment being offered in their hospital, resulting in a small control group of only nine women in this study. The remaining two studies attempted to reduce selection bias by using geographical location to determine treatment groups. Despite these limitations, as well as the studies involving only a small number of women, there is acceptance from the medical community that supportive care is a valid treatment option (Royal College of Obstetricians and Gynaecologists 2011a). In a review of treatment options for unexplained recurrent miscarriage, the Special Interest
Group for Early Pregnancy (SIGEP) of the European Society for Human Reproduction and Embryology (ESHRE) recommends supportive care as the only intervention that does not require further RCTs (Jauniaux et al. 2006).

To investigate women’s preferences for care in a subsequent pregnancy, 15 women were interviewed using semi-structured interviews (Musters et al. 2011). The authors reported that women requested medical monitoring that consisted of planning consultations and ultrasounds with their gynaecologist, beta hCG (ßhCG) blood monitoring prior to their first ultrasound to determine foetal viability, frequent (weekly or fortnightly) ultrasounds and a preference to have only one or two gynaecologists involved in their care. They also said that they would prefer to receive advice about diet and lifestyle activities from their health professionals (with referrals to trusted websites to obtain this information), to be asked about their emotional needs and how they were doing, to be taken seriously, to feel they were being listened to and understood, and to be offered counselling and relaxation tools. Women would also prefer not to wait for appointments among women who were obviously pregnant, and they selected scanning of once a week or fortnight in preference to more frequent scanning. A minority of women were interested in complementary and alternative medicine (CAM), with acupuncture nominated as the preferred CAM choice.

The authors suggested that this research had implications for health practitioners to focus on providing practical medical advice and supportive care in addition to their early investigations and consultations. However, there are limitations in interpreting this research. Although adopting a qualitative approach and stating they were using ‘explorative, semi-structured, in-depth interviews’, this was somewhat limited by the methodology they used, which contained elements of a telephone survey questionnaire. While the interview commenced with an open question that asked the women what they preferred for supportive care during their next pregnancy, this was followed by a structured topic list of supportive care options for the women to comment on. This list comprised 19 set questions, 12 of which asked an initial open-ended question such as ‘What do you expect from your gynaecologist during your next pregnancy?’, followed by a list of additional options to be provided, such as ‘To take you seriously’, ‘To feel heard’, ‘Understanding it is a life event’, ‘Make a plan when pregnant’ and ‘Other’. The remaining seven questions asked for a ‘yes’ or ‘no’ response—for example, ‘Would you
use a relaxation tape?, followed by ‘Why?’. This type of questioning has the potential to channel women’s answers into a set direction and miss valuable insights that may arise if women are encouraged to spend more time discussing what is important to them. There were also assumptions made with specific questions that linked together concepts relating to care that the women may not have discussed without this prompting—for example, asking if they would want to be admitted to a hospital ward at the same gestational age as previous miscarriages.

The qualitative analysis in this study was reported as being of a phenomenological approach. However, it appears as though the questions’ responses were grouped and then reported as themes, with selected extracts used to report on the questions asked rather than to support an analysis that identified themes across the entire data set. This approach could be seen as inappropriate because the data were merely reported on rather than appropriately analysed (Braun & Clarke 2006). Nevertheless, this study was an important first step in exploring the care that women perceive as valuable. It suggested that, for women who have experienced two or more previous unexplained miscarriages, their expectations of care included more from their health professionals that only medical monitoring.

1.3.9 Clinical Guidelines for Threatened Miscarriage

Clinical guidelines exist for the assessment of pregnant women presenting with bleeding to Early Pregnancy Assessment Units and hospital emergency departments. However, these guidelines relate to establishing foetal viability and then proceed to outline the treatment options for women experiencing a miscarriage (Royal College of Obstetricians and Gynaecologists 2006; Women’s Hospitals Australasia 2008). Currently, there are no clinical guidelines for treatment options, dietary and lifestyle advice or recommended follow-ups for women when a diagnosis of threatened miscarriage has been established. To date, the focus in the medical literature has been on developing prediction models of miscarriage risk using factors such as maternal and gestational age, bleeding and hormonal assessments, and ultrasound results so that when women present with threatened miscarriage, appropriate resources can be directed towards those who are most at risk of a subsequent miscarriage (Adam et al. 2011).
This lack of practical information on treatment options or advice that can be offered to women once viability has been established is also evident in the nursing and midwifery literature on the treatment of vaginal bleeding in early pregnancy, where recommended clinical care focuses on ‘watchful waiting’ (Krause & Graves 1999) and providing advice and support to women experiencing a miscarriage (Marquardt 2011; Snell 2009; Washbourne & Cox 2002; Webster-Bain 2011). When supportive care is mentioned as a possibility, no recommendations are given regarding what this might consist of (Tien & Tan 2007). Interestingly, even in an article called ‘The successful implementation of nurse practitioner model of care for threatened or inevitable miscarriage’, only a brief reference is made to clinical care for threatened miscarriage: ‘Often there is no cause found for the bleeding on pelvic ultrasound and all is well with the pregnancy. This often makes for high levels of stress and anxiety for women and their families’ (Webster-Bain 2011, p. 31). This article then discusses the causes for miscarriage, the psychological effects of miscarriage and providing emotional support for miscarriage. However, no further reference is made to the effects of, or support for, the potential stress and anxiety previously mentioned when a pregnancy remains viable.

1.3.10 Acupuncture Treatment Options for Threatened Miscarriage

The search terms for this acupuncture treatment literature review were ‘acupuncture’, ‘traditional Chinese medicine’, electro-acupuncture’ or ‘moxibustion’ with ‘threatened miscarriage’, ‘threatened abortion’ or ‘early pregnancy loss’. One RCT, one case history and one debate article were found that were relevant to the use of acupuncture to treat threatened miscarriage, and they are discussed below. Ten articles in Russian were located that contained the words for acupuncture and threatened abortion in their title; however, as these articles dated from 1980 to 1987, no abstracts were presented, and because translation was not available, they have been excluded from this review. Animal studies have also been excluded from this review.

1.3.10.1 An RCT for threatened miscarriage

To date, the only RCT reported that involved acupuncture consists of a clinical trial from China (Li & Xie 2005). Clinical trials from China are often developed to meet different criteria compared to clinical trials involving acupuncture in Western medical
settings. In China, there is often an acceptance that acupuncture is an effective treatment, and trials may be undertaken to demonstrate how, rather than if, they should be used in a public health system (Birch & Lewith 2008). The study outlined in Table 1.2 is an example of this; it compares different styles of acupuncture, and no attempt has been made to evaluate the acupuncture treatment against a control group. The acupuncture treatments used in this study were assumed by the authors to be well-known techniques, although this is not necessarily the case for practitioners outside of China.

The description of the two styles of acupuncture, the acupuncture points and the techniques used were not described in enough detail in the report to allow for replication. The methodology of this study is poor and has a high risk of bias, highlighting that the results should be interpreted with caution and giving no confidence in the reported results.

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Li &amp; Xie (2005)</td>
<td>RCT</td>
<td>60 women aged 20–41 years with vaginal bleeding of less than 24 hours. Women recruited from a hospital clinic with 5–27 gestational weeks.</td>
<td>Women allocated to two treatment groups, with each group receiving a different style of acupuncture. Treatment delivered once a day for 10 days.</td>
<td>Reported as a 90% live-birthing rate in one group vs. 60% in the other (p&lt;0.01).</td>
<td>High due to: No details of randomisation process. No allocation concealment. No blinding of participants or outcome assessors. No reporting of incomplete data or loss to follow up. No reporting of the characteristics for each group at the baseline. No attempt to stratify women for confounding variables of maternal and gestation age.</td>
</tr>
</tbody>
</table>
1.3.10.2 A case history report for threatened miscarriage

Case histories are retrospective, observational, practitioner-based reported studies that may be biased towards their own clinical practice; as such, they offer the lowest level of scientific evidence. While accepting that case histories do not report the level of evidence required to make objective decisions for evidence-based clinical decisions, and that any conclusions that can be inferred are limited, they may have a place in the field of TCM by stimulating practitioner discussion and providing a means for generating questions for further research (Ferrigno et al. 2006).

From the databases searched, one case history was found (Stanford 2009), which detailed acupuncture treatment for a woman whose pregnancy was at risk due to low hormonal levels and vaginal spotting.

The case history describes the treatment of a woman presenting with a reported threatened miscarriage. The woman had previously experienced four consecutive miscarriages. During her fourth pregnancy, she was prescribed progesterone supplements; however, her serum progesterone level fell to below 20 nmol/L in the ninth week of the pregnancy and she subsequently experienced a pregnancy loss.

While she was taking progesterone supplements with this pregnancy, she was distressed and worried about the possibility of another miscarriage, as her current serum progesterone level was 12 nmol/L. A level of 20 nmol/L was reportedly required to sustain the pregnancy. Following acupuncture treatment, her serum progesterone levels rose to a level of 20.8 nmol/L three days following treatment. She continued to receive acupuncture treatment throughout her pregnancy, and her serum progesterone remained within an acceptable range. She subsequently delivered a baby at term.

This single case history reporting on a clinical observation raises an interesting question about the possibility of acupuncture treatment assisting hormonal functioning in early pregnancy and subsequently improving pregnancy live-birthing outcomes. However, there are limitations on case histories that need to be considered. The greatest of these limitations is selection bias, which has the potential to compromise the validity of treatment outcomes. The case history does not attempt to evaluate this, with enthusiastic
reporting of the pregnancy outcome being related to the treatment received. There is no discussion of the selection bias that is likely to result from the women seeking acupuncture treatment or the limitations of a single case history compared to a case series. No consideration has been made for confounding factors in the analysis of the treatment outcome; in this case, where a women is presenting with recurrent miscarriage, it is certainly relevant that research literature demonstrates improved live-birthing outcomes when women receive supportive care from medical practitioners without any treatment intervention (Brigham et al. 1999; Clifford et al. 1997; Liddell et al. 1991; Stray-Pedersen & Stray-Pedersen 1984).

Further, the practitioner’s diagnosis and the rationale for the treatment were not reported. The acupuncture techniques or points used were not detailed, therefore providing limited information that is transferrable to clinical practice. There was no identifiable literature search in the report, with several statements made regarding the hormonal levels during pregnancy and the role of acupuncture treatment that requires further clarification and referencing to provide confidence in accurate reporting.

While this clinical observation raises an interesting question for further investigation concerning the role of acupuncture and hormonal levels during early pregnancy, the inadequate referencing and inadequate reporting in this case history provides no confidence in the interpretation that the treatment received was beneficial.

1.3.10.3 The role of acupuncture as a therapeutic treatment for threatened miscarriage

The potential for acupuncture to be offered as a therapeutic treatment for threatened miscarriage has been outlined in the context of the physiological processes of early pregnancy together with the concept of providing supportive care and acupuncture as a specific therapy (Betts et al. 2012) (see Appendix A). This article provides a rationale for why acupuncture may be a useful treatment in certain circumstances; however, as yet, this remains only a theoretical concept.
1.3.11 Acupuncture Use in Fertility Treatment

Although quality research does not exist to support the use of acupuncture for threatened miscarriage, some limited research has examined the use of acupuncture among women experiencing fertility-related issues, which may be relevant. This research examines both how women experience the care they receive and their physiological responses in terms of beneficial hormonal responses.

In an attempt to gather information about how infertile women viewed the acupuncture treatment they received, an RCT examined the effectiveness of acupuncture in reducing infertility-related stress. This involved 32 women receiving acupuncture compared with a wait-list control (Smith et al. 2011). Women in the acupuncture group reported changes on a validated questionnaire called the Fertility Problem Inventory (FPI), which assessed infertility-related stress. It demonstrated changes that were statistically significant for less relationship concern (mean difference (MD), 3.66; 95% CI, 6.80, 0.052, p=0.02) and approached significance for less social concern (MD, 3.75; 95% CI, 7.58, 0.84, p=0.055). In the qualitative arm of the study, women described positive benefits in terms of feeling relaxed, calm and gaining a sense of control.

Although this was a randomised study, caution is required when interpreting the results because the participants were aware of the treatment they received and the small number of participants. However, this pilot study provides preliminary data that shows that acupuncture treatment is a feasible and acceptable intervention for women with fertility-related issues, and women perceive that it improves their ability to cope with fertility-related stress.

These findings build on a previous qualitative study that explored the experiences of women receiving acupuncture treatment to improve their fertility. In this study (de Lacey et al. 2009), all eight women interviewed expressed positive emotional effects specifically relating to treatment. These benefits included their ability to cope with daily life stress, any medical treatment undertaken and regaining a sense of personal control. These benefits were reported even when there was no positive pregnancy outcome. This exploratory research suggested that women view acupuncture as providing supportive care and beneficial effects in terms of their ability to cope when confronted with
infertility-related issues. However, there were limitations due to the small number of participants. Twenty women were initially approached, but only nine consented to be interviewed; thus, there may be implications for the validity of this research due to the possibility that the women who did not consent to an interview had divergent views that were not captured in the research.

In an attempt to examine physiological responses to acupuncture treatment, women in a small prospective study were tested for hormonal changes while undergoing in vitro fertilisation (IVF) treatment (Magarelli et al. 2009). The 34 women receiving acupuncture treatment demonstrated significant beneficial changes in serum cortisol and prolactin levels (stress hormones thought to affect IVF pregnancy rates) compared to the 33 women receiving IVF medication. In addition, the study found a significant reduction in miscarriage rates among women receiving acupuncture treatment (p<0.05). This study had limitations because participants entered the acupuncture group through personal choice, allowing for a possible selection bias. To reduce any further bias, medical staff did not know which women were in which study groups at the time of their IVF treatment, and the statistician was blinded until after analysis. All data were reported and there was no loss to follow up. Despite the limitations of selection bias, this article contributed to the currently limited understanding of how acupuncture treatment may contribute to hormonal regulation during IVF treatment. While further studies are required to confirm any effects of acupuncture treatment, acupuncture may have the potential to promote beneficial hormonal responses in early pregnancy that would be advantageous to women presenting with threatened miscarriage.

1.4 Research Rationale

The current evidence suggests that women presenting with threatened miscarriage face risk factors for subsequent pregnancy loss and pregnancy complications that include premature delivery. While medical guidelines exist to determine foetal viability, there are no guidelines for care once a diagnosis of threatened miscarriage has been determined, with medical advice for this common complication of early pregnancy focusing on a ‘wait and see approach’.
Current medical guidelines recommend that when women have experienced several miscarriages, an investigation should be conducted to determine possible causative factors; however, for approximately half of these women, causative factors are never identified. Thus, supportive care is recommended for women with unexplained recurrent miscarriage. While the mechanism explaining why supportive care increases live births remains unknown, it has been suggested that this care may reduce stress for these women, which in turn positively affects pregnancy outcomes. These findings may be relevant for women presenting with threatened miscarriage. While it is known that chromosomal abnormalities are responsible for approximately 50% of miscarriages, for women where these factors are not present, therapeutic treatment options that involve reducing maternal stress responses may be available.

Acupuncture treatment is recommended in acupuncture textbooks as a therapeutic treatment for threatened miscarriage, and it is offered to women by acupuncturists in private clinical practices and midwives who have undertaken specialised acupuncture courses; however, the only research located was a trial performed in China, which involved small numbers of women and was of poor methodological quality. While acupuncture treatment recommendations are made in acupuncture texts, they list differing opinions regarding acupuncture points and treatment modalities for women presenting with threatened miscarriage. Despite acupuncture being recommended in acupuncture textbooks as a treatment, no quality trials have been conducted to determine whether acupuncture is a safe or effective treatment to offer women. It is also not known whether acupuncturists are interested in using acupuncture as a treatment for threatened miscarriage and what they consider to be optimal clinical practice.

To date, while research has examined the experiences of women who miscarry, it is unknown how women experience receiving a diagnosis of threatened miscarriage and how they perceive the care they receive from either Western-trained health practitioners or through receiving acupuncture. It is also unknown what Western-trained health practitioners perceive as optimal advice and support in the form of medical monitoring and dietary and lifestyle advice for women presenting with threatened miscarriage.

The use of mixed methods research (MMR) provides the potential to examine these unknown aspects by selecting the most appropriate research techniques—such as
quantitative, qualitative or a combination of both—to investigate a research question. Collecting and analysing quantitative and qualitative data in order to integrate the findings allows acupuncture as a possible therapeutic treatment for threatened miscarriage to be examined and reported on in a way that is not possible when using quantitative or qualitative research in isolation.

1.5 Research Aim

The overarching aim of this study is to explore supportive care with a focus on the role of acupuncture in the treatment of threatened miscarriage. The following research questions are addressed in their relevant chapters, and the details of the study design and analysis are discussed in Chapter 2:

1. What is the current interest and use of acupuncture among acupuncturists in Australia and New Zealand for treating threatened miscarriage? (Chapter 3).
2. What are acupuncturists’ considerations for optimal clinical practice for this presentation compared to textbook recommendations? (Chapter 3).
3. Is it feasible to deliver an acupuncture intervention to women with threatened miscarriage? (Chapter 4).
4. What effect does acupuncture have on quality-of-life and pregnancy outcomes for women with threatened miscarriage compared to women receiving supportive care? (Chapter 4).
5. What are women’s experiences of receiving acupuncture or supportive care? (Chapter 4).
6. What do Western-trained health practitioners consider optimal clinical practice for the treatment of threatened miscarriage, including lifestyle and dietary advice, in their clinical practice? (Chapter 5).
7. What are women’s experiences of threatened miscarriage and the care they receive as described on Internet forums for threatened miscarriage? (Chapter 6).
1.6 Structure of this Thesis

Chapter 2 describes the methodology used in this thesis. The first section outlines the study design and provides theoretical justification for using an MMR design and how TCM is used as a perspective for this study. The second section details the integration of data and research findings in this thesis. The third section details the methods and analysis for the different research methods used in this thesis, including an acupuncture practitioner survey, an RCT, semi-structured interviews and web-based data collection. The final section outlines how quality assessment was addressed.

Chapter 3 reports on the findings of an online survey that examines clinical practice among acupuncture practitioners in New Zealand and Australia for women presenting with threatened miscarriage. The chapter also reports the findings of semi-structured interviews from acupuncturists who were purposely selected because of their survey responses in order to explore specific aspects of their clinical practice in greater depth.

Chapter 4 reports on the findings of an RCT designed for women presenting with threatened miscarriage. It explores the feasibility of conducting a trial to evaluate acupuncture in the treatment of threatened miscarriage when compared to an active control group of women receiving touch at non-acupuncture points. Both groups receive supportive care, with the acupuncture group receiving additional diet and lifestyle advice from a TCM perspective. This chapter also reports on the findings of the semi-structured interviews conducted with these women after exiting the study.

Chapter 5 reports on the findings of a qualitative analysis examining Western health practitioners’ considerations for clinical practice. These practitioners have a variety of medical, nursing and midwifery backgrounds, and all practitioners are involved in assessing women who present with vaginal bleeding in the Wellington and Hutt Valley regions of New Zealand.

Chapter 6 reports of the findings of a qualitative analysis of data collected from Internet forums. These data were collected from the postings made by women and their partners to Internet discussion forums relating to threatened miscarriage.
Chapter 7 brings together the findings for this thesis.

Chapter 8 discusses these findings and their implications for clinical practice and future research.
Chapter 2: Methodology Study Design—Mixed Methods: A Dialectic Approach

Section 2.1 begins with a discussion of the epistemology and methodology that guides the research design used in this study, which is a mixed methods design using a dialectic approach. Section 2.2 details the integration of data and research findings in this thesis. Section 2.3 details the qualitative and quantitative data collection methods and their analyses, as well as ethical concerns. Section 2.4 discusses the criteria for quality assessment for the MMR and how this relates to this study.

2.1 Epistemology

Issues that relate to epistemology (beliefs about the nature of knowledge) have been discussed since the early writings on the use of MMR (Teddlie & Tashakkori 2010). These issues relate to beliefs about the nature of knowledge, and while researchers may not always acknowledge them, they influence research decisions about what type of knowledge is collected and reported in any given study. This section examines the use of mixed methods as a research design, the paradigms for the pragmatic and dialectic stance, and why and how the dialectic stance is used throughout this thesis.

2.1.1 Mixed Methods as a Research Design

MMR allows researchers to select the most appropriate paradigm (or paradigms) and the most appropriate research methods (quantitative or qualitative) to investigate their research question. Tashakkori and Teddlie (2010, p. 8) called this ‘methodological eclecticism’. However, the use of a mixed methods design should not be taken by researchers as permission to use an free for all approach without an understanding of how paradigms influence research decisions (Giddings 2006; Giddings & Grant 2006).
2.1.2 Paradigms

Paradigms can be seen as a set of basic beliefs, or a worldview, concerning the nature of reality and of knowledge. In research these are a ‘basic set of assumptions that guide a researcher’s inquiry’ (Creswell 1998, p. 74); thus, they determine how and why research is conducted. These assumptions influence the decisions researchers make in the research methods they use (Greene & Caracelli 1997). This is self-evident in that, if objective knowledge is viewed as more ‘truthful’ and therefore believed to be more valuable, there will be a focus on using methods that are able to report results in an objective manner. However, if subjective knowledge is valued, the research methods and reporting will reflect these beliefs.

These differences in paradigms or worldviews concerning what knowledge is viewed as the most valuable can be traced back to ancient Greece, where Plato (429–347 BCE) and Socrates (470–399 BCE) viewed knowledge as being either true or false, rejecting the arguments of fellow Greek teachers (the Sophists), who stated that truth can be relative and depends on the situation, context, purpose or perspective (Burke & Gray 2010). Burke and Gray (2010) claimed that paradigm debates are primarily about knowledge, noting that seeking the ‘truth’ remains the goal of the quantitative paradigm (where quantitative knowledge can be linked to objectivity), while the qualitative paradigm (where qualitative knowledge can be linked to subjectivity) maintains that truth is relative. There does not appear to be an easy solution to reconciling these views; Burke and Gray (2010, p. 74) commented that ‘one can safely conclude that this is a long-standing debate and it is not likely to be resolved any time soon’.

There is a view—labelled the ‘incompatibility thesis’—that different types of knowledge are directly linked to the different paradigms of quantitative and qualitative knowledge, and that research can only be carried out according to the guidelines in these separate world views (Bednarz 1985). However, the proponents of MMR have rejected this argument, stating that, while it is indeed ‘risky businesses’ to mix paradigms (Morgan 1998), the mixing of methods is a separate consideration. This mixing of methods becomes possible when methods and methodology are viewed as separate concepts (Teddleie & Tashakkori 2003).
2.1.3 Methods and Methodology

Methods can be viewed as the tools used to implement, analyse and interpret research. As research tools, they are not restrained by any particular research paradigm and can therefore be ‘mixed’, allowing practitioners of MMR to select and then integrate the most appropriate techniques, such as quantitative or qualitative research methods, to thoroughly investigate their research question.

Although method and methodology can be used interchangeably in the research literature, methodology can be viewed as a separate concept (Giddings 2006). This separation of methodology from method allows methodology to be viewed as a separate paradigm from the research method used in a study, with methodology guiding researchers in relation to the methods they use to generate and justify knowledge (Greene & Hall 2010).

In MMR, this methodology paradigm is not restricted to a particular world view; indeed, it may include a variety of paradigms that can be used as an underlying philosophy to guide research, resulting in ‘paradigm pluralism’ (Teddlie & Tashakkori 2010). This pluralism may include a pragmatic stance, which creates opportunities for researchers where the guiding methodology is one that relates to the research itself being ‘the principal line of action’ to investigate the research question rather than philosophical assumptions (Morgan 2007, p 68). Johnson and Onwuegbuzie (2004, p. 17) discuss this pragmatic approach as one in which researchers are able to ‘choose the combination or mixture of methods and procedure that works best for answering your questions’, thus providing a logical needs-based approach for researchers that permits methodological mixing.

2.1.4 Pragmatic Stance

Adopting a pragmatic stance allows researchers to draw from the full complement of research methods and paradigms available (Patton 1985). Patton argued that the importance of paradigms in research could be de-emphasised in a pragmatic stance by describing how different perspectives could be agreed upon to find results that are convincing and useful. An analogy he used to illustrate this concept is the way a skilful
teacher can work with people of different religious backgrounds without having to resolve which religion’s beliefs are correct.

As a research approach, pragmatism has wide appeal because it offers researchers a practical ‘bottom line’ to help them answer their research questions using what that they view as the most appropriate methods (Johnson & Onwuegbuzie 2004, p. 16). This practical approach has become historically associated with MMR, and it is the most popular alternative paradigm for many practitioners of MMR (Teddlie & Tashakkori 2010). However, it is not the only approach available for researchers using MMR.

2.1.5 Dialectic Stance

While pragmatism has been frequently used in MMR, there are other options for researchers to consider. The dialectic stance assumes that all paradigms have value and that by seeking out the conflict and differences between multiple worldviews in a study, researchers create the potential to generate a greater understanding of the phenomenon they are studying (Greene & Hall 2010). In this stance, paradigms are not ‘de-emphasised’; rather, the different paradigms provide useful contradictions through their different worldviews. By valuing and exploring the conflicts occurring between the different data sets collected, there is potential to create new insights (Greene 2005). This approach of being aware and respectful of different worldviews is at the core of the dialectic approach. In this way, paradigms are viewed as important to examine, as it is from the differences in these paradigms that the researcher ‘aspires to generate deep, insightful, comprehensive understandings—woven from an integration of the various methods used and data sets collected’ (Greene & Hall 2010, p. 138).

Although the dialectic stance is seen as an approach for MMR (Greene & Hall 2010; Greene & Caracelli 1997; Greene & Caracelli 2003; Greene 2007), it is not currently well represented in health science research. However, when used, this approach has been described as beneficial. Betzner (2008) compared two MMR approaches—a dialectic approach and a pragmatic approach—when investigating the extent to which local smoking regulations affected participants involved in a smoking-cessation program. Her findings suggested that although both mixed method approaches produced unique insights, the dialectic method, which was used to examine conflicting findings
between two research methods (a telephone survey and phenomenological interviews), generated a more in-depth understanding compared to the pragmatic approach. Betzner (2008) found that while smoke-free regulations did not directly contribute to participants quitting, they triggered emotional responses that motivated people to quit.

A dialectic stance was also used to examine differences between the paradigms of health-care providers by analysing contradictions that occurred in a qualitative analysis of nurses and doctors working together as a health-care team (Martin et al. 2008). Through the analysis of the divergent views held by these two health professions, specific factors were identified, which the authors discussed as providing opportunities and insights into how collaboration between these practitioners could be improved.

The approach of valuing different paradigms and exploring these differences was also recommended as an educational approach for midwives and CAM practitioners as a means to develop a collaborative understanding (Steel & Adams 2012). The authors suggested that interactive workshops that provided both CAM practitioners and midwives with the opportunity to discuss their key philosophies, terminologies and principles of practice with equal respect would improve communication between practitioners. This process of understanding the different paradigms can be seen as an important aspect to building professional relationships to ensure a safe approach to the care of pregnant women.

A dialectic stance is used in this thesis to explore and analyse the different worldviews of what constitutes valuable or legitimate knowledge in the practice of Western medicine and TCM for women presenting with threatened miscarriage. This thesis deliberately draws on these two different paradigms of medical knowledge to explore the different understandings of what knowledge is valuable and therefore legitimate when diagnosing and validating treatment.

To date, health research has not examined the conflicts in order to understand the potential insights that TCM and Western medicine worldviews have to offer each other. While qualitative research has been used to explore how TCM is perceived by patients (Barlow et al. 2011; de Lacey et al. 2009; Paterson et al. 2010; Paterson et al. 2008; White et al. 2012) and how acupuncture practitioners perceive and deliver care (Evans
et al. 2011; MacPherson & Thomas 2008; MacPherson et al. 2006; Paterson et al. 2012; Paterson et al. 2008), these frame TCM as either existing in the worldview of CAM as holistic medicine, or in Western medical concepts such as psychosocial care. TCM has its own medical paradigm, with medicinal theories reflecting the knowledge that was valued as the medicine developed, and with underlying philosophies that reflect how acupuncture is used today. The worldview in TCM has beliefs and views that may differ from those of other CAM therapies and from how Western medicine defines psychosocial care. A dialectic stance is used in this thesis to examine any contradictions between the different worldviews of TCM and Western medicine, with the aim of providing new insights and understandings regarding the care of women presenting with threatened miscarriage.

2.1.6 Integration and Inference of Data and Research Findings with MMR

MMR studies are becoming increasingly common in health services research, with the primary focus on using qualitative research combined with a randomised trial (O’Cathain et al. 2007). This rise in MMR use is understandable when researchers are able to claim a ‘better understanding’ in their research. However, concern has been expressed that if qualitative research is not implemented with appropriate rationale and integration, there is a danger that it may be added as an afterthought to quantitative-focused research projects—for example, as a few interesting comments to add interest to a report (Giddings 2006).

Concerns have also been raised about the reporting of MMR findings in health research. In an evaluation of MMR studies funded by the Department of Health in England between 1994 and 2004, concerns were expressed about the transparency of reporting, which made it difficult to assess the quality of the studies (O’Cathain et al. 2008). While the roles of the quantitative and qualitative methods were communicated well in proposals and reports and the components of the studies were usually completed, there was a tendency for researchers to keep the qualitative and quantitative components separate rather than attempt to integrate data or findings in reports or publications. The absence of integration results in findings that resemble two separate studies being reported, rather than generating knowledge where the ‘whole is greater than the sum of its parts’ (Moran-Ellis et al. 2006, p. 50).
The integration and inference of research findings in MMR can be addressed using numerous designs. Teddlie and Tashakkori (2010) grouped these into two categories: a component design, which separates quantitative and qualitative components, with integration occurring only at the level of inference; and an integrated design, where the quantitative and qualitative components are integrated throughout the study. This thesis uses two quantitative studies: an online survey and a pilot RCT trial. In addition, there are four qualitative studies: three of these involve the use of semi-structured interviews and one uses data collected from an Internet forum. The data collection synthesis and integration for this study have been integrated at various phases and are reported on as outlined in Figure 2.1. The specifics relating to the analysis of each data set generated in this study, as well as the integration of these findings, are outlined below.
Figure 2.1: Data collection, synthesis and integration
2.2 Integration of Data and Research Findings in this Thesis

The data or findings of MMR can be integrated in a study in various ways. O’Cathain et al. (2010) outlined three techniques to assist health researchers to integrate their data or findings when using MMR. This thesis uses one of these techniques, proposed by Moran-Ellis et al. (2006) called ‘following a thread’. In this technique, the initial analysis of each data set generated using MMR is undertaken using the appropriate quantitative or qualitative techniques in order to identify relevant key findings. The data sets are then placed together and a key theme or analytic question is identified from one data set using the original research questions and relevant literature. This theme or research question is then followed across the other data sets to create a ‘thread’ that interweaves the findings that have emerged from each data set. Moran-Ellis et al. (2006) proposed that this approach to integrating research findings preserves the value of qualitative research—that of open, exploratory inquiry—while incorporating the focus and specificity valued in quantitative data.

This study utilises a variety of methods, including a pilot RCT for women presenting with threatened miscarriage; an online survey of acupuncture practitioners; qualitative interviews that include women experiencing threatened miscarriage, Western medical practitioners and acupuncturists treating women with threatened miscarriage; and online web-based data collection of women experiencing threatened miscarriage.

In this thesis, Chapter 3 reports the findings of the online survey of acupuncturists in Australia and New Zealand, which are analysed using descriptive statistics. Of the practitioners participating in the survey, 13 were purposely selected to participate in semi-structured interviews, which were analysed using thematic analysis. The findings of the online survey and interviews are initially integrated into Chapter 3. As illustrated in Figure 2.1 these findings were not intended to provide information for the planning of the RCT and therefore remain separate until final integration and a discussion of the findings using the ‘following-a-thread’ approach presented in Chapter 7.

Chapter 4 reports the findings of a pilot RCT involving women presenting with threatened miscarriage, which were analysed using descriptive and inferential statistics.
Eleven women participating in this trial were interviewed on exiting the trial using semi-structured interviews, and these data were analysed using thematic analysis. These findings are initially integrated into Chapter 4, with final integration and a discussion of the findings using the ‘following-a-thread’ approach presented in Chapter 7.

Chapter 5 reports the findings of 12 semi-structured interviews conducted among Western health practitioners involved in the care of women presenting with threatened miscarriage. These data are analysed using thematic analysis, and the results are presented in Chapter 5, with integration and a discussion presented in Chapter 7.

Finally, Chapter 6 reports on the data collected from threatened miscarriage threads in Internet forums. These data are analysed using thematic analysis and presented in Chapter 6, with inferences and a discussion presented in Chapter 7.

### 2.3 Methods and Analysis

This section details the qualitative and quantitative data collection methods and their analysis, as well as the details of the ethics approvals obtained. The different studies in this thesis are presented in the order that they appear in the chapters.

#### 2.3.1 Chapter 3: Online Acupuncture Practitioner Survey

The aim of this research was to investigate the current use of acupuncture among acupuncturists in Australia and New Zealand for threatened miscarriage, and to examine their clinical practice compared to textbook recommendations. The specific research questions were:

1. Among acupuncturists in Australia and New Zealand, what is the current interest and use of acupuncture to treat threatened miscarriage?
2. Do acupuncture practitioners have safety and ethical concerns relating to the treatment of women presenting with threatened miscarriage, and what are these concerns?
3. Given the different recommendations for treatment in acupuncture texts, what specific treatment modalities, acupuncture points and techniques do practitioners use when treating threatened miscarriage?

4. Where do practitioners seek out the information they consider useful to inform their clinical practice?

5. What are the major referral sources of patients for practitioners treating threatened miscarriage?

2.3.1.1 Study design

A questionnaire survey utilising a web-based self-completed questionnaire was used to collect data from practitioners in Australia and New Zealand. The survey was accessed through the Internet provider Survey Monkey (http://www.surveymonkey.com). This allowed the collected data to be stored online and exported directly into an Excel spreadsheet by the researcher, Debra Betts (DB).

Internet surveys are being increasingly used in research, although the quality of design is highly variable (Couper et al. 2001). Specific aspects should be considered for successful web-based surveys, including ensuring privacy for participants and knowing how to use the wide range of textual options, format control and graphics, as these may affect response rates (Andrews et al. 2003; Couper et al. 2001). For this survey design, a best-practice survey guide on the Survey Monkey website was used to develop the questionnaire, taking into consideration the practical aspects of question layout, length and sequence, and maximising the response rate. In addition, to preserve privacy, professional associations sent out the survey information from their databases.

2.3.1.2 Self-Completed Questionnaire

The literature review did not identify any quality information on whether practitioners were treating threatened miscarriage in clinical practice or how they delivered any treatment. The questions for this survey were therefore developed specifically by the researcher (DB) and subsequently piloted by a team of 11 acupuncture practitioners. Practitioners were asked if they had treated women with threatened miscarriage within the past year and an open ended question asked if they had any safety or ethical
concerns about treating women with threatened miscarriage. The purpose of this survey was also to explore practitioners’ clinical use of acupuncture in the context of the conflicting treatments recommendations found in acupuncture texts (detailed section 1.3.4). To address this, questions were developed that focused on practitioners preferred treatment for each of these conflicting areas of practice. These questions explored the conflicts within the literature concerning acupuncture points to be avoided in pregnancy (Betts & Budd 2011, Cummings 2011, Guerreiro da Silva et al, 2011, Roemer 2005), and text book indications for the correct use of abdominal points and acupuncture points with blood-moving functions, as well as the use of moxibustion on specific points (Betts 2006; Low 1990; Lyttleton 2004; Maciocia 1998; Marchment 2007; West 2001). Practitioners were therefore asked if and how they used these acupuncture points and treatment modalities within their clinical practice.

The questionnaire consisted of 14 items for practitioners who had not actively treated threatened miscarriage in the past year and 23 items for those who had. Questions related to the incidence of treatment in the past year (one question), safety and ethical concerns (four questions), and demographic information (seven questions) (see Appendix B).

For those who had not treated in the past year, follow-up questions asked why they had not treated in the past year and whether they would be willing to treat in the coming year. For practitioners who had treated women in the past year, additional questions were asked regarding the learning resources they had found useful for clinical practice (one question), the acupuncture points avoided in clinical practice (two questions), treatment modalities used in clinical practice (five questions), how patients were referred to their practice (one question) and willingness to be interviewed about clinical practice (two questions). Answers were given in a multiple-choice format, with specific questions providing an option for respondents to make comments. These responses were given as yes/no answers or as a choice made from a list of statements.

The entire survey required less than 20 minutes to complete. The survey used skip logic so that practitioners who had not treated threatened miscarriage in the previous year were taken immediately to the demographic section, while practitioners who identified
as treating women in the previous year answered questions about their treatment modalities before being taken to the demographic section.

2.3.1.3 Participants

As it was not possible to identify practitioners specifically involved in this specialised area of clinical practice, a broad response was sought from acupuncturists belonging to the main professional acupuncture bodies of Australia and New Zealand. All acupuncturists were eligible if they belonged to these professional bodies and had Internet access.

2.3.1.4 Survey administration

An anonymous online survey was conducted in April and May 2011. E-mail invitations were sent to all members of the main acupuncture bodies of Australia and New Zealand: the Australian Acupuncture and Chinese Medicine Association (AACMA), Australian Traditional-Medicine Society (ATMS), Acupuncture Association of Australia (ACUPAA), New Zealand Register of Acupuncture (NZRA), New Zealand Chinese Medicine and Acupuncture Society (NZCMAS) and New Zealand Acupuncture Standards Authority Incorporated (NZASA). The invitation to participate was in the form of an e-mail that described the study and contained a link inviting practitioners to visit the survey site. The invitation also contained the researcher’s contact details and invited potential participants to contact the researcher (DB) if they had any questions. Following this initial e-mail, the professional bodies sent two e-mail reminders to their members one month after the first invitation and prior to the survey closing. From these six professional acupuncture bodies, an invitation to participate in the online survey was sent to a total of 3,151 practitioners in New Zealand and Australia.

2.3.1.5 Validity and reliability of survey

The questionnaire was developed by the researcher (DB) and piloted by a team of 11 acupuncture practitioners who are actively involved in the area of women’s health in the Wellington area, New Zealand. Seven of these practitioners then contributed to a Content Validation Survey (see Appendix C). The survey questions were assessed for
clarity of wording, relevance to research question and appropriateness for the population to be surveyed. The practitioners were asked to make judgements of unclear or clear for clarity of wording, and to give ratings ranging from 1 to 4 for relevance and appropriateness. A four-point score was used with a score of 1 to describe a response that was not relevant or appropriate, and a score of 4 for highly relevant or appropriate. The number of assessors that agreed that the question was clear, had relevance or was appropriate at the level of 3 or 4 was then divided by the total number of assessors to give a content validity index (CV-I). A CV-I of between 0.85 and 1 was achieved for all questions. This met the recommendation that a score of 0.78 should be achieved to demonstrate that questions were clear and relevant (Polit & Beck 2008). The results of the pilot survey and content validation led to no significant changes being made to the survey. However, a minor change from practitioners’ initial feedback was incorporated into a second pilot survey. This comment concerned the demographic section, which allowed practitioners to select multiple styles of acupuncture practice. The second pilot survey was then sent to four practitioners for final comments; no further changes were made.

2.3.1.6 Statistical analysis

The researcher (DB) undertook data analysis with guidance from a statistician and supervisor, Caroline Smith (CS). Data were collected anonymously by downloading directly from the Survey Monkey site. They were collected in the form of an Excel spreadsheet and exported to SPSS version 9.1 for analysis. Demographic data from participants were used to summate the characteristics of survey respondents. Univariate descriptive statistics were used, including frequencies and percentages, for categorical data. The effect of other variables on patterns of use were examined using bivariate statistics, including t-tests and chi-square tests, with P<0.05 considered statistically significant. Where the expected numbers were below five, a Fisher’s exact test was used to determine statistical significance.
2.3.1.7 Semi-structured interviews

Semi-structured interviews were used to develop a rich understanding of practitioners’ experiences in treating women presenting with threatened miscarriage. The aim of these interviews was to examine acupuncturists’ considerations for clinical practice when treating threatened miscarriage. The specific research questions were:

1. What do practitioners consider best clinical practice when using acupuncture to treat women with threatened miscarriage?
2. What do practitioners consider best clinical practice when using additional traditional Chinese modalities to treat women with threatened miscarriage?
3. What do practitioners view as the possible benefits of offering treatment to women with threatened miscarriage?
4. How do practitioners judge if their treatment has been useful to women?

Participants were selected for an interview using purposeful sampling from the online survey. This type of sampling is non-random and is based on the researchers’ perception that the selected cases will provide rich and insightful information for the research question (Collins 2010). Participants initially self-selected themselves by indicating that they would be willing to be interviewed by the research investigator using the Skype computer program. The participants who were interested were invited to leave their contact details in a specific section of the survey. Of the 48 practitioners who left their contact details, 10 were excluded because they did not have more than six years of clinical experience, and 14 were excluded because they had treated less than five women in the previous year. Therefore, 24 practitioners were eligible. Practitioners were then selected due to the acupuncture treatment and treatment modalities they selected in the survey. Initially, eight practitioners who indicated that they would use the contraindicated points were contacted, with six available for an interview. Of the 16 remaining practitioners, three were selected because they indicated that they did not use abdominal points, and one because she stated that she would not use blood-invigorating or blood-moving points. Following these 10 interviews, practitioners were approached for an interview according to their time spent in clinical practice; those with over 20 years’ experience were approached first. Three more practitioners were interviewed before saturation was achieved and no further themes were revealed, giving a total of 13 practitioners.
Determining saturation can be complex, and while the concept of saturation is often described in literature as the point at which no new information or themes are observed in the data, practical guidelines for determining sample size are virtually non-existent (Guest et al. 2006). For the interviews, saturation was defined as ‘the point in data collection and analysis when new information produces little or no change to the codebook’ (Guest et al. 2006, p. 65).

The interview schedule was structured using a topic guide with open-ended questions to ensure that specific topics were explored, while encouraging participants to share their personal stories and perspectives in their own words. The written topic guide for the interviews asked participants to explore their experiences of providing care for women presenting with threatened miscarriage. In particular, practitioners were invited to share stories that illustrated the treatment modalities they used and to identify any specific treatment issues they may have in relation to determining optimal clinical practice and their expectation of treatment in a clinical environment. Examples of these questions included: When treating blood stagnation, what specific needling and/or moxa techniques do you use and why? Is there any particular diet and lifestyle advice (TCM or medical) that you feel women should be aware of? (See Appendix D).

The face-to-face interviews were conducted through the online medium of Skype, and the interviews were recorded onto the researcher’s (DB) computer. Verbal consent to record the interviews and use participant’s de-identified responses for research was gained at the start of the interview and recorded in the transcript.

2.3.1.8 Ethics approval

The University of Western Sydney Human Research and Ethics Committee approved the survey and interviews for this study—reference number H8935 (see Appendix E).

2.3.2 Chapter 4: A Pragmatic Pilot RCT

The overall aim of this study was to examine the feasibility and acceptability of offering acupuncture and supportive care as therapeutic treatment for women presenting with threatened miscarriage. The specific research questions were:
1. Is it feasible to deliver an acupuncture intervention to women with threatened miscarriage?
2. What are the appropriate and successful recruitment procedures, recruitment rates, referral sources, eligibility criteria, consent rates and randomisation procedures?
3. Are participants compliant with the study intervention, and is the intervention acceptable to women presenting with threatened miscarriage?
4. What are the retention rates for both acupuncture treatment and active control groups?
5. Are the outcome measures suitable for assessing: pregnancy-related fear and quality of life during the first trimester of pregnancy and on-going pregnancy at 12 gestational weeks; pregnancy and neonatal complications; and live births?
6. Is a manualised acupuncture treatment protocol suitable for delivering treatment in a trial?

The primary hypothesis of the study was that for women presenting with threatened miscarriage, receiving acupuncture compared to supportive care only would reduce pregnancy-related fear in the first trimester of pregnancy and improve quality of life by reducing symptoms experienced by women that they considered distressing.

The secondary hypothesis was that acupuncture compared to supportive care only would reduce miscarriage rates and increase live-birth outcomes, and reduce premature birth, intrauterine growth restriction and APH.

2.3.2.1 Study design

The pilot study was a pragmatic trial with randomisation into two groups: an acupuncture intervention with a manualised acupuncture protocol that included medical and individualised diet and lifestyle advice, and an active control group that received touch intervention with medical, diet and lifestyle advice. The rationale for using this study design is discussed in detail below. The specifics of the protocol used in this study are then outlined.
2.3.2.2 Rationale for a pilot study

A pilot study was considered necessary because, as outlined in Chapter 1, there are no previous studies of acceptable quality that have investigated acupuncture as a treatment intervention for threatened miscarriage. Thus, a pilot study can determine the feasibility of conducting a larger-scale trial (Thabane et al. 2010). For this reason, feasibility objectives were outlined as above, with the feasibility aspects reported in Chapter 4.

2.3.2.3 Pragmatic trial design

The term ‘pragmatic’ was proposed by Schwartz and Lellouch in 1967 to describe randomised trials in which design choices maximise the applicability of the trial’s results to usual care settings and are tested in a wide range of participants (Zwarenstein et al. 2008). The potential choices include a variety of elements, which means that a pragmatic trial is not an ‘either/or’ choice of design in relation to an explanatory trial, but can instead be viewed as an approach.

Zwarenstein et al. (2008) illustrated the key differences in the choices between pragmatic and explanatory trials by comparing two trials at each end of the continuum. One trial examined the use of carotid endarterectomy and best medical therapy on major stroke incidence or death over a two-year period and focused on efficacy—does the treatment work when used in an ideal setting? The trial was carried out in a highly resourced setting, had strict participant selection, an intervention that was strictly enforced and monitored, and it was seen as having a highly explanatory attitude. The second trial examined acupuncture as a treatment for persistent non-specific low-back pain. The trial focused on effectiveness—does the intervention work when used in normal practice? The trial took place in a normal acupuncture practice setting, had limited selection beyond those presenting with the required diagnosis, had a flexible acupuncture intervention, and it was seen as having a highly pragmatic approach.

Explanatory trials are appropriate for acupuncture trials seeking an explanation for specific needling actions or a set needling protocol. However, acupuncture can be seen as a ‘complex’ intervention, where treatment effects are not only derived from the use of needles, but also through dietary and lifestyle advice specifically tailored to meet
diagnostic criteria that involve participants (Evans et al. 2011; MacPherson & Thomas 2008; MacPherson et al. 2006). To fully investigate acupuncture as a complex intervention, it has been suggested that acupuncture trials utilise a pragmatic design (Langevin et al. 2011; Lewith 2008; MacPherson et al. 2008; Sherman et al. 2008).

This study uses a trial design towards the pragmatic end of the continuum, with a design choice of a manualised acupuncture protocol to deliver acupuncture treatment that reflects a flexible treatment approach that is applicable to real-world acupuncture. Reporting of this trial follows the guidelines as recommended in extension of the CONSORT statement Improving the reporting of pragmatic trials (Zwarenstein et al. 2009) and the revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines: extending the CONSORT Statement (MacPherson et al. 2010).

2.3.2.4 Manualised acupuncture protocol

A manualised treatment protocol developed by researcher (DB) was used in this study. This was a pragmatic intervention reflecting clinical practice where an individualised differential diagnosis is considered the essence of TCM (Maciocia 2005). A range of protocol approaches are used in acupuncture trials. These range from treatments using set points, treatment that allow the practitioner to individualise parts of the treatment to flexibility to use any treatment style and may include therapeutic modalities such as herbs and nutritional supplements which may not be directly related to TCM theory (Schnyer et al. 2008). While standardisation of the acupuncture treatment used within a trial is important for internal validity, individualisation of acupuncture treatment is important to reflect clinical practice. Manualisation is an approach developed by Schnyer et al (2002) to address these concerns, with some constraints in that the acupuncture theories and styles of practice are specified, however, guidelines for diagnosis and treatment allow practitioners to individualise their treatment. The treatment protocol in this study uses this approach, with the acupuncture system, style and techniques specified while the guidelines for diagnosis and treatment are specified but there is the flexibility for multiple diagnoses and for the treatment to meet the individual needs of the patient as treatment progresses. This approach allows for a transparent intervention to be used in a randomised trial that provides internal validity.
while retaining flexibility to provide an intervention that has external validity for generalisation to clinical practice.

There is no quality research detailing treatment for threatened miscarriage, therefore the treatment protocol for this study was drawn from the established textbook recommendations (Betts 2006; Lyttleton 2004; Maciocia 1998; West 2001). To reflect clinical practice there was additional flexibility to diagnosis and treat underlying patterns of disharmony according to an established acupuncture text (Maciocia 2005). Although practitioners were surveyed as to their preference for clinical practice, this survey was not intended to provide expert opinion for the development of a study protocol and was developed, administered and analysed after the trial had commenced.

2.3.2.5 Active control group

The acupuncture trial compared the effectiveness of acupuncture treatment to that of an active control group. While usual care is recommended as a control for use in pragmatic trials, there is currently no usual care for threatened miscarriage other than a ‘wait and see approach’. There were ethical concerns that recruiting women to a trial with an intervention to improve pregnancy outcomes and then randomising women to a no-treatment group was unacceptable. Therefore, an active control group was used to deliver touch to non-acupuncture points. The active control group offered components to control for the supportive care offered by acupuncture, such as receiving attention, touch, time out to rest, having a health practitioner to consult and receiving medical health advice.

Touch in the form of pressure to specific non-acupuncture body points was included to account for the non-specific therapeutic treatment effects that could be present in the acupuncture treatment group, such as attention, care, respite from daily stress, a relaxing environment, treatment and spending time with a treatment provider. Light touch was used in the trial because it has been successfully used in acupressure trials during childbirth to control for these non-specific therapeutic effects (Chung 2003; Hamidzadeh et al. 2012; Hjelmstedt et al. 2010; Lee et al. 2004).
The touch protocol for the trial was developed by the researcher (DB). These points were chosen because they were non-acupuncture points. Due to the pragmatic nature of the trial where various acupuncture points may be selected, it was not possible to select touch points close to the acupuncture points that may have been used. Therefore a selection of body locations was chosen to encompass the chest, arm, hand, leg and foot. This use of touch provided non-specific therapeutic effects including that of palpation, resting for 20 minutes and consultation with a practitioner but excluded specific acupuncture point stimulation. As this was an active control where women were aware they were randomised to receive touch, there was no assessment for this as a control for credibility.

2.3.2.6 Participants

The participants for this trial comprised women with vaginal bleeding in early pregnancy that received a medical diagnosis of threatened miscarriage in the Wellington and Hutt Valley areas of New Zealand.

Inclusion criteria:
- women with sufficient English language skills to provide informed consent
- vaginal bleeding and a viable pregnancy of 6–11 completed gestational weeks
- viable pregnancy demonstrated by a transvaginal ultrasound examination confirming foetal cardiac activity
- vaginal bleeding defined as either light or heavy bleeding, with light bleeding lasting longer than a day and described by the women as less than the flow of a usual menstrual period, and heavy bleeding defined as bleeding of any duration that is heavier than the flow of a usual menstrual period.

Exclusion criteria:
- women with insufficient English language skills to provide informed consent
- non-viable pregnancy or ectopic pregnancy, twin or multiple pregnancy, women with three or more previous miscarriages
- vaginal bleeding that consists of spotting of less than one day duration, and women under the care of an obstetrician for underlying medical conditions.
2.3.2.7 Recruitment

Recruitment was undertaken through health professional referral in the Wellington and Hutt Valley regions of New Zealand. Referral was through a fertility unit, a Women’s Assessment Unit, a Maternity Assessment Unit (MAU), Accident and Emergency departments, GP referral and midwifery referral through midwives who acted as lead maternity caregivers (LMCs).1

Women were offered entry into the study following a routine medical or midwifery assessment offered when they presented with vaginal bleeding. After being informed of the study by their health professional, women had the option of providing their details to be contacted by the researcher or to initiate telephone contact themselves. On contact with the researcher, their suitability through the inclusion/exclusion criteria was assessed and, if appropriate, an appointment interview was arranged.

In this interview, a final assessment was undertaken to ensure the inclusion/exclusion criteria were met. Intake assessment and data collection were then undertaken, randomisation was applied and the treatment programme was outlined and commenced. The baseline data collected included: maternal age, gestational age, previous pregnancies, previous miscarriages, extent and type of vaginal bleeding, pre-pregnancy BMI, blood pressure, ethnicity, and medical history including any medications, whether they smoked and the present use of dietary and herbal supplements.

To inform eligible women of the study, a range of recruitment techniques was undertaken among Western and acupuncture health practitioners who had potential contact with women presenting with threatened miscarriage. In addition, public notifications and social media were used so that women could self-refer into the trial.

2.3.2.8 Face-to-face contact

Meetings were held with hospital staff in both the Wellington and Hutt hospitals’ Accident and Emergency departments, the Women’s Assessment Unit at Wellington

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1 In New Zealand, midwives can act as independent practitioners, delivering care during pregnancy, childbirth and the postpartum period as LMCs.
Hospital, The Hutt Hospital MAU, local acupuncturists and radiology providers for the region (Pacific Radiology and Horizon Radiology) and Hutt Hospital to inform health providers about the study, answer any questions they had and provide material that could be given to eligible women.

Meetings were also held with six independent midwife groups in the Wellington and Hutt Valley regions, and with all nursing staff at Wellington’s only fertility centre, Fertility Associates. These were informal meetings with regular follow-ups to update progress. More formal meetings occurred through midwifery council meetings, where further details about this study were presented and discussed.

2.3.2.9 Posters, information letters and newsletters

Posters with information about the trial and contact details for the researcher (DB) were placed in the Accident and Emergency departments of the Wellington and Hutt Valley hospitals, the Women’s Acute Assessment Centre at Wellington Hospital and the radiography department at Hutt Hospital. These posters had tear-off slips with the researcher’s contact details and were replaced as needed.

Five newsletters were created throughout the time of recruitment. These newsletters provided further information, updated the study progress and thanked those referring into the trial. They were distributed to staff at the MAU at Hutt Valley Hospital, Fertility Associates, and Pacific and Horizon Radiology. Independent midwives received these newsletters through their hospital cubbyholes (Wellington Hospital) or personal folders at the hospital delivery suite (Hutt Valley Hospital). Newsletters were also distributed to 12 obstetricians through a personally addressed letter.

In addition, midwives were informed about the study progress in three updates in the New Zealand College of Midwives regional newsletter that is sent to approximately 200 midwives in the Wellington and Hutt Valley areas.

Information was emailed to GPs through an official health organisation, with a postal follow-up through a MAU as part of their regular mail out in the Hutt Valley region. Seventy-five GP practices in the Wellington region were informed of the trial through a letter individually addressed to practice nurse managers. A folder containing
information about the study and pamphlets for women was distributed by visiting 39 GP practices identified by midwives and the Practice and Community Nursing coordinator as those that may be interested in the study.

2.3.2.10 Public information

A local newspaper (*The Wellingtonian*) was approached to publish a story informing residents in Wellington and the Hutt Valley that the study was currently recruiting. Social media was also used with permission from the moderators of three New Zealand web-based miscarriage sites to place information and contact details on the sites’ discussion threads.

A Facebook advertisement was created, which led to a Survey Monkey website that had further information about the study and asked any interested persons to leave their contact details. Using a Facebook advertisement enabled the direct targeting of women who lived within 50 miles of Wellington, New Zealand, and who were aged 18 years or older. A final attempt to use social media involved creating a Facebook page to provide information, research updates and contact information for any women interested in enrolling in the study.

Permission was obtained from the president of the New Zealand Playcentre Association to place posters with information and contact details onto the noticeboards of 32 local Playcentre groups. Playcentre is a mother-run association that provides an early childhood learning environment for preschool-aged children. It is seen as a place where women who may experience threatened miscarriage or who know others in this situation may be present.

2.3.2.11 Randomisation

The randomisation sequence was computer-generated and managed by Sealed Envelope, an Internet randomisation service. Allocation was held centrally and accessed

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2 http://www.kidspot.co.nz/contact-kidspot.asp
http://www2.everbody.co.nz/forum/ubbthreads.php/topics/2002754/2
http://www.treasures.co.nz/Community/Forum/Room/Topic/?topicId=32800&p=2
3 http://www.facebook.com/EarlyPregnancyBleedingStudy?ref=hl
by computer by the researcher (DB). Randomisation was in two study groups: acupuncture plus supportive care and supportive care only.

2.3.2.12 Treatment schedule

The treatment schedule consisted of women receiving two visits for the first week of intervention, then a weekly visit until 12 completed gestational weeks was reached. Each treatment session consisted of a 20-minute treatment intervention with paperwork and any discussion completed in the allocated time of one and a half hours for the initial visit and 45 minutes for subsequent visits.

2.3.2.13 Acupuncture treatment

The acupuncture intervention included: needles, moxibustion therapy, cupping, and dietary and lifestyle advice that was specific to the acupuncture diagnosis made by the acupuncturist (DB).

The acupuncture treatment rationale and administration for this study is reported according to the revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines (MacPherson et al. 2010). The acupuncture treatment in this trial involved:

1. treatment based on an eight-principals TCM diagnosis
2. a selection of acupuncture points for each TCM diagnosis, along with the appropriate indications for the use of moxibustion and/or cupping recognised acupuncture obstetric texts (Betts 2006; Maciocia 1998; West 2001)
3. recommendations for dietary and lifestyle advice that is specific for each TCM diagnosis according to recognised acupuncture obstetric texts (Betts 2006; Maciocia 1998; West 2001)
4. needling specifications for needling depths according to a recognised acupuncture text (Deadman, Al-Khafaji & Baker 2001)
5. needling, moxibustion and cupping techniques for early pregnancy according to recognised acupuncture obstetric texts (Betts 2006; Maciocia 1998; West 2001)
6. manual needling technique for obtaining deqi for each point and needle retention time of 20–30 minutes in each session
7. The number of acupuncture points per treatment was chosen by the acupuncturist as required in acupuncture diagnosis, with 1 being the minimum number of acupuncture points and 6 being the maximum number to be used in a single treatment (see Appendix F).

A written sheet detailing dietary and lifestyle risk factors was given to women receiving acupuncture care. These diet and lifestyle sheets were based on the TCM diagnosis women received.

The diagnosis included pattern differentiation based on a TCM paradigm and a treatment documented within a recognised acupuncture obstetric text (Betts 2006; Maciocia 1998; West 2001). Terminology of TCM terms and meridians was based on WHO International Standard Terminologies (WHO 2007).

**Lung Disharmonies**
- Lung qi deficiency
  LU 9, BL 13, BL 43
- Lung yin deficiency
  LU 9, BL 13, BL 43

**Kidney Disharmonies**
- Kidney qi deficiency
  KI 3, CV 4, GV 4, BL 23, GV 20
- Kidney yin deficiency
  KI 3, CV 4, GV 4, BL 23, GV 20, CV 4
- Kidney yang deficiency
  KI 7, CV 4, GV 4, BL 23, GV 20, CV 4

**Spleen Disharmonies**
- Spleen qi deficiency
  GV 20, BL 20, BL 21, BL 43, CV 4
- Spleen yang deficiency
  GV 20, BL 20, BL 43, CV 4
- Spleen failing to control the blood
  GV 20, BL 17, BL 20, CV 4, SP 10
- Dampness damaging Spleen yang
  SP 9, CV 12, BL 20, BL 21
- Spleen deficiency with dampness accumulation
  SP 9, SP 9, CV 12, BL 20, BL 21
- Sunken Spleen qi
  GV 20, BL 20, CV 4
- Spleen—Stomach weakness
  BL 20, ST 36
**Heart Disharmonies**
- Heart qi deficiency
  PC 6, HT 5, BL 15, CV 17, Yin Tang
- Restless Heart qi
  PC 6, Yin Tang, GB 13, DU 24
- Heart yin deficiency
  HT 7, PC 6, HT 6, KID 7, KI 6, CV 14, Yin Tang
- Heart yang deficiency
  PC 6, HT 5, BL 15, CV 17
- Heart blood deficiency
  HT 7, PC 6, CV 14, CV 15, BL 17, BL 20
- Phlegm—fire harassing the Heart
  PC 7, CV 17, BL 15, CV 12, ST 40, LR 2, LR 3
**Liver Disharmonies**
- Constrained Liver qi
  LR 3, LR 14, LR 13, PC 6
- Liver blood deficiency
  BL 17, BL 18, BL 20, LR 8, ST 36
• Ascendant hyperactivity of Liver yang
LR 2, LR 3

**General Disharmonies**

• Qi deficiency
GV 20, ST 36, CV 12, CV 4

• Qi deficiency failing to control Blood
GV 20, ST 36, BL 17, CV 4

• Qi deficiency with Blood stasis
GV 20, ST 36, SP 10, BL 17, KI 9, CV 4

• Blood stasis
SP 10, BL 17, KI 9

• Blood heat
SP 10, BL 17, LI 11, LR 2, LR 3, SP 1, KI 2, PC 3

• Trauma
GV 20, CV 12, PC 6

**Exterior Disharmonies**

• Exterior cold
LU 7, TE 5, GB 20

• Exterior heat
LI 11, TE 5, GV 14, GB 20

The practitioner delivering the treatment (DB) was a licensed practitioner with the New Zealand Register of Acupuncture with over 20 years clinical experience and experience in delivering acupuncture during pregnancy including four years working within a hospital antenatal clinic. All acupuncture treatment was carried out in accordance with the ethical and skin penetration guidelines issued by the New Zealand Register of Acupuncture.
Further components of treatment that included written sheets detailing diet and lifestyle advice were compiled by the researcher (DB). These diet and lifestyle recommendations gave advice concerning the types of foods and exercise that women may find useful according to their individual TCM pattern of disharmony. Dietary information sheets were prepared for qi depletion, blood depletion, yin depletion, yang depletion, true heat, true cold and dampness. Lifestyle information sheets were prepared for qi depletion, qi stagnation, yin depletion and yang depletion (Appendix G).

In addition to receiving acupuncture treatment, women received a written sheet detailing Western medical dietary and lifestyle risk factors. This medical advice sheet was compiled by the researcher (DB) using evidenced-based research and the expert opinion of midwives from the Hutt Valley Hospital MAU. The detailed advice included the known effects of smoking and alcohol consumption in pregnancy, contact numbers for women seeking assistance to stop using these substances, information on recommended limits for caffeine consumption, and information stating that there was no evidence to recommend any treatment through vitamin supplements, abstaining from sexual relations or through bed rest (see Appendix H).

2.3.2.14 Supportive care intervention

The active control group received the written information sheet detailing Western medical dietary and lifestyle risk factors as detailed above. Women also received touch care in the form of pressure applied to non-acupuncture points on their face and head to provide non-specific therapeutic effects. There were five points used, with each point lightly held for four minutes in the following order, giving an overall treatment time of 20 minutes:

**Point 1**
- Located on the dorsum of the foot. In the hollow distal to the junction of the 3rd and 4th metatarsal bones, midway between the GB and ST channel, approximately at the level of LR 3

**Point 2**
- Located on the anterior crest of the tibia, 7 cun below the base of the patella, 1 cun distal and 1.5 cun medial to ST 37
**Point 3**
- Located on the extensor surface of the forearm, midway between LI and TH channels one cun distal and one cun lateral to LI 11

**Point 4**
- Located on the dorsum of hand in the hollow distal to the base of the 2nd and 3rd metacarpal bones, midway between the SJ channel and the extra point Luo zhen (M-UE-24), approximately at the level of SI 3

**Point 5**
- Located on the antero lateral aspect of the chest. Inferior border of the clavicle, 5 cun lateral to the midline, midway between the ST and LU channels—at the level of ST 13.

Treatment consisted of two treatments in the first week of entering the trial followed by a weekly visit until participants reached 12 completed weeks of gestation. Further details are reported in Appendix F.

### 2.3.2.15 Endpoints

**Primary endpoints:**
1. Maternal stress changes as documented in a pregnancy-related fear questionnaire collected at weekly intervals following study entry until exiting at 12 completed gestational weeks
2. Quality-of-life changes measured using the Measure Yourself Medical Outcome Profile (MYMOP) questionnaire collected at weekly intervals following study entry until exiting at 12 completed gestational weeks
3. Maternal dietary and lifestyle activities by analysing diary entries that recorded smoking, coffee consumption, bed rest, exercise patterns, relaxation techniques, alternative treatments or homeopathic remedies, and vitamin and herbal supplements taken; data were collected at weekly intervals following study entry until exiting at 12 completed gestational weeks.

**Secondary endpoints:**
1. Ongoing clinical pregnancy at 12 gestational weeks, as demonstrated by foetal heart activity on ultrasound
2. ongoing pregnancy rates, with pregnancy loss prior to 20 gestational weeks defined as miscarriage and pregnancy loss at 20 gestational weeks and/or over 400 g defined as stillbirth

3. preterm birth defined as birth occurring before 37 completed gestational weeks (very preterm birth defined as birth occurring before 34 completed weeks)

4. APH defined as vaginal bleeding after the 20th week of gestation and before the onset of labour

5. low birth weight defined as <2500 g

6. intrauterine growth restriction defined as a foetus whose estimated weight is below the 10th percentile for its gestational age and whose abdominal circumference is below the 25th percentile

7. Apgar scores <7 at five minutes as documented in hospital birthing records.

Endpoints to assess study feasibility:
1. recruitment rate from referral sources
2. suitability of eligibility criteria
3. recruitment rate from eligible participants
4. randomisation achieved successfully using an Internet randomisation service
5. acceptability of randomisation procedures by women for an acupuncture or support intervention through the completion of consent forms
6. compliance with acupuncture and support intervention assessed through the attendance of appointments until study conclusion and adverse events
7. compliance with completing data collection tools: pregnancy fear questionnaire, MYMOP questionnaire, and diet and lifestyle diary
8. suitability of acupuncture treatment protocol through diagnostic patterns and acupuncture points used in treatment.

Data collection tools:
1. Pregnancy-related fear questionnaire (see Appendix I), was used to assess women’s fear of pregnancy loss. This was chosen as the most appropriate questionnaire as it contained a specific question asking women to rate their concern over vaginal bleeding and as discussed in section 1.2.7.2 this questionnaire demonstrated an association with elevated pregnancy fear and early pregnancy complications including vaginal bleeding (Fertl et al. 2009).
However a State–Trait Anxiety Inventory within the same study examining apprehension, tension, and nervousness demonstrated no effect on vaginal bleeding or early pregnancy complications. This Pregnancy-related fear questionnaire was reported by Fertl et al. (2009) as having been validated via a principal component analysis and subsequent varimax rotation of data from 519 pregnant women (Cronbach’s α=0.75). For the purposes of this study, women experiencing a threatened miscarriage completed this questionnaire upon entering the study in order to provide a baseline and then at weekly intervals until exiting at 12 completed gestational weeks in order to assess the effect of treatment intervention.

2. MYMOP, which is a patient-centred questionnaire that asks participants to rate their health concerns on a 6-point Likert scale (see Appendix J). MYMOP was selected as a questionnaire to examine women’s perception of what they consider to be important. This questionnaire asks for patient-centred identification of health concerns and in addition records treatment effects for general health and wellbeing from the women’s viewpoint, without practitioners presenting women with their perceptions of possible health concerns. This is an ideal assessment tool when assessing acupuncture treatment that may provide a range of whole body health effects in addition to the symptom presented for treatment. This problem-specific questionnaire has been shown to be a reliable tool when used in acupuncture studies that measure the quality of changes that are the most important concerns for individuals receiving treatment (Hull et al. 2006; Paterson 1996; Paterson & Britten 2003; Paterson et al. 2010). MYMOP is an ideal assessment tool for this study because it provides patient-centred identification of health concerns and records treatment effects for general health and wellbeing from the women’s viewpoint without practitioners presenting women with their perceptions of possible health concerns. For the purposes of this study, women experiencing a threatened miscarriage completed this questionnaire upon entering the study in order to provide a baseline and then at weekly intervals until exiting at 12 completed gestational weeks in order to assess the effect of treatment intervention.

3. On a weekly basis, women completed a diary detailing the diet and lifestyle activities undertaken in the previous week. The diary included dietary information such as coffee consumption, vitamins and supplements, and lifestyle
information relating to alcohol, smoking, sexual intercourse, additional bed rest, exercise longer than 20 minutes, Internet use of miscarriage sites, time at work or CAM therapies (see Appendix K). This diary was included in an attempt to examine the potential impact that TCM diet and lifestyle advice may have on women’s behaviour in comparison to women receiving medical diet and lifestyle advice. The diary form was given to the women in an envelope at the beginning of the week, and the completed form was given back to the researcher in a sealed envelope during the next visit. This was then placed into a locked cabinet until analysed by the researcher (DB) at the trial’s conclusion. A sealed envelope was used in an effort to provide a more accurate record of women’s compliance with dietary and lifestyle advice due to women potentially being reluctant to disclose information in full while receiving treatment. On exiting the trial, women were also asked what support, if any, they had found useful while participating in the trial.

4. Ultrasound at 12 and 20 gestational weeks: An ultrasound demonstrating cardiac activity is the most accurate measurement for confirming a viable pregnancy. This ultrasound examination was undertaken by the various providers of foetal ultrasound assessments in the Wellington and Hutt Valley regions, which included medical personal at the fertility unit, ultrasound technicians from Hutt Valley Hospital and ultrasound technicians from two private companies (Pacific Radiology and Horizon Radiology). Data collection and reporting of ultrasound reports was undertaken by the researcher (DB).

5. Hospital birthing records: These records detail the gestational age at delivery, infant weight at delivery and Apgar scores at five minutes post-delivery for all women delivering in hospital. They were accessed by the health practitioners via computer at the request of the study investigator (DB). For women birthing at home, a follow-up telephone call was made by the researcher (DB) to the midwife concerned to collect this follow-up information

2.3.2.16 Sample size

No previous randomised trials have evaluated the potential of acupuncture on pregnancy outcomes for women presenting with threatened miscarriage. In this pilot trial, a modest sample size of 40 women was sought to provide data to answer the study questions.
This number of participants allowed for the examination of the study questions relating to feasibility.

2.3.2.17 Statistical analysis

Data analysis was undertaken by the researcher (DB) with guidance from statistician and supervisor (CS). Data were entered into an Excel spreadsheet and exported to SPSS version 9.1 for analysis.

Data analysis used descriptive statistics to examine the demographic and baseline characteristics of trial participants and to examine whether randomisation was successful. The analyses of the endpoints used an ‘intention to treat’ approach and compared differences in the primary and secondary outcomes of the groups. Pre- and post-intervention comparisons were made for pregnancy fear scores, MYMOP scores, diet and lifestyle changes, pregnancy loss and pregnancy complications. These were analysed between groups using a mean t-test and chi-square tests with P<0.05 considered statistically significant. Where the expected numbers were below five, a Fisher’s exact test was used to determine statistical significance. For Risk Ratio calculations the statistical programme Review Manager 5.2 was used.

2.3.2.18 Blinding during analysis

Participants were not blinded to group allocation. Data entry was undertaken blind to the study group and analysis was undertaken by DB blind to group allocation.

2.3.2.19 Ethics approval

The Lower South Ethics Committee, New Zealand, approved this study—reference number LRS/10/07/030 (see Appendix L), as did the University of Western Sydney Human Research and Ethics Committee—reference number H8603 (see Appendix M). Locality assessments were obtained from the Wellington and Hutt Valley district health boards, which included ethics approval from the relevant Maori ethical committee personnel. Following initial approval, an amendment was sought and subsequently
approved to include women presenting with threatened miscarriage until 11 completed gestational weeks.

2.3.2.20 Semi-structured interviews

Semi-structured interviews were undertaken to collect data in order to understand the experiences of the women who took part in the RCT and the care they received. Women taking part in the RCT from both treatment groups were given the opportunity to participate in an interview upon exiting the trial. The aim of these interviews was to explore their experiences of threatened miscarriage and the care they received during the trial. The specific research questions for this study were:

1. What were women’s experiences of threatened miscarriage?
2. What, if any, benefits did they experience from the care they received while in the trial?

Women were invited to participate by ticking a box on the initial consent form when entering the study (see Appendix N). All of the women contacted agreed to be interviewed. Eleven women were contacted and interviewed in the order they left the trial before it was identified that saturation had been reached and no new themes were emerging from the data.

A written topic guide for these interviews was used, which asked the participants to share their experiences of receiving acupuncture and supportive care, or touch and supportive care. In particular, women were invited to share stories that illustrated the effect of these therapies on their lifestyle and their physical and emotional wellbeing. Examples of the questions asked include: Were there any specific effects that you noticed immediately following the treatment? Do you feel that the treatment you received made you feel any differently about your threatened miscarriage? (see Appendix O).

These face-to-face interviews were conducted by an independent researcher with a background in conducting qualitative research. Interviews were recorded on a portable digital recorder, with interview times ranging from 45 to 90 minutes. An independent researcher was used to ensure that participants were not constrained in their responses.
because of any potential relationships they may have formed with the researcher administering treatment (DB), and to reduce any possible bias from responses being prompted by the researcher.

2.3.2.21 Ethics approval

The Lower South Ethics Committee, New Zealand, approved this study—reference number LRS/10/07/030 (see Appendix L).

2.3.3 Chapter 5: Western Health Practitioners’ Interviews

Western health personnel currently involved in the assessment of women presenting with threatened miscarriage in the Wellington and Hutt Valley regions were invited to participate in semi-structured interviews. This invite was through a personally addressed e-mail or self-referral.

The aim of these interviews was to examine what Western-trained health practitioners considered optimal clinical practice for the treatment of threatened miscarriage, including lifestyle and dietary advice, in their clinical practice. The specific research questions were:

1. What do Western medical health practitioners consider optimal clinical practice for the treatment of threatened miscarriage?
2. What, if any, dietary and lifestyle advice do they give in clinical practice?
3. How do they perceive the use of CAM therapies and, in particular, TCM for women presenting with threatened miscarriage?

Participants were purposely selected due to their involvement in the health system in assessing women presenting with threatened miscarriage. Participants were recruited from the Women’s Acute Assessment Centre at Wellington Hospital, the MAU at Hutt Valley hospital, a fertility unit, midwives who acted as LMCs and from a GP practice. Thirteen Western health practitioners were interviewed before it was determined that saturation had been reached and no new themes were emerging from the data.
A written topic guide asked participants to explore their experiences of providing care for women presenting with threatened miscarriage. In particular, practitioners were invited to share stories that illustrated the treatment modalities they used and that identified any specific treatment issues they had in determining optimal clinical practice, as well as their expectation of treatment in a clinical environment. Examples of the questions asked in the topic guide were: What do you think is important care to provide to the women you see presenting with a threatened miscarriage? Is there any particular diet and lifestyle advice you feel women should be aware of? (see Appendix P).

Prior to the interview commencing, participants provided written consent for their interviews to be recorded (see Appendix Q) and for their de-identified responses to be used for research purposes. The face-to-face interviews were conducted by the researcher (DB) and recorded on a portable digital recorder. The majority of interviews were conducted in 30 minutes.

2.3.3.1 Ethics approval

The University of Western Sydney Human Research and Ethics Committee approved this study—reference number H8935 (see Appendix D). Due to the medical practitioners residing in New Zealand, approval was also obtained through an amendment from the Lower South Ethics Committee, New Zealand—reference number LRS/10/07/030 (see Appendix R).

2.3.3.2 Data collection and analysis for all interviews

Each interview was recorded and saved to an MP3 auditory file. Files were transcribed verbatim and then returned to the researcher (DB) as Word files for analysis. These files were then de-identified by creating pseudonyms or identifying participants by numbers. A Word document linking the participants to the de-identified participants was kept in a separate computer file by the researcher (DB).

Thematic analysis was used to formally analyse and code the data because it unearths patterns in the data, allowing for the discovery of the true meaning of the data (Boyatzis 1998; Grbich 2007). While thematic analysis is not always acknowledged as a specific
method of qualitative analysis, it is widely used as a foundation in qualitative analysis (Braun & Clarke 2006). Indeed, Braun and Clark (2006, p. 80) argued that ‘a lot of analysis is essentially thematic but is either claimed as something else or not identified as any particular method at all’. The authors also argued that thematic analysis is an important skill for researchers to learn because of the flexibility and useful ‘core skills’ it provides for a variety of qualitative analysis techniques. They identified six phases to performing thematic analysis, which were used as a guide in this study and are outlined below.

2.3.3.2.1 Familiarisation with the data

For this study, transcribed data were received as a Word document. The original MP3 file was then listened to and compared with the written report to detect any errors that may have occurred during the transcription process. The data were then read and re-read as a whole interview before being entered into the computer program NVivo 9 as a Word document.

2.3.3.2.2 Generating initial codes

NVivo 9 was then used to create codes for what was perceived as interesting features of the data. Each interview was coded in a systematic fashion by creating codes and placing the selected data of interest into each code. Using NVivo 9 allowed these coding categories to be sent for comparison and verification to the thesis supervisors (CS and Hannah Dahlen (HD)).

2.3.3.2.3 Searching for themes

The collected codes were then grouped into potential themes; the data relevant to each potential theme were gathered together. This was done by creating and using charts in Word documents rather than NVivo 9. The created themes were then sent to the thesis supervisors (CS and HD) for comparison.
2.3.3.2.4 Reviewing themes

Feedback was received and a comparison process was undertaken with the supervisors (CS and HD) to examine whether themes worked in relation to previous coding and the initial interviews.

2.3.3.2.5 Defining and naming themes

Ongoing analysis was then undertaken to refine the specifics of each theme and to generate clear definitions and names for each theme. This was done through a content-comparison process using Skype interviews and face-to-face discussions with the thesis supervisors (CS and HD).

2.3.3.2.6 Producing the report

A final opportunity for analysis was then undertaken to produce the final report. This involved selecting vivid, compelling examples from the data and relating these examples to the research question and literature to produce a final analysis.

2.3.4 Chapter 6: Online threatened miscarriage forums

The aim of this study was to develop a rich understanding of women experiencing threatened miscarriage through participants who chose to post comments on Internet forums devoted to this topic. The specific research question was: What are women’s experiences of threatened miscarriage as expressed on Internet forums?

2.3.4.1 Study design

An Internet alert from the search engine Google was created by the researcher (DB) to receive alerts when postings concerning threatened miscarriage were made on Internet forums. The Google search engine provides a free service of alerts posted directly to an e-mail address. To create this alert, the Google Alert homepage was accessed and the appropriate details were entered. This included the search terms ‘threatened miscarriage’, ‘threatened abortion’, the information type of ‘everything’, the delivery
frequency of ‘daily’ and the option of ‘all results’, with a contact e-mail address belonging to the researcher (DB). Once completed, an alert was created that required verification via email before the alert commenced.

2.3.4.2 Study rationale

Social media can be a valuable source of information for health researchers, as it provides flexibility in terms of time, access to a population not limited by geography considerations and the possibility of obtaining different insights compared to face-to-face encounters because there is anonymity (Chen 2012; Eastham 2011). Various types of Internet formats may be utilised for research, including health information sites, media sites, governmental and educational sites, personal blogs and discussion forums.

Health information sites, media sites, and governmental and educational sites are created with the aim of providing information. Personal blogs are set up by authors for self-expression, and they have been compared to online versions of diary-keeping or letter-writing (Friedman & Calixte 2009). Discussion forums provide advantages for examining specific health-related experiences because they can be seen more as a written ‘real-time’ conversation between those discussing a specific topic of interest. As such, researchers may obtain different insights into the issues and experiences of those participating on these forums compared to other Internet media.

As outlined in Chapter 1, to date, research has not examined the experiences of women with threatened miscarriage through online discussion forums. The use of online discussion groups in this thesis was a way to examine women’s experiences, as initial postings were usually made a short time after receiving a diagnosis. This offered a specific advantage over mediums such as face-to-face interviews and focus groups, where practical considerations involve a time lag between women presenting with threatened miscarriage and the research being conducted. In this time lag, women will have either continued with their pregnancy or experienced pregnancy loss, which could affect their subsequent recollections. Data obtained from these forums also examined how women expressed themselves to other women who shared a similar experience, providing a potentially different perspective to data gathered from health practitioners and researchers.
2.3.4.3 Participants

The participants for this study were members of the general population with access to the Internet who self-selected themselves to post on open-access threatened miscarriage sites. While some Internet forums require participants to sign up in order to post or view postings, the data collected for this study were only from open-access postings that were freely available to the public. The Internet forums could be accessed by anyone who used a computer with access to an Internet search engine.

2.3.4.4 Data collection

Daily emails were sent to the researcher (DB) that contained hyperlinks to information appearing on the Internet that corresponded to the specified search terms. These alerts were viewed by the researcher (DB), and those relating to Internet postings on threatened miscarriage forums were identified according to the date and Internet forum before being stored in a Word file for further analysis. Postings were de-identified using the first two letters of the pseudonym supplied by the person making the post. These alerts were received over a seven-month period (22 April to 21 November 2011).

The discussion threads on the online forums followed a defined structure. To initiate a posting, an individual created a specific entry in an existing discussion forum. This initial posting formed a discussion thread through the responses of others, with the thread ending when no further postings were made to that particular discussion. These threads were collected as individual Word documents for each new discussion thread created. Any additional update postings where a single entry was posted at a later date to inform others of a pregnancy outcome, was added to the original discussion thread rather than collected as a new discussion thread.

2.3.4.5 Data analysis

The data obtained from the Internet postings were analysed according to the thematic analysis guidelines provided by Braun and Clark (2006) and outlined in section 2.3.3.2 for the interviews of this study. The creation of the Word documents containing the forum comments followed the initial thread posted on the forum, which ranged from a
posting that received a single reply to those that continued over several A4 pages. Seventy-two initial threads were collected over a four-month period (22 April 2011 to 21 August 2011). The threads were read and re-read before coding in NVivo 9. Following initial coding and analysis for initial themes, data collection continued for another three months, with an additional 49 threads collected, giving a total of 121 threads before saturation was reached and no new themes were identified.

2.3.4.6 Ethics approval

Ethics approval was not considered a requirement due to public access to the information. The data were only collected from forums that required no password access or where those who posted were required to join as members. The data collected on the threatened miscarriage Internet forums were not only freely accessible to the public, but those posting comments were also aware that they were posting on a public forum. This decision reflects that of other researchers using the Internet to collect data from public postings. This includes Google alerts created to collect media alerts concerning midwives and obstetricians, and comments from blogs concerning vaginal birth following a caesarean section (Dahlen & Homer 2011, 2012). A discussion paper on the ethics of collecting blog-based Internet data also states that ethics approval is not considered a requirement for publically posted blogs (Eastham 2011).

2.4 Quality Assessment

While there is a growing body of literature concerning the assessment of quality standards in MMR, at present, there is no agreement regarding a specific criterion that constitutes a quality assessment of MMR (O’Cathain et al. 2010). Important questions to consider when evaluating MMR include: What is important to evaluate? Should the components of the different designs of a study be assessed separately or together? Is it necessary to evaluate in terms of how final inferences are used? (Tashakkori & Teddlie 2010). Tashakkori and Teddlie (2010) argued that while it is possible to evaluate the components of the quantitative aspects of a study using criteria from quantitative literature and to evaluate qualitative components using criteria from qualitative literature, MMR is not merely a juxtaposition of two types of results. The authors
proposed a systematic approach that would be more useful to evaluate MMR. This approach uses three elements—inputs, process and outcomes—to determine inferences. This approach was used in this study.

2.4.1 Inputs, Process, Outcomes and Inferences

The term ‘inputs’ refer to the ideas in a research project, including the research questions asked and the prior knowledge that a researcher brings to the study. The term ‘process’ refers to the analysis of this collected data, including the summarising, categorising, linking, comparing and integration of all evidence. In this study, this applies to the analysis of the RCT and online acupuncture survey using quantitative analysis and the qualitative thematic analysis generated from semi-structured interviews with women exiting the RCT, acupuncturists participating in the online survey, Western health practitioners in contact with women presenting with threatened miscarriage and women posting on Internet threads discussing threatened miscarriage.

‘Outcomes’ refer to the inferences made from comparing and contrasting the quantitative and qualitative components of the study. ‘Inference’ is a term used by Tashakkori and Teddlie (2010) to describe making sense of the results produced in the study and the conclusions. The terms ‘inference quality’ and ‘inference transference’ are proposed to describe the quality of the conclusions and how they may be applicable to settings other than those investigated in the study.

Assessing the quality of the inputs, process, outputs and inferences in a study is not only important in each section, but it is also of vital importance because of their interrelated effects (Tashakkori & Teddlie 2010). For example, a poorly conceptualised question is not a self-contained problem in a study because it leads to inconsistent research design, poor analysis and inferior outcomes. It also follows that, even with a well-conceptualised and articulated question, well-designed data collection and analysis are required to produce quality research. The final aspect of this quality assessment involves interpretation, as the inappropriate interpretation of findings results in low-quality inferences being made.
For this study, the inputs in terms of research aims and questions were stated at the beginning of each chapter. The analytical process that was used for the data for each of the studies was outlined in this chapter. The findings for each study are presented in chapter 3 to 6. For the chapters 3 and 4 that contain quantitative and qualitative components, the findings are initially integrated into the relevant chapter. Chapter 7 integrates all data with a discussion of the inferences. Chapter 8 discusses the findings and employs a dialectic stance to search for an understanding of the conflicts in the findings. It concludes with recommendations for future research and clinical practice.

2.4.2 Personal reflection as the lead researcher

As stated by Tashakkori and Teddlie (2010), the study input not only refers to the questions asked in a study, but also to the knowledge that researchers bring to the study. As a researcher, my background knowledge affected how the study was conceptualised and the questions that I felt were important to ask. On reflection, it is likely that my interest in using a dialectic approach reflected my experiences as a health-care provider, which involved a Western medical nursing background of neonatal intensive care nursing and a CAM background as an acupuncturist. The approach of considering Western medicine and TCM as both having value in a clinical treatment setting and that examining the conflicts and differences between these two systems may generate new understandings reflects my clinical experiences and personal interests. In addition, my experiences as an acupuncture lecturer who has taught TCM concepts to acupuncture students and midwives reinforce that developing an understanding between these two medical systems is worth exploring.

For the qualitative research in this thesis, I have attempted to understand the personal experiences of the participants. An important aspect of analysing and interpreting these data involved reflection on how my own actions, values and perceptions affected how the data were collected and reported. Lambert et al. (2010) suggested that the personal input of a researcher could be explained using the mental model of a photographer looking through the lens of a camera, with this model comparing data to the photograph, while the researcher corresponds to the photographer and the research project the image produced. In this way, researchers collect and interpret data while acknowledging that it is through their eyes and keeping the research project in focus. As an acupuncture
practitioner researching acupuncture practice, it was important to remain open to the possibility of bias resulting from my previous clinical experience, and to discuss this possibility with my supervisors (CS and HD).

While acknowledging that my experiences and beliefs affect my interest in this research as well as the framing of the research questions, the process involving the research analysis and the resulting outcomes and inferences reflect the research process detailed in this methodology chapter, with the aim of reducing bias in the collection, analysis and reporting of data.

2.5 Summary

Section 2.1 discussed the epistemology and methodology that guided the research design used in this study. This involved examining the use of pragmatic and dialectic stances with MMR and outlining the rationale for the dialectic stance used in this study.

Section 2.2 detailed the integration of data and research findings in this thesis. Section 2.3 detailed the qualitative and quantitative data collection methods used in this study and discussed how these data were analysed, as well as how specific ethical concerns were addressed.

Section 2.4 closed with a discussion on quality assessment in MMR and how this was addressed in the study. The following chapters report the results, with Chapter 3 discussing the findings of an online survey of acupuncture practitioners to demine the current use of acupuncture among acupuncturists in Australia and New Zealand for threatened miscarriage and their considerations for optimal clinical practice for this presentation compared to textbook recommendations.
Chapter 3: Clinical Practice Considerations Among Acupuncturists—A Survey and Semi-structured Interviews

3.1 Introduction

This chapter presents the findings of an online survey and semi-structured interviews with acupuncturists. The aim of this research was to investigate the current use of acupuncture among acupuncturists in Australia and New Zealand for threatened miscarriage and to examine their considerations for optimal clinical practice compared to textbook recommendations. The overall research questions were:

1. What is the current interest and use of acupuncture among acupuncturists in Australia and New Zealand for treating threatened miscarriage?
2. What are acupuncturists’ considerations for optimal clinical practice for this presentation compared to textbook recommendations?

As part of the mixed methods approach being used for this study, an online survey was initially conducted, followed by in-depth interviews. This chapter first presents the findings of the survey, followed by the findings of the semi-structured interviews. The chapter concludes with an integration of these findings. Further integration of these findings with the findings in other chapters of this thesis occurs in Chapter 7. A discussion of these findings is presented in Chapter 8.

3.2 Online survey of acupuncture practitioners in Australia and New Zealand

This survey contributed descriptive statistics about the practice of acupuncture for threatened miscarriage, including the interest in providing treatment among practitioners, any safety and ethical concerns they may have, and the treatment modalities used in clinical practice. In addition, qualitative comments made by the participants as part of the open-ended questions provided further details about these aspects. The use of specific acupuncture points contraindicated in pregnancy was also
examined using bivariate analysis to explore any associations between practitioner characteristics that may have influenced the use of these points.

### 3.3 Survey results

#### 3.3.1 Response Rate

A total of 3,151 practitioners from three Australian and three New Zealand professional associations received an invitation (2,453 in Australia and 698 in New Zealand) to participate in the survey. Three hundred and seventy replies were received from practitioners who self-selected themselves as being interested in this area of practice—an overall response rate of 11.7%. An analysis of the response rate of practitioners in Australia and New Zealand identified that 223 (60.3%) resided in Australia, giving a response rate of 9.0%. The response rate for New Zealand practitioners was 8.3%, with 58 (15.7%) participants identified as residing in New Zealand.

Despite the invitation to the online survey only being sent to professional organisations in New Zealand and Australia, the survey link was subsequently posted on two Facebook sites and the website of the British Acupuncture Association (BAcC). Upon discovering these postings, the individuals concerned were contacted and the links were removed. However, this resulted in 10 (2.7%) responses that could be identified from their IP addresses as being from the UK, Ireland, Canada and Norway. Seventy-nine participants (21.4%) did not supply information regarding whether Australia or New Zealand was their county of residence.

#### 3.4 Demographics

Of the 370 participants responding to this survey, 214 (57.8%) indicated that they had treated women for threatened miscarriage in the past year, with 156 (42.2%) stating that they had not. However, not all participants proceeded to answer further questions. For those individuals treating women in the past year, 50 participants supplied no further information and were thus excluded from the analysis, leaving a denominator of 164 participants for further analysis. For those who had not treated threatened miscarriage in the past year, 15 participants supplied no further information and were excluded from
further analysis, leaving a denominator of 141 participants for further analysis. Details of the baseline demographic information for the total 305 participants are presented in Table 3.1.

Table 3.1: Demographic characteristics for participants responding to the survey (n=305)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Participants (n=305)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>197</td>
<td>64.6</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>91</td>
<td>29.8</td>
<td></td>
</tr>
<tr>
<td>Did not complete</td>
<td>17</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 40 years</td>
<td>132</td>
<td>43.2</td>
<td></td>
</tr>
<tr>
<td>40 years and older</td>
<td>156</td>
<td>51.1</td>
<td></td>
</tr>
<tr>
<td>Did not complete</td>
<td>17</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>223</td>
<td>73.1</td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td>58</td>
<td>19.0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>Did not complete</td>
<td>14</td>
<td>4.6</td>
<td></td>
</tr>
<tr>
<td><strong>Years in practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 10 years</td>
<td>173</td>
<td>56.7</td>
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</tr>
<tr>
<td>10 years or more</td>
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</tr>
<tr>
<td>Did not complete</td>
<td>14</td>
<td>4.6</td>
<td></td>
</tr>
<tr>
<td><strong>Place of practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sole practice or with CAM practitioners</td>
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<td>78.4</td>
<td></td>
</tr>
<tr>
<td>With medical practitioners</td>
<td>81</td>
<td>26.6</td>
<td></td>
</tr>
<tr>
<td>In fertility unit</td>
<td>21</td>
<td>6.9</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>Did not complete</td>
<td>14</td>
<td>4.6</td>
<td></td>
</tr>
<tr>
<td><strong>Style of practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eight principals</td>
<td>204</td>
<td>66.9</td>
<td></td>
</tr>
<tr>
<td>Five phase</td>
<td>88</td>
<td>28.9</td>
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</tr>
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<td>Japanese</td>
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<td>1.6</td>
<td></td>
</tr>
<tr>
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<td>7.2</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>54</td>
<td>17.2</td>
<td></td>
</tr>
<tr>
<td>Did not complete</td>
<td>14</td>
<td>4.6</td>
<td></td>
</tr>
<tr>
<td><strong>Highest qualification held</strong></td>
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<td></td>
</tr>
<tr>
<td>Diploma</td>
<td>64</td>
<td>21.0</td>
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<td>166</td>
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<tr>
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</tr>
<tr>
<td>Did not complete</td>
<td>14</td>
<td>4.6</td>
<td></td>
</tr>
</tbody>
</table>

* More than one answer possible

The majority of respondents were female (197, 64.6%), practicing in Australia (223, 73.1%), with just over half having been in practice for less than 10 years (173, 57.6%). The majority practiced as sole practitioners or worked with other CAM practitioners
(239, 78.4%) and selected their main style of acupuncture as ‘eight principals’ (204, 66.9%). Approximately half of the participants held a Bachelor’s Degree as their highest acupuncture qualification (166, 54.4%) and were over 40 years old (156, 51.1%).

The practice of treating women with threatened miscarriage was not associated with the sex of the practitioner, country of residence, years in practice, qualification or style of practice (Table 3.2).

Table 3.2: Comparison of demographic characteristics for participants who were actively treated compared to those who did not actively treat women with threatened miscarriage in the past year

<table>
<thead>
<tr>
<th>Variable</th>
<th>Participants actively treating</th>
<th>Participants not actively treating</th>
<th>Participants Total number</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex (n=288)</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>(111) 56.3</td>
<td>(86) 43.7</td>
<td>197</td>
<td>0.15</td>
</tr>
<tr>
<td>Male</td>
<td>(43) 47.3</td>
<td>(48) 52.7</td>
<td>91</td>
<td></td>
</tr>
<tr>
<td><strong>Country (n=291)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>(126) 56.5</td>
<td>(97) 43.5</td>
<td>223</td>
<td>0.11</td>
</tr>
<tr>
<td>New Zealand</td>
<td>(24) 41.4</td>
<td>(34) 58.6</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>(6) 60.0</td>
<td>(4) 40.0</td>
<td>10</td>
<td></td>
</tr>
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<td><strong>Years in practice (n=291)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Less than 10 years of practice</td>
<td>(86) 49.7</td>
<td>(87) 50.3</td>
<td>173</td>
<td>0.07</td>
</tr>
<tr>
<td>10 or more years of practice</td>
<td>(71) 60.2</td>
<td>(47) 39.8</td>
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<td><em><em>Place of practice</em> (n=291)</em>*</td>
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<td>(107) 44.8</td>
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<td>With medical practitioners</td>
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<td>Eight principals</td>
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<td>(2) 40.0</td>
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<td>(14) 63.6</td>
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<td>0.11</td>
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<td>(37) 57.8</td>
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<td>(73) 44.0</td>
<td>166</td>
<td></td>
</tr>
<tr>
<td>Masters</td>
<td>(23) 65.7</td>
<td>(12) 34.3</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>PhD</td>
<td>(2) 33.3</td>
<td>(4) 66.7</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>(12) 60.0</td>
<td>(8) 40.0</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

* More than one answer possible
** P<0.05

4 Acupuncture styles of practice can be identified according to theories developed in China (eight principals and five phases), Japan and Korea.
However, the place of practice was associated with significantly more acupuncturists located in fertility units and treating threatened miscarriage compared with those not treating \((n=18, 85.7\%)\) \((x^2 9.19, p=0.03)\). However, this finding involved only a small number of participants treating in a fertility unit \((n=21)\).

The results of this survey are now presented through first examining the responses from those participants who had not treated women in the past year. The following section outlines why acupuncturists had not treated women with threatened miscarriage, any safety and ethical concerns they had and their future interest in treating threatened miscarriage.

### 3.5 Participants who had not used acupuncture for threatened miscarriage in the past year

When practitioners were asked why they had not treated women with threatened miscarriage in the past year, the majority of participants \((100, 70.9\%)\) stated that they would have been happy to treat but had not done so because no one had presented in their clinic. A minority of three participants \((2.1\%)\) did not think that acupuncture was a suitable treatment for threatened miscarriage and nine \((6.4\%)\) indicated that they wanted more information before offering treatment. Twelve practitioners \((8.5\%)\) stated that they did not treat women with threatened miscarriage because they did not treat any pregnant women in their practice. The remaining 17 practitioners \((12.1\%)\) gave a variety of reasons, including referral to another practitioner, referral for Western medical treatment, only using traditional Chinese herbs or they were not presently practicing.

When asked if they were interested in treating women with threatened miscarriage in the coming year, the majority \((88, 64.7\%)\) expressed an interest, with 35 \((25.7\%)\) stating that they were unsure and a minority \((13, 9.5\%)\) stating that they were not interested.

### 3.6 Safety and ethical concerns

While the majority of practitioners \((113, 80.1\%)\) considered acupuncture a safe and ethical treatment, some practitioners had concerns, with 28 practitioners \((19.9\%)\) stating
safety concerns in terms of being held responsible in the case of a subsequent miscarriage or incorrect treatment resulting in miscarriage. Ethical concerns were also expressed, with 24 (17.0%) practitioners concerned about aspects such as prolonging a pregnancy that was going to subsequently miscarry, allowing a baby with deformities to be carried to term and believing that Western medical treatment would be a more effective treatment. The remaining responses to the survey were from participants who had treated women in the past year.

3.7 Participants who had used acupuncture for threatened miscarriage in the past year

Practitioners who were actively treating women for threatened miscarriage responded to questions designed to elicit information concerning their current use of acupuncture for threatened miscarriage and their considerations for optimal clinical practice compared to textbook recommendations. The responses below are presented with the number of women treated in the past year, followed by any safety and ethical concerns, the education sources they found to be the most useful and details of the treatment modalities they used. This section concludes with the referral sources for their practice.

3.8 Number of women treated in the previous year

Of the participants who reported treating women with threatened miscarriage, 140 (85.4%) had treated less than 10 women in the previous year. Although approximately half (95, 57.9%) of the participants in the survey had treated four or less women, a minority (23, 14.0%) appeared to specialise in this area, having treated 15 or more women in the previous year.

3.9 Safety and ethical concerns

While 20 practitioners (12.2%) had safety concerns about treating women with threatened miscarriage, this differed from the concerns reported by those who had not treated women in the previous year. Only one practitioner was concerned about being held responsible for a miscarriage, with the remaining 19 practitioners expressing
concern about fellow practitioners having the potential to cause a miscarriage. These concerns included those who were inadequately trained, those using inappropriate treatment, those who lacked an adequate understanding of TCM concepts and those ‘who did not appreciate their own limitations’. Of the 16 practitioners (10.1%) who expressed ethical concerns, these focused on two aspects: prolonging an inevitable miscarriage and a woman carrying a baby to term with abnormalities.

3.10 Educational resources

Participants were asked where they had obtained the information they had found to be the most useful for their clinical practice. Their responses are given in Figure 3.1. The majority of practitioners selected acupuncture textbooks as an educational resource above all other sources. The use of acupuncture textbooks by 125 practitioners (76.2%) was supplemented by the use of acupuncture journals for 40 practitioners (24.4%). For approximately half of the practitioners, useful information came from formal and informal interactions with other acupuncturists, including acupuncture seminars (82, 50%), undergraduate training (81, 49.4%) and informal discussions with other practitioners (72, 43.9%).

Medical books and journals, along with Internet sources, were viewed as the least useful, with only 21 (12.9%) practitioners utilising Western medical sources of information and 18 (11%) utilising Internet-based information. Other sources of information were used by 27 (16.5%) practitioners, including their own experiences and postgraduate training with experienced practitioners, as well as time spent in hospitals in China and Japan.
3.11 Treatment modalities

3.11.1 TCM modalities used

Participants were asked about the general treatment modalities they would consider using in addition to manual acupuncture for women presenting with threatened miscarriage. Moxibustion\(^5\) was the most frequently used modality, with 111 (67.6%) practitioners stating that they would consider using it. Chinese herbal medicine and diet and lifestyle advice were also used by the majority of practitioners, with 110 (67.0%) practitioners indicating that they would use Chinese herbs, 103 (62.8%) giving lifestyle advice related to traditional Chinese concepts and 84 (51.2%) giving dietary advice related to traditional Chinese concepts.

\(^5\) Moxibustion is a therapeutic procedure involving the herb mugwort (Artemesiae Vulgaris) to apply heat to specific acupuncture points or areas of the body to regulate the function of the meridians and visceral organs (WHO International Standard terminologies). Moxibustion may involve a variety of methods, of which the most common involves the use of a prepared moxa stick, which is lighted and held over a specific area.
A minority of practitioners used other treatments, with 28 (17%) applying ear acupuncture, six (5.4%) using cupping therapy and eight (4.8%) using Tuina (Chinese massage). Only two participants (1.2%) used electro acupuncture and three (1.8%) used Western herbal medicine. Fifteen practitioners (9.1%) selected other treatment modalities such as Qigong (Chinese breathing, movement and mediation techniques), acupuncture tuning forks, heat lamps on acupuncture points, relaxation techniques, Western herbal supplements and yoga exercises.

3.11.2 Use of contraindicated acupuncture points in pregnancy for women presenting with threatened miscarriage

Participants were asked if there were acupuncture points listed in TCM textbooks as forbidden or contraindicated in pregnancy that they would avoid when treating threatened miscarriage. These contraindicated points were those cautioned against because of their use in inducing labour and those cautioned against by some authors but without a rationale. Figure 3.2 presents the results of participants’ responses regarding contraindicated points because of their use in inducing labour that they would not avoid when treating threatened miscarriage.

![Figure 3.2: Contraindicated acupuncture points participants would not avoid (n=164)](image)

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6 A microsystem acupuncture therapy in which the points are located on the auricle of the ear and needled for therapeutic purposes (WHO International Standard terminologies).
7 A therapeutic method involving the application of suction by placing a vacuumised cup onto a specific acupuncture point or area of the body (WHO International Standard terminologies).
LI 4 is listed in the majority of acupuncture textbooks as a point to be avoided in pregnancy, although 21 participants (12.8%) indicated that they did not avoid this in practice. Thirty-six practitioners (22%) indicated that they would not avoid using SP 6, with 42 practitioners (25.6%) indicating that they would not avoid GB 41 in their clinical practice. Although used as induction points, BL 31, BL 32, BL 33 and BL 60 can also be used as points to treat back pain, with over one-third of practitioners (51–73, 31.1–44.5%) indicating that they would not avoid using these points. Approximately half of the participants (83, 50.6%) indicated that they would not avoid using BL 67—an induction point that is also indicated for use in promoting the optimal position of a breech or posterior baby after 34 weeks. In addition, five participants (3%) indicated that they did not avoid any points when treating threatened miscarriage.

Characteristics such as the practitioners’ style of practice and their experience may affect the use of these contraindicated points. The relationship between these variables is examined in Table 3.3. These findings suggest statistically significant differences for practitioners who would not avoid using contraindicated points who identified as medical acupuncturists compared with non-medical practitioners. These practitioners were more likely to use the acupuncture point GB 21 (p=0.002) and approached statistical significance for the acupuncture points LI 4 (p=0.058) and SP 6 (p=0.056). Practitioners with 10 or more years of clinical practice were significantly more likely to use acupuncture points LI 4 (p=0.002), SP 6 (p=0.001), GB 21 (p=0.012) and BL 60 (p=0.001) compared with acupuncturists with less experience. However, there were no statistically significant differences for practitioners who identified as practicing a Japanese style of acupuncture or those who had treated more than 10 women in the previous year.
**Table 3.3: Comparison of participants who would not avoid contraindication acupuncture points for style of practice (medical and Japanese) and experience (length of time in practice and number of women treated)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Practitioners who do not avoid acupuncture points</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Practitioners who do not avoid acupuncture points</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical (n=8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-medical (n=150)</td>
<td></td>
</tr>
<tr>
<td>LI 4</td>
<td>3 (37.5)</td>
<td>16 (10.7)</td>
</tr>
<tr>
<td></td>
<td>(13.4, 69.6)</td>
<td>(6.58, 16.7)</td>
</tr>
<tr>
<td>SP 6</td>
<td>4 (50.0)</td>
<td>29 (19.3)</td>
</tr>
<tr>
<td></td>
<td>(21.5, 78.4)</td>
<td>(13.7, 26.4)</td>
</tr>
<tr>
<td>GB 21</td>
<td>6 (75.0)</td>
<td>32 (21.3)</td>
</tr>
<tr>
<td></td>
<td>(40.0, 93.6)</td>
<td>(15.5, 28.6)</td>
</tr>
<tr>
<td>BL 31</td>
<td>3 (37.5)</td>
<td>52 (34.7)</td>
</tr>
<tr>
<td></td>
<td>(13.4, 69.6)</td>
<td>(27.5, 42.5)</td>
</tr>
<tr>
<td>BL 32</td>
<td>3 (37.5)</td>
<td>43 (28.7)</td>
</tr>
<tr>
<td></td>
<td>(13.4, 69.6)</td>
<td>(22.0, 36.3)</td>
</tr>
<tr>
<td>BL 33</td>
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<td>55 (36.7)</td>
</tr>
<tr>
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<td>(13.4, 69.6)</td>
<td>(29.3, 44.6)</td>
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<td>BL 60</td>
<td>4 (50.0)</td>
<td>63 (42.0)</td>
</tr>
<tr>
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<td>(21.5, 78.4)</td>
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</tr>
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<td>75 (50.0)</td>
</tr>
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<td>(13.4, 69.6)</td>
<td>(42.1, 57.9)</td>
</tr>
<tr>
<td>Japanese (n=27)</td>
<td></td>
<td></td>
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<tr>
<td>LI 4</td>
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</tr>
<tr>
<td></td>
<td>(3.03, 28.8)</td>
<td>(7.56, 19.0)</td>
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</tr>
<tr>
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<td>(7.72, 37.1)</td>
<td>(15.1, 29.2)</td>
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</tr>
<tr>
<td></td>
<td>(3.03, 28.8)</td>
<td>(21.9, 37.3)</td>
</tr>
<tr>
<td>BL 32</td>
<td>6 (22.2)</td>
<td>40 (30.5)</td>
</tr>
<tr>
<td></td>
<td>(10.2, 41.1)</td>
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</tr>
<tr>
<td></td>
<td>(12.9, 44.9)</td>
<td>(28.8, 45.1)</td>
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<td>8 (29.6)</td>
<td>50 (38.2)</td>
</tr>
<tr>
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<td>(15.6, 48.6)</td>
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<td>BL 67</td>
<td>9 (33.3)</td>
<td>69 (52.7)</td>
</tr>
<tr>
<td></td>
<td>(18.5, 52.2)</td>
<td>(44.1, 61.0)</td>
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<td>Less than 10 years in practice (n=86)</td>
<td>More than 10 years in practice (n=72)</td>
<td></td>
</tr>
<tr>
<td>LI 4</td>
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</tr>
<tr>
<td></td>
<td>(1.46, 11.7)</td>
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</tr>
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<td>SP 6</td>
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<td></td>
<td>(5.40, 18.9)</td>
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<td>BL 31</td>
<td>28 (32.6)</td>
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<td>(23.5, 43.0)</td>
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<td>30 (41.7)</td>
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<td>(23.5, 43.0)</td>
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<td></td>
<td>(20.4, 39.4)</td>
<td>(46.8, 69.0)</td>
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<tr>
<td>BL 67</td>
<td>37 (43.0)</td>
<td>41 (56.9)</td>
</tr>
<tr>
<td></td>
<td>(33.0, 53.5)</td>
<td>(45.4, 67.7)</td>
</tr>
<tr>
<td>Less than 10 women (n=139)</td>
<td>More than 10 women (n=23)</td>
<td></td>
</tr>
<tr>
<td>LI 4</td>
<td>18 (12.9)</td>
<td>2 (8.7)</td>
</tr>
<tr>
<td></td>
<td>(8.26, 19.6)</td>
<td>(1.25, 27.9)</td>
</tr>
<tr>
<td>SP 6</td>
<td>29 (20.9)</td>
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</tr>
<tr>
<td></td>
<td>(14.8, 28.4)</td>
<td>(12.2, 46.7)</td>
</tr>
<tr>
<td>GB 21</td>
<td>36 (25.9)</td>
<td>9 (39.1)</td>
</tr>
<tr>
<td></td>
<td>(19.3, 33.7)</td>
<td>(22.1, 59.2)</td>
</tr>
<tr>
<td>BL 32</td>
<td>40 (28.8)</td>
<td>9 (39.1)</td>
</tr>
<tr>
<td></td>
<td>(21.8, 36.8)</td>
<td>(22.1, 59.2)</td>
</tr>
<tr>
<td>BL 33</td>
<td>35 (26.0)</td>
<td>11 (47.8)</td>
</tr>
<tr>
<td></td>
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<td>(29.2, 67.0)</td>
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<td>BL 67</td>
<td>70 (50.4)</td>
<td>11 (47.8)</td>
</tr>
<tr>
<td></td>
<td>(42.1, 58.5)</td>
<td>(29.2, 67.0)</td>
</tr>
</tbody>
</table>

* P<0.05

In addition to those points contraindicated due to their use in inducing labour, there are contraindicated points listed in textbooks without a rationale of why they are contraindicated. Figure 3.3 presents participants’ avoiding the use of specific acupuncture points.
Figure 3.3: Acupuncture points that practitioners would avoid when treating threatened miscarriage (n=164)

Around one-fifth (9.7–20.7%) of practitioners indicated that they would avoid acupuncture points (KI 6, Hua Tuo Jia Ji points, SP 3, LU 7, BL 63 ST 21). These points are contraindicated in certain texts but are recommended for pregnancy-related complaints in other texts. The remaining point ST 12 is not specifically recommended for pregnancy-related conditions, although 34 practitioners (22.6%) indicated that they would avoid this point. Just over 20% of participants indicated that they would also avoid additional points, which they listed as KI 1, KI 3, ST 36, LV 3, GV 20, GB 20, GB 34, SP 3, SP 1, HT 9 and SP 10. These points included commonly used acupuncture points to treat a variety of conditions that are recommended for use in acupuncture pregnancy texts.

3.11.3 Use of abdominal points with acupuncture or moxibustion

Participants were asked how they used these abdominal points in their clinical practice, including whether they would use the points only for a specific diagnosis or in all cases they treated (see Figure 3.4).
There was a divided response to this question, with practitioners selecting differing treatment options. Just over one-third of practitioners (53, 32.3%) indicated that they would avoid abdominal points completely, while 58 (35.9%) indicated that they would use abdominal points with either moxibustion or acupuncture, depending on the specific TCM diagnosis. Of the practitioners who would use abdominal points but would only consider using either moxibustion or acupuncture, this was also divided, with no consensus on using one specific modality. Twenty-four practitioners (14.6%) would only use acupuncture on these points, while 17 practitioners (10.4%) would only use moxibustion. Only five practitioners indicated that they would use abdominal points as a standard treatment without having a specific TCM diagnostic pattern, and six practitioners did not answer this question.

3.11.4 Use of acupuncture points that have functions for moving or invigorating blood

Participants were asked whether they used acupuncture points, when appropriate, that have functions for moving or invigorating blood when treating threatened miscarriage (see Figure 3.5). These acupuncture points were generally avoided during pregnancy, except in circumstances relating to obvious uterine trauma. However, in the case of threatened miscarriage, they may be appropriate where bleeding is related to uterine hematomas.
Practitioners were divided about the use of these points in clinical practice. Seventy-nine participants (48.2%) were not willing to use these points at all, while 71 (43.3%) indicated that they would use these points when appropriate. Five practitioners used techniques other than acupuncture; one practitioner used herbal medicine and four practitioners used other acupuncture points to indirectly influence treatment through energetic actions unrelated to moving or invigorating blood. Six practitioners did not answer this question, and three practitioners indicated that they would use these points in all cases of threatened miscarriage.

**3.11.5 Use of acupuncture point SP 1 in the treatment of threatened miscarriage**

Practitioners were asked how they used SP 1 in their clinical practice (see Figure 3.6). This acupuncture point is historically used to treat bleeding from the uterus, although the modality differs in textbooks: some recommend using it only with moxibustion for threatened miscarriage and others recommend using it with needling or moxibustion.
Sixty-one practitioners (37.2%) did not use SP 1 at all in treatment. While the majority of the remaining practitioners used this acupuncture point, it was divided between those who would use acupuncture or moxibustion depending on the TCM diagnosis. Fifty-five practitioners (33.6%) would use it with moxibustion or acupuncture depending on their diagnosis, while 33 practitioners (20.1%) would only use moxibustion as a treatment. Nine acupuncturists (5.4%) would use this point in all cases of threatened miscarriage, and two practitioners used other modalities (a laser and a heat lamp) on this acupuncture point.

3.11.6 Further treatment modalities

Practitioners were asked about the use of cupping on acupuncture point CV 8 (a point situated over the umbilicus that can be used in the treatment of threatened miscarriage). Although this is not a treatment recommended in English acupuncture textbooks, it has been reported by practitioners as a treatment used in Chinese hospitals. An overwhelming majority of 146 practitioners (89.0%) did not use technique, with only 14 practitioners (8.6%) using this technique in their clinical practice.
3.12 Treatment referral

The final question in this survey asked practitioners about where the women they saw for threatened miscarriage were referred from (see Figure 3.7).

![Figure 3.7: Participants’ patient referrals (n=164)](image)

Eighty practitioners (48.8%) indicated the majority of women they treated for threatened miscarriage came to them as current fertility patients, while 52 practitioners (31.7%) indicated that their referrals came from patients they were treating for other conditions or through referral from previous patients. Eighteen practitioners (10.9%) indicated that the majority of their patients were referred from other Western-trained health practitioners, including GPs, midwives, hospital departments and fertility units. Of this collective of Western-trained health practitioners, three participants indicated that the majority of their referrals came directly from fertility units. A further four practitioners indicated that the majority of their referrals came through CAM-trained health practitioners, and four practitioners selected the ‘other’ option, stating that their referrals were from various sources.

This concludes the reporting of the results from the online survey. Next, this chapter discusses the findings of the semi-structured interviews.
3.13 Thematic analysis from acupuncture practitioner interviews

This section presents the findings of the analysis of 13 in-depth interviews undertaken over Skype with Australian and New Zealand acupuncturists concerning their clinical practice when treating women presenting with threatened miscarriage. The aim of this research was to identify what practitioners considered the key aspects of acupuncture treatment for women experiencing threatened miscarriage compared to textbook recommendations.

Of the 13 practitioners interviewed, 12 were female, 11 were from Australia and two were from New Zealand. Four practitioners had over 20 years’ clinical experience, four had approximately 10 years’ experience and the remaining five cited at least six years’ clinical experience. In terms of the acupuncture points and modalities used, six stated that they would use contraindicated points compared to seven who would not, eight would use abdominal points compared to five who would not, and 11 would use blood-moving points compared to two who would not.

An overarching theme emerged from the data of ‘safety first—a therapeutic balancing act’, which encompassed three main themes: ‘well I’m safe because…justifying diverse approaches’, ‘empowering women in a unique way’ and ‘acquiring trustworthy knowledge’. Together, these themes reflect acupuncturists’ views on the challenges of providing care for women in this specialist area of practice that has the potential for early pregnancy loss. The main themes are discussed below, and then each theme is presented in more detail, along with its associated subthemes. This chapter then concludes with a discussion that incorporates the findings of the thematic analysis and the survey data.

3.14 Overview of themes

‘Safety first—a therapeutic balancing act’ was the central unifying theme from these interviews. Three major themes have been used to structure the data, with each theme generating several subthemes. These themes and subthemes are presented in Table 3.4 and Figure 3.8. The first theme, ‘Well I’m safe because…justifying diverse
approaches’, captures how all practitioners viewed themselves as providing safe treatment, but used diverse and often conflicting approaches when providing this treatment, including their approach to using specific acupuncture points and TCM modalities, as well as their approach to working with Western-trained medical practitioners.

The second theme, ‘empowering women in a unique way’, illustrated how acupuncturists viewed themselves as being able to offer women beneficial treatment that was not available to them in the Western medicine health system. Treatment in a traditional Chinese framework included not only the use of needles and traditional Chinese modalities such as Chinese herbal medicine, but also support and specific diet and lifestyle advice.

The final theme, ‘acquiring trustworthy knowledge’, illustrated how practitioners educated themselves in this specialised field when there was limited and often conflicting educational material in acupuncture texts. It also illustrated the knowledge that they found valuable for clinical practice.

**Table 3.4: Themes from acupuncture practitioners’ interviews**

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub themes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety first—a therapeutic balancing act</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Well I’m safe because…justifying diverse approaches</strong></td>
<td>Questioning and respecting historical knowledge</td>
</tr>
<tr>
<td></td>
<td>Adapting treatment</td>
</tr>
<tr>
<td></td>
<td>Claiming authority</td>
</tr>
<tr>
<td><strong>Empowering women in a unique way</strong></td>
<td>Framing advice to avoid self-blame</td>
</tr>
<tr>
<td></td>
<td>Providing a supportive relationship</td>
</tr>
<tr>
<td></td>
<td>Managing treatment expectations</td>
</tr>
<tr>
<td><strong>Acquiring trustworthy knowledge</strong></td>
<td>A limited knowledge base—sorting it out for yourself</td>
</tr>
<tr>
<td></td>
<td>Confidence through clinical feedback</td>
</tr>
</tbody>
</table>
Figure 3.8: Themes from acupuncture practitioners’ interviews

3.15 Presentation in the text

The quotations used in this chapter are identified according to numbers assigned to the practitioners (e.g. P1 for practitioner one), followed by the number of years they have been practicing acupuncture. An ellipsis (…) is inserted where words have been removed from a comment. Square parentheses [ ] are used to maintain anonymity where specific locations or names were used.

3.16 Safety first—a balancing act

This overarching theme captures how practitioners dealt with providing treatment when women were presenting with a condition that involved the potential for pregnancy loss. ‘Safety first—a therapeutic balancing act’ was used to capture how all practitioners sought to provide treatment that they considered both therapeutic and safe:
I’m usually very on the safe side because I do very light treatments compared to some other people. I hope they’re strong enough to do something therapeutically but not so strong as to cause harm if you like (P10, 20 years experience).

This ‘balancing act’ included making decisions concerning the acupuncture treatment and the self-care advice provided. Treatment decisions involving acupuncture included balancing what practitioners saw as effective treatment points and techniques with historical concepts of acupuncture points and techniques documented as contraindicated in pregnancy. Treatment decisions regarding self-care advice required maintaining a balance between the diet and lifestyle advice that practitioners considered important as part of their treatment, with the potential that woman could experience distress if they were unable, or chose not, to follow this advice and experienced a subsequent miscarriage:

I think also it’s important when you’re giving lifestyle advice and so particularly to this bunch of women to—for them not to take on too much responsibility for what happens as well, because that can be quite a difficult thing (P4, six years experience).

There were also ethical considerations in providing women with realistic treatment expectations. There was awareness that women were undertaking treatment in the hope of a continuing pregnancy and that, while this was the aim of the treatment, this hope should be balanced with the reality that miscarriage is a potential clinical outcome of threatened miscarriage:

It’s an attempt to support the body if we can. So I guess it’s a matter of communicating to them what you think is realistic and preparing them for the case that it may not be successful and give it your best shot (P10, 20 years experience).

A further aspect to achieving a therapeutic treatment balance was one of maintaining professional safety. As TCM practitioners in the Western medical system there was a balance to maintain between their preferred treatment options and the professional relationships they had with Western-trained medical practitioners. All participants expressed the importance of maintaining these professional relationships and how this involved moderating their treatment options to accommodate the expectations of Western-trained health practitioners:

I was very, very respectful of their first care provider and what their wishes were. I mean, as a practitioner, you don’t want to bite the hand that feeds you.
So giving herbs to a client that was under an obstetrician, if anything went wrong, it was me, my license. So you have to be practical. I would offer and have it available for any of my clients but it wasn’t par for the course (P3, 11 years experience).

The overarching theme of ‘safety first—a therapeutic balancing act’ links the three main themes from these interviews, which are presented in this chapter in the following order: ‘Well I’m safe because…justifying diverse approaches’, ‘empowering women in a unique way’ and ‘acquiring trustworthy knowledge’.

3.17 Well I’m safe because… justification for diverse approaches

The theme ‘well I’m safe because…justifying diverse approaches’ illustrates how all practitioners saw themselves as providing safe treatment, despite some participants using acupuncture points and techniques that other acupuncture practitioners considered as contraindicated in pregnancy, or the use of modalities such as Chinese herbal medicine, which other acupuncture and Western-trained health practitioners might not view as safe practice. All participants viewed themselves as practicing safely in a Western medical system, despite a range of approaches in how they worked with Western-trained health practitioners and how they integrated women’s Western medical diagnostic tests. The justifications for these diverse, often contradictory, treatment approaches is presented in the subthemes ‘questioning and respecting historical knowledge’, ‘adapting treatment’ and ‘claiming authority’.

3.17.1 Questioning and respecting historical knowledge

This subtheme reflects practitioners’ conflicting views on using the acupuncture points or treatment modalities cited in acupuncture texts as requiring caution in pregnancy due to their use in facilitating labour. This can be seen as a process in which practitioners either questioned the value of the knowledge presented in historical texts and chose to use all or some of these, or chose to respect this knowledge and refrained from using certain points and treatment modalities. For one practitioner, this questioning was related to all contraindicated acupuncture points and was justified due to the practitioner’s theory on modern needling techniques:

I don’t really see that there would be a problem. Because my technique…I think in the earlier books they are talking about thick needles and really strong
technique. Not so much with the fine needles that we have these days (P7, 20 years experience).

Other participants focused on specific acupuncture points that they felt could be useful, with participants citing various theory rationales for doing so. For example, some acupuncture points could be used individually in some circumstances, provided a specific needling technique was applied:

The classic combination of LI 4 and SP 6, obviously I never, never, never, never. But I have used LI 4 on its own. What I’ll do is just leave it on for a couple of minutes and take it out (P5, seven years experience).

Others felt that they could use specific points due to their understanding of Western medical physiology, and this practitioner explained the use of acupuncture points BL 31 and BL 32:

It just switches off that fight/flight response, get’s them really relaxed. I don’t have a problem with that (P4, six years experience).

Other participants cited reassurance gained from observing the practice of other health professionals—for example, using BL 32 bilaterally because ‘to me it’s just like a chiropractic adjustment. So it wouldn’t even hit my radar that they’d be forbidden’ (P9, 11 years experience).

In contrast, other practitioners were careful to avoid points and treatment modalities traditionally labelled as requiring caution in pregnancy. Due to the historical cautions of these points in textbooks, there was concern that using these points would jeopardise their professional reputation:

If the woman did have a miscarriage and she took a lawsuit out against me, if it was a point that in every textbook—like SP 6, for instance, or LI 4, there’s no way that I would be able to stand up and say well, I chose that point for something else (P3, 11 years experience).

There’s the books that sort of say avoid the abdominal points for the first trimester. I just play it very, very safe. I sort of really practice that insurance-based medicine, I suppose (P5, seven years experience).

Participants’ personal experiences (and those of trusted others) reinforced the conflicting viewpoints on these contraindicated points, either providing justification for
questioning and then using, or respecting and then avoiding, these points in early pregnancy:

I used all the forbidden points and it didn’t work. So it made me go well are they really forbidden? Do they really do anything? (P9, 11 years experience).

I do actually know of people who have tried to abort and were utterly unsuccessful. I’ve heard [name of acupuncture teacher] talk about it, how he knows of people who’ve tried. In China it’s been tried, that gives you positive feedback that even if you try really hard to induce a miscarriage, it’s not usually successful (P10, 20 years experience).

I had a girlfriend who found that she was pregnant and she said, I don’t want to have this baby. I said, well let’s just do some acupuncture and see what happens. Whether or not it would have happened anyway, but she did miscarry with that pregnancy (P6, six years experience).

3.17.2 Adapting treatment

The subtheme of ‘adapting treatment’ reflects how some practitioners felt that safe clinical practice involved adapting their treatment because Western-trained health practitioners were ‘the ones with the primary responsibility’ (P4, six years experience). Their concerns specifically centred on the safety of using herbal medicine, with concerns about possible reactions to using both herbal treatment and Western medications:

If a doctor has said they have to take it. I say okay. But you are taking herbs and acupuncture. If they are already taking aspirin and my herbs I actually have to reduce or not use herbs (P1, 28 years experience).

Some practitioners also modified the self-care advice they gave to prevent emotional stress if women had received conflicting self-care advice by Western-trained health practitioners:

If a doctor is giving them some advice and a midwife is giving her some advice and you want to give really different advice, I think it’s really important to bear in mind what the other person has said and modify your advice accordingly, if they’ve seen the other first so that they’re not in a state of disarray really (P2, 20 years experience).

Practitioners were also concerned for their own professional safety and adapted their treatment to maintain their professional relationships with Western-trained health practitioners:
I always kind of err on the safer side. A part of that is also about respecting and maintaining those relationships that I can develop with the obstetricians (P4, six years experience).

I had quite a few obstetricians referring and they generally didn’t like any of their clients having herbs. So generally if a client was under an obstetrician, I just wouldn’t do herbs (P2, 20 years experience).

While practitioners incorporated the diagnostic information offered by Western medicine into their diagnosis and treatment, this was not a straightforward adaption of Western information to inform diagnosis. While practitioners usually took the information into consideration, this was done in a way that did not replace their TCM diagnostic skills:

If they’ve been ever diagnosed with antiphospholipid antibodies or they have got a history of endometriosis or anything like that, then I’ll pay particular attention to their immune system (P2, 20 years experience).

I do take it into account, but I don’t have it as the be all and end all. I wouldn’t go, right okay, you’ve got a hematoma; this is what we’re going to do. I don’t feel like I would be guided effectively into a good treatment, if I was just going by what an ultrasound report said (P6, six years experience).

3.17.3 Claiming authority

In contrast to the theme of ‘adapting treatment’, there was ‘claiming authority’, where practitioners felt that they had a responsibility to promote the TCM treatment that they felt would be therapeutic, even if this meant a conflict with Western medicine practice. For the majority of practitioners, this meant discussing with women the self-care advice that they thought was important rather than agreeing with a ‘there is nothing you can do’ approach:

Where Western medicine might not have treatment for these women, and they’re like, look, there’s nothing more we can do…we have the education and the knowledge to be able to say to them, look, from a Chinese medical perspective, these are the foods that are going to be really important for you. These are the activities that are going to be really important to you (P5, seven years experience).

However, for one practitioner, this claiming authority also included using Chinese herbal medicine despite the potential for conflict with the woman’s Western-trained health practitioner's advice:
My rationale that I give is that I can only offer what I think is the best treatment. If they choose not to take it on, well, then I can’t necessarily give my best treatment. If they are coming to me for my advice, this is my advice. Yes, there’s resistance but most of the time, women are quite happy to take herbs (P6, six years experience).

### 3.18 Empowering women in a unique way

The theme ‘empowering women in a unique way’ reflects practitioners’ views that they were able to offer women not only an active treatment in the form of acupuncture, but also beneficial self-care advice and support that was not available in the Western medical health system. For all participants, the diet and lifestyle advice they gave was individualised according to traditional Chinese principles:

> With my diagnosis I give a different advice for them. If a Yin deficiency⁸ I will say have a very good sleep. It depends on what kind of - their problem. I put number one, number two, number three. So, basically—you know, lifestyle include emotions, sleep, and nutrition, food. But I’m not only talking about protein, red meat, minerals. This is one thing and plus Chinese medicine, you know Ying-Yang food⁹ (P1, 28 years experience).

Due to specific TCM concepts on how both emotional and physical health can affect women’s bodies in early pregnancy, providing emotional support and giving women self-care advice was seen as an important aspect of treatment. Overall, practitioners viewed providing support and self-care advice as more than something ‘extra’. It was seen as an important way to assist women to place themselves in the best possible position to optimise pregnancy outcomes. This included the importance of women remaining emotionally calm, as there are connections in TCM theory in which specific emotional responses have the potential (due to their effect on the channels nourishing the uterus) to influence the way that the uterus functions in early pregnancy:

> The main aim is to calm the spirit, calm the Shen¹⁰ because of the connection between the Heart¹¹ and the Bao Mai,¹² so that uterus and Heart connection—I mean once the pregnancy has started the Heart’s responsible for keeping the

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⁸ A pathological change marked by a deficiency of yin with diminished moistening, calming, down-bearing and yang-inhibiting function (WHO International Standard terminologies).

⁹ In TCM, all food has yin and yang qualities that affect the body (Betts 2006).

¹⁰ A term used in TCM to indicate the whole sphere of emotional, mental and spiritual aspects of a human being (Maciocia 1989).

¹¹ The heart as an organ in TCM theory has functions that extend beyond the anatomical function of Western medicine (Maciocia 1989).

¹² A meridian that connects the heart, kidneys and uterus in TCM theory (Lyttleton 2004).
uterus closed. So you don’t want to disturb the Heart in any way…It’s important that the Heart is calm and still. I think that’s huge. I think even just the fact that you are there like something that holds that woman when she comes every week for her treatment and she knows that you’re available by phone, that’s probably a huge, huge part of it (P2, 20 years experience).

There are also important connections in which beneficial responses are optimised through physical rest. According to TCM theory, this is seen as something very real that needs to occur to support the way that the body adapts to the changes of early pregnancy. If a woman is physically tired with corresponding TCM diagnostic patterns, promoting physical rest to restore the body’s optimal level of functioning is seen as a vital part of the treatment:

If there is a threatened miscarriage, basically you stop work, you rest. I mean I know people say look if you’re going to lose the baby, you’re going to lose the baby, just go on as usual but I totally disagree with that. Because by definition in the first trimester the Kidney is—any pregnancy loss is going to involve Kidney deficiency,13 pretty well and rest is really really important (P2, 20 years experience).

Dietary advice was also seen as important—in part, as an opportunity to assist the physiological functioning of specific organs and also by being able to make choices about beneficial foods. This advice can give women a sense of helping themselves, which provided beneficial emotional responses:

I get a lot of women calling me or before I even get to the diet, what should I be eating? They’re desperate for things to do. So that’s another way of empowering them with the tools to help heal themselves, so that they’re actually really, physically playing a part in getting their pregnancy right (P5, seven years experience).

The way that practitioners used acupuncture and traditional Chinese concepts to provide support and advice about beneficial self-care is outlined in the following subthemes: ‘framing advice to avoid self-blame’, ‘providing a supportive relationship’ and ‘managing treatment expectations.’

13 A general term for a deficiency condition involving the Kidney, which has a function related to fertility and reproduction in TCM (Maciocia 1989).
3.18.1 Framing advice to avoid self-blame

The theme ‘framing advice to avoid self-blame’ reflects participants’ concerns that diet and lifestyle advice was not given in a way that leads women to blame themselves in the event of a subsequent miscarriage:

I think it’s important to kind of say look, these are some tools that can be helpful. That can really support your body as best it can to deal with what’s going to happen (P4, six years experience).

An important aspect of providing the information that they felt was important was the concept of giving women choices and providing them with self-care activities that they saw as beneficial to their diagnosis, even if this required adapting this advice to individual circumstances:

I give a lot of handouts or I do up sheets for people with information. I always say, look what you do with this is really up to you but I really want you to be aware of the impact that these certain things could have on your body (P5, seven years experience).

I always emphasise that okay, you might have to go to work, because that might be something that you can’t change, but you have choices while you’re there. You have choices about what you put in your mouth. We’re not talking about for the rest of your life. We’re talking about getting you through this particular moment in time…so I think when you put it like that to a client, it seems—because it is, it’s just a small thing most women, I find, are receptive to it (P5, seven years experience).

These choices should be centred on specific choices that the women could make rather than allowing them to be overwhelmed by general self-care advice:

Then it becomes a balance between being obsessed by doing everything as well, because then they do too much, where they read everything online. They’re 100 per cent with their diet where they will try to be so restricted that it’s not funny, because they’ve read that you can’t eat this, you can’t do this, you can’t eat that. So, yeah, it’s trying to find that balance between doing something but not becoming obsessed by it (P8, six years experience).

3.18.2 Providing a supportive relationship

‘Providing a supportive relationship’ is a subtheme that reflects practitioners’ views that their support is an important contribution to the treatment they provided, and that the women might not be receiving it from anywhere else:
I think some of the treatment is really just having a forum for them to be able to talk to somebody that has got a bit more time for them and that kind of cares about their pregnancy and how they’re feeling. Because a lot of women as you know like don’t really share with their friends and family until they feel confident that the pregnancy’s going to continue so they’re very, very isolated (P4, six years experience).

I think it’s the support that we can give them. Just being there for them and when they have questions try to answer their questions and feel that they can ask you questions. Because I get that a lot where they ask me questions rather than their doctors, because the doctors aren’t available or they only see them for five minutes or something like that. All the emotional stuff that we can do and relaxing stuff that we can do with the acupuncture and the Chinese medicine is important (P8, five years experience).

For one practitioner, a supportive relationship was important not only as part of the treatment for threatened miscarriage, but also for future treatment, even if the pregnancy outcome was one of miscarriage:

You’ve either established a relationship to support them throughout the rest of their pregnancy or if the miscarriage comes inevitable, then you can support them either to successfully move through that miscarriage—like if they can avoid a D&C [Dilation and Curettage] with your acupuncture and herbs, that’s great. If not, then you can again support them afterwards to replenish blood and help them to prepare for the next one (P4, six years experience).

3.18.3 Managing treatment expectations

This subtheme reflects participants’ concerns that while offering women support and hope for a positive pregnancy outcome, it was important that women did not have unrealistic expectations of the treatment. While they would be doing their best to offer a treatment they saw as therapeutic, it was not a guarantee that the women’s pregnancy would continue:

It’s an attempt to support the body if we can. So I guess it’s a matter of communicating to them what you think is realistic and preparing them for the case that it may not be successful and give it your best shot (P10, 20 years experience).

I would make sure that they felt very calm, they understood that I knew what I was doing and that what they were coming for, I was going to help them with to the best of my ability. It might work, it might not, but I would give it my absolute best energy (P3, 11 years experience).
While practitioners offered treatment believing that it was a beneficial approach, there was awareness that there were limitations; for example, acupuncture could not always offer a treatment that would maintain a pregnancy. Thus, it was important to be realistic, as miscarriage would be inevitable for some women:

But if HCG levels are too bad I tell them that this is miscarriage you can’t—even if you use acupuncture or herbal medicine, you can’t help. But sometimes the people say could you just try you best to help me and sometimes it can be successful and sometimes not (P1, 28 years experience).

Several practitioners expressed that they were aware of other acupuncture practitioners who were not as realistic about the limitations of acupuncture as a treatment. They were concerned that these practitioners were overstating the benefits of receiving acupuncture in the way that they promoted it as a treatment for threatened miscarriage:

So I always make that clear with my patients. I don’t give them that false hope. I’ve seen some acupuncturists that advertise that they have success rates or what have you, which I think is a bit dodgy (P13, six years experience).

In addition to regarding it as unprofessional to advertise using clinical results that may be biased or inaccurate, there was also potential for acupuncturists to over-represent the effects of the advice they were offering, with this seen as being unsupportive for women seeking their assistance:

There was a practitioner who, I probably don’t need to name, but she made a comment in one of the posts about how nobody in her practice who had followed her advice had ever miscarried. It was quite shocking. I think it’s—we’ve actually got a responsibility to do the opposite of that. Like recognise our limitations as well as other people’s choices in life and just support them as best we can (P4, six years experience).

3.19 Acquiring trustworthy knowledge

The theme ‘acquiring trustworthy knowledge’ reflects that participants had to actively seek out the knowledge they used to treat women with threatened miscarriage rather than it being readily available through their undergraduate training or in their textbooks.

For one practitioner, this knowledge was gained by working in a Chinese Hospital for 10 years. For the remainder of practitioners, this knowledge was not easily accessed;
finding knowledge that they felt was trustworthy had been difficult. Many practitioners still felt that they would like more information:

I feel like we’re really left on our own with this. I think a lot of people are quite—maybe even scared (P4, six years experience).

I did feel pretty—a bit scared and isolated. I think probably even now…I still feel reasonably left alone with it I guess (P10, 20 years experience).

3.19.1 A limited knowledge base—sorting it out for yourself

The subtheme ‘a limited knowledge base—sorting it out for yourself’ illustrates how some practitioners felt that it was up to them:

You can try and do research but then you are left with not a hell of a lot. You’ve got to use basically your common sense and your intelligence and a bit of creativity I guess (P10, 20 years experience).

It was seen that there were additional difficulties in this area of practice because of the conflicting information in literature and concerns about dealing with women with an at-risk pregnancy. Although conflicting opinions were generally seen as a disadvantage, one practitioner saw it as a way of ensuring that practitioners remained cautious:

There’s a lot of rumour around all of this—things that you should and shouldn’t do in pregnancy. I think it leaves people a little bit afraid of what to do, which I think in some cases is useful, because it is a specialised area and there’s a lot that you do need to know, I think, in order to be effective (P6, six years experience).

Some practitioners deliberately sought out experienced teachers to receive extra training or to talk with more experienced practitioners:

I started treating straight away and had women from the [name of hospital] coming through but I also did a master’s apprentice [with an experienced practitioner] for just under two years (P3, 11 years experience).

I’ve found that the most useful information has not been in textbooks, it’s been from talking to practitioners who’ve been in practice for 15/20 years plus (P6, six years experience).

Others felt that clinical practice added to their knowledge over time, as presented in the following subtheme.
3.19.2 Confidence through clinical feedback

The subtheme ‘confidence through clinical feedback’ reflects the confidence gained from the realities of clinical practice. In this case, the effect of the treatment was not through evaluating pregnancy outcomes because it was recognised that this may have been inevitable despite the treatment:

In a threatened miscarriage situation, you don’t know whether it is going to actually happen or not anyway and whether what you do is going to actually change the course of what’s going to happen. So it’s very hard to know if you, as a practitioner, did you actually change the course of that in any way, be it diet and lifestyle, be it the acupuncture, be it just listening. Did it actually make an effect? I’d like to think it did. When you talked to them, they just felt able to cope better. I don’t know that I can say that it’s definitely the needles. Part of it would’ve been the conversation but I would definitely think that they felt stronger as a result of having the treatments (P3, 11 years experience).

The effect and value of the treatment practitioners gave was instead seen through the physical and emotional impacts on the individual women.

Whether or not that’s going to get them the outcome they want, then I don’t know. But if I have a woman that is smiling by the time she walks out, feeling more hopeful because she’s been absolutely beside herself when she’s walked in, I think that’s a measure of success in itself. I think if you can have a change in the symptoms, perhaps the bleeding has slowed or it’s stopped from maybe one treatment to the next, then you’re looking at those sorts of symptoms as well (P5, seven years experience).

They feel that their abdomen is light and warm so that there’s no more any sensations of grabbing, pulling discomfort so that’s gone and that they feel comfortable in themselves. So they feel calm and they feel supported (P2, 20 years experience).

3.20 Integration of findings from the online survey and interviews

The findings from the online survey demonstrated that acupuncture was used to treat threatened miscarriage, with 57.8% of participants treating women in the previous year. The majority of these practitioners’ patients were existing patients who had previously received acupuncture for fertility-related treatment. There was additional interest in treating threatened miscarriage among practitioners not currently treating, with 64.7% of participants expressing an interest in treating this presentation in the future.
Practitioners raised a concern in the online survey of safe practice in terms of a miscarriage occurring following treatment. These concerns focused on the possibility that incorrect treatment could stimulate a miscarriage or that others could perceive any treatment as having stimulated a subsequent miscarriage. However, these concerns differed between practitioners who had treated threatened miscarriage in the previous year and those who had not. While the majority of practitioners not actively treating threatened miscarriage were concerned about the possibility of their treatment causing a miscarriage, practitioners who were actively treating were concerned that other practitioners could cause a miscarriage through inappropriate treatment. Further, all practitioners believed they provided safe treatment despite their use of diverse and often conflicting treatment approaches.

The practitioners interviewed also spoke about safety issues concerning Chinese herbal medicine and their awareness of concerns by Western-trained health practitioners and women presenting with threatened miscarriage. Practitioners using Chinese herbal medicine either refrained from prescribing to women in order to maintain professional relationships or they continued to promote herbal treatment by claiming authority from TCM theories as a rationale.

Practitioners in the online survey stated that they used diverse modalities when treating threatened miscarriage. An unexpected finding was that 21–51 (12.8–31.1%) practitioners would not avoid using acupuncture points contraindicated in acupuncture textbooks due to their use as labour-induction points. While practitioners in the online survey viewed the acupuncture treatments they used as safe, the semi-structured interviews illustrated how individual practitioners used different justifications for why the points and modalities they used were safe. These justifications came from accepting or challenging the knowledge presented in historical texts, personal opinions and experiences in practice. While practitioners referred to historical knowledge in TCM texts and advice they received from experienced practitioners as part of these justifications, there was no reference to the Western medical literature on the physiology of early pregnancy or miscarriage influencing their treatment decisions.

The online survey found that 50% of practitioners used TCM diet and lifestyle advice, while the semi-structured interviews found that those practitioners viewed this self-care
advice as an important aspect of treatment due to the TCM theories of how diet and lifestyle influenced women’s bodies in early pregnancy. It was seen as important that this advice was individualised to the women’s TCM diagnosis and framed to be achievable to avoid blame in event of women being unable to follow this advice and experiencing a miscarriage. Together with the acupuncture treatment, this diet and lifestyle treatment was viewed as supporting and empowering women by offering an alternative to the ‘wait and see’ approach presently offered to women through their Western-trained health practitioners.

The online survey also indicated that the most useful source of information for the majority of practitioners was TCM textbooks. In the semi-structured interviews, it emerged that practitioners resolved the limited, and at times conflicting, treatment information in these texts by seeking out other experienced practitioners and through the confidence they gained over time with their own clinical experience.

3.21 Summary

The findings from the online survey indicated that there is interest amongst acupuncturists in treating threatened miscarriage, with a majority of practitioners treating women within the past year. A minority of practitioners expressed safety concerns; these concerns differed between those actively treating women and those who were not. In clinical practice diverse treatment strategies existed between practitioners treating women with threatened miscarriage, with this diversity involving how acupuncturists used acupuncture and moxibustion on abdominal points, an acupuncture point (SP 1) recommended in obstetric text books and points that moved or invigorated blood. A minority of practitioners were utilising acupuncture points that are considered contraindicated during pregnancy. A minority also considered Western medical sources of information useful for their clinical practice despite the majority of patient referrals coming from current fertility patients.

Themes from the qualitative data illustrated how acupuncturists saw themselves treating women in this area of practice. The theme ‘well I’m safe because…justifying diverse approaches’ added to the survey findings to illustrate that all acupuncturists viewed
themselves as safe practitioners. ‘Empowering women in a unique way’ expanded the survey information on the modalities of practice to show that practitioners viewed themselves as having a therapeutic supportive relationship with women. ‘Acquiring trustworthy knowledge’ identified how practitioners dealt with the limited, and often conflicting, treatment literature available to them. The overarching theme of ‘Safety first—a therapeutic balancing act’ was the central unifying theme from these interviews. It was used to show how all practitioners sought to provide treatment that they considered both therapeutic and safe when treating a condition that involved potential pregnancy loss.

The use of acupuncture as a treatment for threatened miscarriage is explored further in Chapter 4, which reports the results of an RCT using acupuncture compared to a control group receiving touch. It also analyses the results of the interviews undertaken with women participating in the trial.
Chapter 4: The Role of Acupuncture in the Treatment of Threatened Miscarriage: Findings from a Pilot Randomised Trial and Semi-structured Participant Interviews

4.1 Introduction

This chapter presents the findings of the RCT and semi-structured interviews with women presenting with a diagnosis of threatened miscarriage in the Wellington and Hutt Valley regions of New Zealand. The overall aim of this study was to examine the feasibility and acceptability of offering acupuncture and supportive care as a therapeutic treatment for women presenting with threatened miscarriage. The overall research questions were:

1. Is it feasible to deliver an acupuncture intervention to women with threatened miscarriage?
2. What are women’s experiences of threatened miscarriage and the care they receive?

The primary hypothesis of the study was that for women presenting with threatened miscarriage, receiving acupuncture compared to supportive care only would reduce pregnancy-related fear in the first trimester of pregnancy, and improve quality of life by reducing symptoms experienced by women that they considered distressing. The secondary hypothesis was that acupuncture compared to supportive care only would reduce miscarriage rates and increase live-birth outcomes, reduce premature birth, intrauterine growth restriction and APH.

This chapter presents the findings of the pilot RCT, followed by the findings of the semi-structured interviews. The chapter concludes with an integration of these findings. These findings are integrated with the findings in other chapters in Chapter 7. Chapter 8 presents the discussion of these findings.
4.2 Pilot RCT

The results of this trial are reported with the referral sources, recruitment into the study and participant flow through the study, followed by the characteristics of women at the trial entry and the outcomes of the study against the nominated study endpoints.

4.3 Referral sources

Women were referred to the trial from October 2010 until June 2012 by receiving information from a health-care provider or through self-referral using public media. A total of 149 women with a diagnosis of threatened miscarriage were originally assessed for eligibility (see Figure 4.1). This included women presenting at the MAU, those expressing interest to their health-care provider after being informed about the study and those who contacted the researcher of their own initiative. Of these 149 women, 104 (69.9%) presented through the MAU and 45 (30.2%) through the fertility unit, midwives or through self-referral. The referral sources for women entering the trial are presented in Table 4.1.

<table>
<thead>
<tr>
<th>Referral sources</th>
<th>Entered trial (n=40)</th>
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<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Maternity Assessment Unit</td>
<td>17</td>
</tr>
<tr>
<td>Fertility associates</td>
<td>9</td>
</tr>
<tr>
<td>Independent midwives</td>
<td>9</td>
</tr>
<tr>
<td>Radiologists</td>
<td>4</td>
</tr>
<tr>
<td>Posters placed in Hospital departments</td>
<td>1</td>
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<tr>
<td>Total</td>
<td>40</td>
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There were three major sources of referral for the 40 women entering the trial: the Hutt Hospital MAU, Fertility Associates and independent midwives. Seventeen women (42.5%) were referred from the MAU, nine (22.5%) from Fertility Associates and nine (22.5%) from independent midwives. There were four referrals from radiologists, giving a 10% referral from this group. One woman entered the trial after seeing the posters placed in a hospital Accident and Emergency department.
There were no referrals from GPs or acupuncture practitioners. While four women contacted the researcher following the publication of the newspaper article, none of them entered the trial because they did not meet the eligibility criteria. Finally, three women contacted the researcher after viewing social media sites (one each from the discussion threads, Facebook advertisement and Facebook page), although none of them joined the trial because they did not meet the eligibility criteria.

### 4.4 Eligibility

On assessment for eligibility, 78 (52.3%) of the 149 women initially assessed did not meet the entry requirements. Of those who did not meet the requirements, 44 women (56.4%) exceeded the gestational week limit. Initially, a pregnancy of less than 10 completed gestational weeks was set as the entry criteria. However, as women were being excluded from entry to the trial because they presented between 11 and 12 gestational weeks, an ethics amendment was applied for and received to allow women to enter the trial until 11 completed gestational weeks. Nine women were excluded prior to this amendment approval being granted. Further, 35 women who presented with threatened miscarriage between 12 to 19 gestational weeks were not eligible. Other reasons why women did not meet eligibility criteria included: nine women (11.5%) who had experienced three or more miscarriages, seven women (8.9%) with a twin or triplet pregnancy, seven women (8.9%) who were only visiting the area, six women (7.6%) receiving specialist care for a medical condition, two women (2.5%) who had English as a second language and did not want to sign the consent form, and one woman (1.2%) for each of the following reasons: not currently pregnant, pregnant but not bleeding or miscarried before the appointment for randomisation.

### 4.5 Recruitment of eligible women

Of the 71 women who were eligible, 22 (30.9%) stated that they were not interested in entering a trial. This included three women who directly expressed that they did not want to receive acupuncture and one woman who contacted the researcher to say she was no longer interested because her husband did not want her to enter a study. Five women (7%) who were initially interested subsequently decided to consult an
acupuncturist independently of the trial, as they did not want to be randomised to receive a non-acupuncture intervention, and four women (5.6%) declined because they were considering a termination of pregnancy. When women met the eligibility criteria of the trial, there was an interest in participating; of the 71 eligible women, 40 (56.3%) consented to participate and were successfully randomised. The screening of eligibility criteria is presented in Table 4.2.

### Table 4.2: Screening of eligibility criteria

<table>
<thead>
<tr>
<th>Screening of eligibility criteria (n=149)</th>
<th>n</th>
<th>%</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not meet entry criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exceeded gestational week limit</td>
<td>44</td>
<td>29.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three or more previous miscarriages</td>
<td>9</td>
<td>6.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receiving specialist care for medical condition</td>
<td>6</td>
<td>4.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple pregnancy</td>
<td>7</td>
<td>4.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only visiting area</td>
<td>7</td>
<td>4.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant but no vaginal bleeding</td>
<td>1</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not pregnant</td>
<td>1</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miscarriage prior to appointment</td>
<td>1</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>English as a second language—did not want to sign consent</td>
<td>2</td>
<td>1.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>78</td>
<td>52.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Declined</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stated that they were not interested</td>
<td>18</td>
<td>12.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decided to seek acupuncture treatment</td>
<td>5</td>
<td>3.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Considering a termination of pregnancy</td>
<td>4</td>
<td>2.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not want acupuncture</td>
<td>3</td>
<td>2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Husband objected to participating in a trial</td>
<td>1</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>20.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entered trial</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>26.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>149</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 4.6 Randomisation procedures and participant flow

The 40 eligible women who consented to participate in the trial were randomised into two groups (see Figure 4.1). Nineteen women were randomised to the acupuncture group and 21 women to the touch group. One woman initially allocated to the acupuncture group was excluded post-randomisation; although a scan to confirm study eligibility was undertaken two weeks prior to randomisation, a scan undertaken three days following randomisation reported a missed miscarriage (a non-viable embryo with a gestational age by Crown Rump Length (CRL) of six to seven weeks). As this woman entered the trial at eight gestational weeks, even allowing for the error rate of three to four days in an ultrasound assessment, it was not possible for this foetus to be viable at
the time of entry. This was the first woman to be randomised into this study; following this, all women who contacted the researcher with a scan that was five or more days previous were asked to have a repeat scan to demonstrate viability.

For another woman in the acupuncture group, the entry scan at six gestational weeks plus four days reported ‘faint’ cardiac activity. A follow-up scan at nine weeks reported no cardiac activity and a gestational sac diameter measurement correlating to foetal demise at a gestation of six weeks plus five days. As the woman entered the study at six gestational weeks plus five days, it is possible that this pregnancy loss occurred before any intervention was delivered; however, due to the possible margin of error with an ultrasound assessment, this woman was not excluded from the analysis.

Thirty women received the intended treatment until 12 completed gestational weeks (13 acupuncture, 17 supportive care). During the treatment phase of the trial, two women withdrew from the acupuncture group and one withdrew from the touch group after their first appointment. For those withdrawing from acupuncture, one woman contacted the researcher to say that she was now seeking counselling for a termination, and one woman withdrew due to personal reasons relating to a lack of support from her husband, who did not want her to participate in the trial. One woman withdrew from the touch intervention through non-compliance, as she did not show up for her second appointment and could then not be contacted. One woman who was allocated to the touch group moved to another region in New Zealand; although she withdrew from active treatment, she continued to complete the study paperwork for the trial and was included in the final analysis, giving a total of 31 women included for analysis. Three women from the acupuncture group and two from the touch group exited the study before 12 completed gestational weeks due to miscarriage.
At approximately 20 weeks gestation, a follow-up telephone call was made to confirm a viable pregnancy (confirmed by ultrasound) for the 30 women remaining in the trial, with one woman exiting the study due to a late miscarriage.
Follow-up continued until the women gave birth. One woman moved overseas and could not be contacted, and the remaining 29 completed the final data collection points relating to maternal and neonatal outcomes. There were three data collection points for this study in total: on exiting the trial after treatment at 12 completed gestational weeks, a follow-up telephone call at 20 gestational weeks and birthing records. (Table 4.3).

Data for the pregnancy fear questionnaires and diet and lifestyle diaries were completed by all 31 women leaving the trial at the completion of treatment (12 completed gestational weeks). The MYMOP questionnaires were completed by 29 women; two women did not feel they had any symptoms that concerned them. However, one of these women completed the general wellbeing question on the MYMOP questionnaire, giving a total of 30 women who completed this section of the questionnaire.

When collecting data relating to the maternal and neonatal outcomes, it was found that one woman from the touch group had moved overseas and no data were available. Birthing data were collected for the 13 women in the acupuncture group and 14 women in the touch group that had birthed, with two women in the touch group exiting (one due to a still birth and one due to a neonatal death).

<table>
<thead>
<tr>
<th>Table 4.3: Completed data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>12 completed gestational weeks</strong></td>
</tr>
<tr>
<td>Pregnancy fear questionnaire</td>
</tr>
<tr>
<td>MYMOP—symptoms of concern</td>
</tr>
<tr>
<td>MYMOP—general wellbeing</td>
</tr>
<tr>
<td>Diet and lifestyle diaries</td>
</tr>
<tr>
<td>Exit supportive care information</td>
</tr>
<tr>
<td>20 gestational weeks</td>
</tr>
<tr>
<td>Confirmation of viable pregnancy</td>
</tr>
<tr>
<td>Maternal and neonatal outcomes</td>
</tr>
</tbody>
</table>

Two women (one from each group) did not initially choose any symptoms of concern

One woman did not choose to state initial general wellbeing

One woman (touch intervention) moved and was lost to follow-up
4.7 Characteristics of women at trial entry

The baseline characteristics of women in this study according to allocated group are presented in Table 4.4. The mean age of women entering this study was 30.5 years (SD 5.9). The mean gestational age at which vaginal bleeding commenced was 6.2 weeks (SD 1.8); however, the mean gestational age for entering the trial was 8.3 weeks (SD 1.4). Nine women (23.1%) were receiving current fertility treatment and 16 women (41%) had experienced a previous miscarriage. Twenty-nine women (74.3%) were experiencing bleeding that they considered lighter than a period. Five women (12.8%) were not taking folic acid and 17 (43.5%) were taking medications, including 10 women (25.6%) who were taking medication that their Western medical practitioners had recommended or prescribed for pain relief (NSAID, Paracetamol/Panadol or Codeine), five women (12.8%) were taking progesterone as part of fertility-related treatment and one woman (2.5%) was taking an antiemetic for pregnancy nausea. In addition, six women (16.3) were taking medications for medical-related conditions: four women for asthma, one for eczema and one was taking antibiotics for a chest infection. These baseline data are presented in Table 4.4 according to group allocation.

Table 4.4: Baseline characteristics of participants at entry to trial according to group allocation

<table>
<thead>
<tr>
<th>Variables</th>
<th>Touch (n=21)</th>
<th>Acupuncture (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Maternal age</td>
<td>30.6</td>
<td>7.2</td>
</tr>
<tr>
<td>Gestational age bleeding started</td>
<td>6.5</td>
<td>1.8</td>
</tr>
<tr>
<td>Gestational age at trial entry</td>
<td>8.2</td>
<td>1.3</td>
</tr>
<tr>
<td>BMI</td>
<td>25.8</td>
<td>5.6</td>
</tr>
<tr>
<td>Previous miscarriage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>10</td>
<td>47.6</td>
</tr>
<tr>
<td>%</td>
<td>47.6</td>
<td></td>
</tr>
<tr>
<td>Fertility patient</td>
<td>6</td>
<td>28.6</td>
</tr>
<tr>
<td>%</td>
<td>28.6</td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy</td>
<td>6</td>
<td>28.6</td>
</tr>
<tr>
<td>Light</td>
<td>15</td>
<td>71.4</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>Yes</td>
<td>16</td>
<td>76.1</td>
</tr>
<tr>
<td>Medications</td>
<td>11</td>
<td>52.4</td>
</tr>
</tbody>
</table>

SD=Standard Deviation

The baseline data collected from women at trial entry were visually inspected to examine differences involving clinical characteristics and demographic and lifestyle considerations that may have had the potential to introduce selection bias between the
two groups. Due to the small number of women involved in this study, some baseline differences between the two groups would be expected to occur due to chance. Visual inspection of the data found a six-point difference between the two groups for the gestational age when bleeding commenced; however, this difference was not statistically significant (p=0.30). No further differences of more than five points were detected between the groups, indicating that there were no imbalances at randomisation that required an adjusted analysis.

Socio-demographic characteristics are described in Table 4.5. Twenty-seven women (69.2%) were either in full- or part-time employment, 31 (79.5%) had completed high-school education and 28 (71.7%) had completed further qualifications at a polytechnic or university. Twenty-four women (61.5%) identified as Caucasian, seven (17.9%) as Maori and eight as various ethnic origins such as Asian, Polynesian and Fijian Indian. Thirty-three women (84.6%) were either married or in a de facto relationship.

Eleven women were currently using CAM therapies when they entered the study. This included three women (7.7%) who were taking homeopathic remedies for pregnancy nausea and 10 women (25.6%) who were taking vitamins or supplements such as vitamin B-12, calcium, fish oil, flax seed oil, iron, magnesium, vitamin E and a general vitamin. Thirty-six women (92.3%) had used CAM therapies in the past, including massage (30, 76.9%), acupuncture (15, 38.5%), osteopathy (13, 33.3%), yoga (13, 33.3%), homoeopathy (10, 25.6%), reflexology (7, 20.5%), meditation (7, 20.5%), Western herbs (7, 20.5%) and Chinese herbs (6, 15.4%). In addition, six women had each used one of the following CAM therapies: chiropractic, hypnotherapy, Reiki, Neuro-Linguistic Programming (NLP), Maori medicine and naturopathy.

While there were differences between these variables for the two groups due to the small number of participants involved, it was not considered that they would confound the analysis; therefore, an adjusted analysis was not required for these variables.
Table 4.5: Educational, socio-demographic characteristics and participants’ use of CAM at entry of study

<table>
<thead>
<tr>
<th>Variables</th>
<th>Touch (n=21)</th>
<th>Acupuncture (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time/partial</td>
<td>14</td>
<td>66.7</td>
</tr>
<tr>
<td>Unemployed</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>Student</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>High school</td>
<td>16</td>
<td>76.2</td>
</tr>
<tr>
<td>Polytec</td>
<td>6</td>
<td>28.6</td>
</tr>
<tr>
<td>University</td>
<td>9</td>
<td>42.9</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>11</td>
<td>52.4</td>
</tr>
<tr>
<td>Maori</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>Relationship</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>2</td>
<td>9.5</td>
</tr>
<tr>
<td>Married/de facto</td>
<td>19</td>
<td>90.5</td>
</tr>
<tr>
<td>Current CAM use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past CAM use</td>
<td>8</td>
<td>38.1</td>
</tr>
<tr>
<td>Past acupuncture use</td>
<td>19</td>
<td>90.5</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>33.3</td>
</tr>
</tbody>
</table>

CI=Confidence interval

Women were also asked about their diet and lifestyle activities in the past week at study entry (see Table 4.6). Over half of the women had spent time in the past week either on bed rest (23, 58.9%) or on the Internet searching for threatened miscarriage sites (21, 53.8%). Approximately one-third of women (12, 30.7%) had engaged in sexual intercourse. Twelve women (30.7%) had also experienced at least one episode of heavy lifting. Eleven women (28.2%) had consumed coffee and nine (23.0%) had exercised for longer than 20 minutes in the previous week. Four women (10.2%) had practiced meditation and four (10.2%) were currently smoking, while one (2.5%) had consumed alcohol. As any differences in the groups were likely to be due to the small number of participants involved, it was not considered that they would confound analysis; therefore, an adjusted analysis was not required for these diet and lifestyle activities.
Table 4.6: Participants diet and lifestyle activities at baseline

<table>
<thead>
<tr>
<th>Variables</th>
<th>Touch (n=21)</th>
<th>95% CI</th>
<th>Acupuncture (n=18)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>1</td>
<td>4.8 (0.01, 24.4)</td>
<td>3</td>
<td>16.7 (5.01, 40.0)</td>
</tr>
<tr>
<td>Coffee</td>
<td>7</td>
<td>33.3 (17.0, 54.7)</td>
<td>4</td>
<td>22.2 (8.47, 45.7)</td>
</tr>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>4.8 (0.01, 24.4)</td>
<td>0</td>
<td>0.00 (0.00, 20.6)</td>
</tr>
<tr>
<td>Internet use</td>
<td>10</td>
<td>47.6 (28.3, 67.6)</td>
<td>11</td>
<td>61.1 (38.5, 79.7)</td>
</tr>
<tr>
<td>Sexual intercourse</td>
<td>7</td>
<td>33.3 (17.0, 54.7)</td>
<td>5</td>
<td>27.8 (12.1, 51.2)</td>
</tr>
<tr>
<td>Bed rest</td>
<td>13</td>
<td>61.9 (40.8, 79.3)</td>
<td>10</td>
<td>55.6 (33.7, 75.4)</td>
</tr>
<tr>
<td>Heavy lifting</td>
<td>6</td>
<td>28.6 (13.5, 50.2)</td>
<td>6</td>
<td>33.3 (16.1, 56.4)</td>
</tr>
<tr>
<td>Meditation/relaxation</td>
<td>1</td>
<td>4.8 (0.01, 24.4)</td>
<td>3</td>
<td>16.7 (5.01, 40.0)</td>
</tr>
<tr>
<td>Exercise more than 20 minutes</td>
<td>4</td>
<td>19.0 (7.08, 40.5)</td>
<td>5</td>
<td>27.8 (12.1, 51.2)</td>
</tr>
<tr>
<td>Working full time or part time</td>
<td>2</td>
<td>9.5 (1.45, 30.1)</td>
<td>5</td>
<td>27.8 (12.1, 51.2)</td>
</tr>
</tbody>
</table>

CI=Confidence interval

4.8 Pregnancy fear questionnaire

Women were asked to complete a questionnaire indicating their level of fear of pregnancy loss using a pregnancy fear questionnaire (see Chapter 2 and Appendix I for further details).

At baseline (see Table 4.7), women in both groups expressed a level of fear for each of the questions asked, with the question concerning bleeding demonstrating the highest level. For this question, there was a mean score of 4.6 (SD 1.4) for the touch group and 4.8 (SD 1.4) for the acupuncture group, with a score of 4 corresponding to the 'likely’ option of how frightened they were that bleeding would result in pregnancy loss. As women entered the trial shortly after an ultrasound to confirm foetal viability, this score indicated that they remained fearful despite the results of the ultrasound. There was more than a five-point difference between the groups for women answering question two, which related to their fear of a fall harming their pregnancy. This was statistically significant (p=0.03), however the difference was not adjusted for, as this finding was not seen as influencing any study outcomes.
Table 4.7: Pregnancy fear questionnaire at baseline

<table>
<thead>
<tr>
<th>Variables</th>
<th>Touch (n=21)</th>
<th>Acupuncture (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Q 1 (Sexual intercourse)</td>
<td>2.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Q 2 (Fall)</td>
<td>3.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Q 3 (Lifestyle)</td>
<td>2.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Q 4 (Vaginal bleeding)</td>
<td>4.5</td>
<td>1.4</td>
</tr>
<tr>
<td>Q 5 (Medical exams)</td>
<td>1.6</td>
<td>0.9</td>
</tr>
</tbody>
</table>

SD=Standard Deviation

4.9 Quality of life

Participants were asked to complete the MYMOP 2 questionnaire (see Chapter 2, Appendix J) and score on a continuum between 0 and 6, with 6 being as bad as they could imagine. At baseline (see Table 4.8), the mean for both groups was in the centre of this continuum for general wellbeing (2.9, SD 1.4 for touch; 3.3, SD 1.4 for acupuncture), while their nominated symptom was of a greater concern (4.6, SD 1.2 for touch; 4.7, SD 1.1 for acupuncture). Two women—one from each group—stated that they did not have any symptoms that they were concerned about, so they did not complete this section of the MYMOP form, although one of these women completed the general wellbeing question until she exited the study. Not all women were able to nominate a second symptom they were concerned about; 17 women selected a second symptom.

Table 4.8: MYMOP questionnaire at baseline

<table>
<thead>
<tr>
<th></th>
<th>Touch Mean</th>
<th>SD</th>
<th>Acupuncture Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=20)</td>
<td></td>
<td>(n=18)</td>
<td></td>
</tr>
<tr>
<td>General well being</td>
<td>2.9</td>
<td>1.5</td>
<td>3.3</td>
<td>1.4</td>
</tr>
<tr>
<td>(n=20)</td>
<td></td>
<td></td>
<td>(n=17)</td>
<td></td>
</tr>
<tr>
<td>Symptom 1</td>
<td>4.6</td>
<td>1.2</td>
<td>4.7</td>
<td>1.1</td>
</tr>
<tr>
<td>(n=7)</td>
<td></td>
<td></td>
<td>(n=10)</td>
<td></td>
</tr>
<tr>
<td>Symptom 2</td>
<td>2.8</td>
<td>0.9</td>
<td>3.9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

In total, 37 women who completed the questionnaire selected 54 symptoms of concern (see Figure 4.2). Twenty-four (44.4%) of these concerns related to emotional aspects. Of these, the majority (19, 35.1%) concerned anxiety over bleeding, while four (7.4%) involved feelings of frustration and depression, and one (1.8%) nominated her anxiety over the lack of nausea. For the remaining nominated symptoms, 13 (24.0%) concerned
abdominal cramping pain, 10 (18.5%) involved the discomfort of nausea and the remaining eight (14.8%) symptoms concerned physical symptoms such as back pain (three women), sleep (two women), and headache, constipation and sore breasts (one woman each).

<table>
<thead>
<tr>
<th>Symptoms of Concern (n=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emotional</strong></td>
</tr>
<tr>
<td><strong>Abdominal cramping</strong></td>
</tr>
<tr>
<td><strong>Nausea</strong></td>
</tr>
<tr>
<td><strong>Various ( Back pain, sleep, headache, constipation and sore breasts)</strong></td>
</tr>
</tbody>
</table>

**Figure 4.2: Nominated quality of life symptoms of concerns for all women at baseline**

In summary, the information presented in Table 4.4 to Table 4.6 demonstrates that randomisation was successful without significant selection bias across maternal age, gestational age at the start of vaginal bleeding or at entry into the study, as well as for pregnancy and demographic and lifestyle characteristics, current and previous use of CAM therapies, and past use of acupuncture in both groups at entry. For the pregnancy fear and MYMOP questionnaires at baseline two variables demonstrated differences: women in the touch group indicated more fear of a fall harming their pregnancy, and women receiving acupuncture reported more concern about their nominated second symptom. However, due to the small number of women involved, these variables were not seen as factors that would confound analysis; therefore, an adjusted analysis was not required.
4.10 Primary study endpoints

4.10.1 Pregnancy fear

Among the 31 women exiting the trial at 12 completed gestational weeks, there were no significant differences in pregnancy fear between the groups (see Table 4.9). There may have been a difference between groups in terms of when these concerns decreased; however, due to the number of women entering the study at different gestations and being in the study for different periods of time, this analysis was not considered clinically relevant.

Table 4.9: Pregnancy fear questionnaire on exiting study by study group

<table>
<thead>
<tr>
<th>Question</th>
<th>Touch (n=18)</th>
<th>Acupuncture (n=13)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q 1 (Sexual Intercourse)</td>
<td>2.0 (1.2)</td>
<td>2.0 (1.4)</td>
<td>-0.07</td>
<td>(-1.08, 0.95)</td>
<td>0.87</td>
</tr>
<tr>
<td>Q 2 (Fall)</td>
<td>3.1 (1.6)</td>
<td>2.3 (1.1)</td>
<td>0.72</td>
<td>(-0.33, 1.78)</td>
<td>0.17</td>
</tr>
<tr>
<td>Q 3 (Lifestyle)</td>
<td>2.7 (1.6)</td>
<td>3.1 (1.6)</td>
<td>-0.43</td>
<td>(-1.66, 0.79)</td>
<td>0.47</td>
</tr>
<tr>
<td>Q 4 (Bleeding)</td>
<td>3.6 (1.7)</td>
<td>4.0 (1.7)</td>
<td>-0.33</td>
<td>(-1.64, 0.97)</td>
<td>0.60</td>
</tr>
<tr>
<td>Q 5 (Medical exams)</td>
<td>1.6 (1.0)</td>
<td>2.3 (1.4)</td>
<td>-0.71</td>
<td>(-1.62, 0.18)</td>
<td>0.31</td>
</tr>
</tbody>
</table>

SD=Standard deviation
CI=Confidence interval

4.11 Quality of life

On exiting the study, the MYMOP primary symptom of concern score (see Table 4.10) differed significantly between groups. Women receiving acupuncture indicated less concern, with a mean score of 1.7 (SD 1.6), compared to women receiving touch, with a mean score of 3.1 (SD 1.7) (MD 1.36; 95% CI, 0.07, 2.66, p=0.04). Of these, 29 reported symptoms of concern: 14 (48.3%) for emotional aspects, nine (31%) for nausea and three (10.3%) each for abdominal cramping and various concerns.
Table 4.10: MYMOP scored between groups at 12 completed gestational weeks

<table>
<thead>
<tr>
<th></th>
<th>Touch Mean (SD)</th>
<th>Acupuncture Mean (SD)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMOP general</td>
<td>(n=17)</td>
<td>(n=13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wellbeing score</td>
<td>2.5 (1.4)</td>
<td>2.3 (1.1)</td>
<td>0.22</td>
<td>(-0.75, 1.19)</td>
<td>0.65</td>
</tr>
<tr>
<td>Score 1</td>
<td>(n=17)</td>
<td>(n=12)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.1 (1.7)</td>
<td>1.7 (1.6)</td>
<td>1.36</td>
<td>(0.07, 2.66)</td>
<td>0.04*</td>
</tr>
<tr>
<td>Score 2</td>
<td>(n=6)</td>
<td>(n=6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.3 (2.0)</td>
<td>2.6 (1.8)</td>
<td>-0.33</td>
<td>(-2.86, 2.19)</td>
<td>0.77</td>
</tr>
</tbody>
</table>

*P<0.05
RR=Risk Ratio
CI=Confidence interval

4.12 Diet and lifestyle activities

For the 31 women leaving the study at 12 completed gestational weeks, 14 (45.1%) had spent some time on bed rest in the past week, 11 (35.4%) were working full or part time and 10 (32.2%) exercised more than 20 minutes once a week. Nine (29%) had engaged in sexual intercourse, eight (23.8%) women had used meditation or relaxation techniques in the past week and eight (23.8%) reported at least one episode of heavy lifting, with seven women (22.5%) having consumed coffee. Only three (9.6%) had used an Internet miscarriage site. Two (6.4%) had been smoking and one (3.2%) had consumed alcohol in the previous week. There were no significant differences between the two groups regarding the number of women reporting on these diet and lifestyle activities (see Table 4.11).

Table 4.11: Participants’ diet and lifestyle activities at 12 gestational weeks by study group

<table>
<thead>
<tr>
<th></th>
<th>Touch group (n=18)</th>
<th>Acupuncture group (n=13)</th>
<th>RR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>n</td>
<td>%</td>
<td>1</td>
<td>7.7</td>
<td>1.38</td>
</tr>
<tr>
<td>Coffee</td>
<td>4</td>
<td>22.2</td>
<td>3</td>
<td>23.1</td>
<td>1.04</td>
</tr>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>5.6</td>
<td>0</td>
<td>0.0</td>
<td>0.45</td>
</tr>
<tr>
<td>Internet use</td>
<td>2</td>
<td>11.1</td>
<td>1</td>
<td>7.7</td>
<td>0.69</td>
</tr>
<tr>
<td>Sexual intercourse</td>
<td>3</td>
<td>16.7</td>
<td>6</td>
<td>19.4</td>
<td>2.77</td>
</tr>
<tr>
<td>Bed rest</td>
<td>7</td>
<td>38.9</td>
<td>7</td>
<td>53.8</td>
<td>1.38</td>
</tr>
<tr>
<td>Heavy lifting</td>
<td>5</td>
<td>27.8</td>
<td>3</td>
<td>23.1</td>
<td>0.83</td>
</tr>
<tr>
<td>Meditation/relaxation</td>
<td>6</td>
<td>33.3</td>
<td>2</td>
<td>15.4</td>
<td>0.46</td>
</tr>
<tr>
<td>Exercise more than 20 minutes</td>
<td>6</td>
<td>33.3</td>
<td>4</td>
<td>30.8</td>
<td>0.92</td>
</tr>
<tr>
<td>Working full or part time</td>
<td>4</td>
<td>22.2</td>
<td>7</td>
<td>53.8</td>
<td>2.42</td>
</tr>
</tbody>
</table>

RR=Risk Ratio
CI=Confidence interval
In addition, women were asked to complete a form detailing any diet and lifestyle changes they had made, and about the support they received during the time they had participated in the study. Women nominated any useful changes by completing an open-ended question asking what, if any, changes they had found to be beneficial while in the study. Of the 31 women, 29 (93.5%) nominated beneficial changes, while two (6.5%) stated that they had not found any changes useful (see Table 4.12). In terms of nominating a change they had found to be the most useful, implementing dietary advice and taking appropriate rest was seen as the most beneficial change, with 12 women (38.7%) nominating dietary changes and 10 women (32.2%) increasing the amount of rest they took. This was followed by using relaxation and meditation techniques for five women (16.1%). The remaining changes nominated were one woman (3.2%) refraining from sexual intercourse and one woman (3.2%) purchasing a foetal Doppler. There were no significant differences in these outcomes between groups.

| Table 4.12: Diet and lifestyle changes at the end of the intervention by study group |
|---------------------------------|-----------------|-----------------|--------|----------|--------|
|                                 | Touch group (n=18) | Acupuncture group (n=13) | RR     | 95% CI   | P value |
| Dietary changes                 | 7 n 22.6 %         | 5 n 16.1 %         | 0.99   | (0.04, 2.43) | 0.98   |
| Increasing rest                 | 4 n 12.9 %         | 6 n 19.4 %         | 0.48   | (0.17, 1.37) | 0.17   |
| Using relaxation and mediation techniques | 3 n 9.7 %         | 2 n 6.5 %         | 0.92   | (0.18, 4.76) | 0.92   |
| No benefits                     | 2 n 6.5 %         | 0 n 0.0 %         | 0.27   | (0.01, 5.22) | 0.39   |
| Refraining from sexual intercourse | 1 n 3.2 %         | 0 n 0.0 %         | 0.45   | (0.02, 10.3)  | 0.62   |
| Buying a foetal Doppler         | 1 n 3.2 %         | 0 n 0.0 %         | 0.45   | (0.02, 10.3)  | 0.62   |

RR=Risk Ratio
CI=Confidence interval

When asked if there were any changes they had not found useful, one woman (3.2%) stated that extra bed rest was not useful for her: ‘still felt sick and had another bleed, I was best to keep busy and just get on with it’.

When asked to select from a list of support they had found useful, all 31 women reported the support they had received by the researcher as useful. For seven women (22.5%), the support provided by the researcher was the only form of support nominated as useful. Fifteen women selected support from family (48.4%), 14 women (45.2%)
reported support from friends, 12 (32.4%) received support from a health professional and three (9.7%) selected the Internet as being useful.

Although women were asked to select the type of support they found to be the most useful form of advice, emotional support or physical support, many women selected more than one option. Sixteen women (51.6%) selected both advice and emotional support, 10 women (32.3%) selected emotional support alone and five (16.1) selected advice alone as the most useful type of support.

Eighteen women made additional comments about the support they found useful. Of these, 13 comments concerned the following three aspects: advice that was helpful, the chance to talk to someone about their concerns and feeling that they were doing something positive to help themselves. Three women specifically mentioned reassurance from scanning, including the woman who had purchased a foetal Doppler to use at home between her scans. Two women mentioned acupuncture, with one woman citing the pain-relieving effects and other relaxation effects she felt after treatment.

### 4.13 Secondary study endpoints

### 4.14 Pregnancy and perinatal outcomes

The pregnancy loss between both groups is presented in Table 4.13. There were eight pregnancy losses throughout the study: five occurred before 12 completed gestational weeks, one late miscarriage at 19 gestational weeks, one neonatal death at 23 gestational weeks and one stillbirth at 27 gestational weeks. Although five women experienced a pregnancy loss in the touch group compared to three women in the acupuncture group, this was not statistically significant (RR 0.70; 95% CI, 0.19, 2.13, p=0.58). There were no differences in pregnancy complications between groups for either stillbirth (RR 0.39; 95% CI, 0.02, 8.93, p=0.55) or neonatal death (RR 0.39; 95% CI, 0.02 to 8.93, p=0.55).

There were no documented causes for the early pregnancy losses. However, the ultrasound report at 11 weeks plus 6 days for one woman in the acupuncture group documented an increased nuchal translucency thickness, indicating possible chromosomal abnormality. For the late pregnancy losses, one was unexplained, one
followed an APH at 27 weeks and one woman had PPROM, which resulted in premature labour at 23 weeks.

**Table 4.13: Pregnancy and perinatal outcomes by study group**

<table>
<thead>
<tr>
<th></th>
<th>Touch group (n=21)</th>
<th>Acupuncture group (n=18)</th>
<th>RR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miscarriage prior to 12 gestational weeks</td>
<td>2, 9.5%</td>
<td>3, 16.7%</td>
<td>1.75</td>
<td>(0.33, 9.34)</td>
<td>0.51</td>
</tr>
<tr>
<td>Late miscarriage prior to 20 gestational weeks</td>
<td>1, 4.8%</td>
<td>0, 0.0%</td>
<td>0.39</td>
<td>(0.02, 8.93)</td>
<td>0.55</td>
</tr>
<tr>
<td>Stillbirth</td>
<td>1, 4.8%</td>
<td>0, 0.0%</td>
<td>0.39</td>
<td>(0.02, 8.93)</td>
<td>0.55</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>1, 4.8%</td>
<td>0, 0.0%</td>
<td>0.39</td>
<td>(0.02, 8.93)</td>
<td>0.55</td>
</tr>
<tr>
<td>Total pregnancy loss</td>
<td>5, 23.8%</td>
<td>3, 16.7%</td>
<td>0.70</td>
<td>(0.19, 2.53)</td>
<td>0.59</td>
</tr>
</tbody>
</table>

RR=Risk Ratio  
CI=Confidence interval

There was 20.0% pregnancy loss for women presenting with either light (6, 20.6%) or heavy (2, 20.0%) bleeding at the baseline (RR 0.97; 95% CI, 0.23, 4.04, p=0.96). In addition to the finding that there was no significant difference for pregnancy loss for women presenting with light or heavy vaginal bleeding, all three pregnancy losses later than 12 completed gestational weeks were experienced by women who entered the study with bleeding that they described as ‘light’.

Nine women who entered the study were currently receiving fertility treatment; of these women, three (15%) experienced early pregnancy loss. All three pregnancy losses that occurred later than 12 completed gestational weeks were experienced by women who entered the study with naturally occurring conceptions.

Although the presence and size of subchorionic hematomas were at times reported in ultrasound reports, it was not possible to examine them as a possible cause of pregnancy loss because the reporting was not consistent among the four organisations providing the reports, with some providers not detailing the precise size of the hematoma.
4.15 Premature birth, intrauterine growth restriction and APH

There were no differences in pregnancy complications between groups (RR 0.78; 95% CI, 0.15, 4.15, p=0.77) (see Table 4.14). These pregnancy complications were for two women who gave birth prematurely at a gestation of 33 weeks (RR 1.17; 95% CI, 0.08, 17.3, p=0.91). One premature baby from the touch group was documented as Intrauterine Growth Restricted (IUGR) (RR 0.39; 95% CI, 0.02, 8.93, p=0.55) and spent 33 days in neonatal care before being discharged. The other was a premature baby whose mother was in the acupuncture group; this baby spent 52 days in the neonatal unit before going home. These premature babies were the only two babies in the study with a birth weight below 2,500 g. There were also two women whose hospital birthing records documented an APH, with no differences between groups (RR 1.17; 95% 0.08, 17.3, p=0.91). For one woman from the touch group, this APH occurred when her baby was stillborn at 27 weeks. For the woman from the acupuncture group, this occurred prior to a premature delivery at 33 weeks. This was a complicated pregnancy with ongoing bleeding throughout, which may have been associated with a 9 cm intrauterine growth identified on an ultrasound scan at a gestation of 20 weeks. This was analysed following the birth of her baby and subsequently diagnosed as a molar mass.\textsuperscript{14} There were no babies born with congenital abnormalities to the women in this study.

Table 4.14: Pregnancy complications rates for premature birth, intrauterine growth restriction and APH by study group

<table>
<thead>
<tr>
<th></th>
<th>Touch group (n=21)</th>
<th>Acupuncture group (n=18)</th>
<th>RR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature birth before 34 gestational weeks</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Intrauterine growth restriction</td>
<td>1</td>
<td>4.8</td>
<td>1</td>
<td>5.5</td>
<td>1.17</td>
</tr>
<tr>
<td>Antepartum haemorrhage</td>
<td>1</td>
<td>4.8</td>
<td>0</td>
<td>0.0</td>
<td>0.39</td>
</tr>
<tr>
<td>Total complications</td>
<td>3</td>
<td>14.2</td>
<td>2</td>
<td>11.1</td>
<td>0.78</td>
</tr>
</tbody>
</table>

\textsuperscript{14} A genetic error during fertilisation that leads to growth of abnormal tissue within the uterus. While this can occur with twins (where one embryo implants normally), this is rare, and it is unusual for this pregnancy to remain viable.
4.16 Acupuncture treatment considerations: diagnosis and acceptability

The researcher administering the acupuncture chose from a list of 31 possible acupuncture patterns of disharmony, with the option to combine these patterns to make a multiple diagnosis. No additional diagnosis was required in this pragmatic protocol for the women presenting in this trial. A total of 12 TCM patterns of disharmony were used for the women in this study to treat threatened miscarriage (see Table 4.15). There was a range of these TCM patterns, with constrained Liver qi the most frequent (75%). Liver blood deficiency, Spleen yang depletion and Spleen failing to control blood accounted for one-third (33.3%) of the TCM patterns used. Four TCM patterns accounted for one-quarter (25%) of diagnoses, including Blood stasis, Kidney yang deficiency, Spleen failing to control blood, and restless Heart qi. These were followed by a diagnosis of Kidney qi deficiency (16.6%). The final TCM patterns involved Kidney yin depletion, Spleen deficiency with dampness accumulation and trauma following a fall (8.3%). Of the 18 women in the study, 14 (77.8%) received a diagnosis involving two to three TCM patterns, while four (22.2%) received a diagnosis involving a single TCM pattern. In addition to these patterns, women received treatment when requested for nausea, back pain, constipation and the onset of cold-related symptoms. A total of 78 acupuncture treatments were administered for back pain (9, 11.5%), nausea (6, 7.6%), constipation (4, 5.1) and cold symptoms (2, 2.5%).

Table 4.15: TCM patterns of disharmony used in diagnosis for threatened miscarriage

<table>
<thead>
<tr>
<th>TCM patterns of disharmony (n=12)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constrained Liver qi</td>
<td>9</td>
<td>75.0</td>
</tr>
<tr>
<td>Liver blood deficiency</td>
<td>4</td>
<td>33.3</td>
</tr>
<tr>
<td>Spleen yang deficiency</td>
<td>4</td>
<td>33.3</td>
</tr>
<tr>
<td>Qi deficiency with blood stasis</td>
<td>4</td>
<td>33.3</td>
</tr>
<tr>
<td>Blood stasis</td>
<td>3</td>
<td>25.0</td>
</tr>
<tr>
<td>Kidney yang deficiency</td>
<td>3</td>
<td>25.0</td>
</tr>
<tr>
<td>Spleen failing to control blood</td>
<td>3</td>
<td>25.0</td>
</tr>
<tr>
<td>Restless Heart qi</td>
<td>3</td>
<td>25.0</td>
</tr>
<tr>
<td>Kidney qi deficiency</td>
<td>2</td>
<td>16.6</td>
</tr>
<tr>
<td>Kidney yin deficiency</td>
<td>1</td>
<td>8.3</td>
</tr>
<tr>
<td>Spleen deficiency with dampness accumulation</td>
<td>1</td>
<td>8.3</td>
</tr>
<tr>
<td>Trauma</td>
<td>1</td>
<td>8.3</td>
</tr>
</tbody>
</table>
Of the 49 possible acupuncture points listed for use in the study protocol, 28 were used in this study (see Table 4.16), with 1–6 points used per treatment. Moxibustion was also used for three women (16.6%) as part of their treatment. This consisted of use at the time of treatment and instructions on use at home between treatments, as required. All three women made use of this moxa stick at least once between their treatment sessions. This range of TCM treatment patterns diagnoses and the flexibility to choose multiple diagnoses and use moxibustion reflects clinical practice in which conditions may co-exist according to the individual’s presentation and underlying conditions. In addition, it may be important to treat the acute presenting symptoms for treatment to be effective.

Table 4.16: Acupuncture points used in treatment

<table>
<thead>
<tr>
<th>Meridian</th>
<th>Acupuncture points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>LU 7</td>
</tr>
<tr>
<td>Large intestine</td>
<td>LI 11</td>
</tr>
<tr>
<td>Heart</td>
<td>HT 7</td>
</tr>
<tr>
<td>Liver</td>
<td>LR 2, LR 3</td>
</tr>
<tr>
<td>Gall bladder</td>
<td>GB 30, GB 34, GB 41</td>
</tr>
<tr>
<td>Spleen</td>
<td>SP 1, SP 4,</td>
</tr>
<tr>
<td>Stomach</td>
<td>ST 36, ST 37</td>
</tr>
<tr>
<td>Kidney</td>
<td>KI 6, KI 9, KI 21, KI 27</td>
</tr>
<tr>
<td>Bladder</td>
<td>BL 20, BL 23, BL 57, BL 62</td>
</tr>
<tr>
<td>Pericardium</td>
<td>PC 6</td>
</tr>
<tr>
<td>Triple energiser</td>
<td>TE 4, TE 5, TE 6</td>
</tr>
<tr>
<td>Conception vessel</td>
<td>CV 4</td>
</tr>
<tr>
<td>Governing vessel</td>
<td>GV 4, GV 20</td>
</tr>
<tr>
<td>Non-meridian</td>
<td>Yin Tang</td>
</tr>
</tbody>
</table>

4.16.1 Acceptability of acupuncture as an intervention

Women from both groups received an average of four treatment sessions. This was a mean of 4.1 (SD 1.6) for women in the touch group and 4.3 (SD 1.8) (MD 0.20; 95% CI, -0.88, 1.28, p=0.72) for women in the acupuncture group. The finding that there was no significant difference in the treatment frequency between groups suggested that women did not reduce treatment frequency in order to avoid receiving acupuncture, and that they found acupuncture acceptable as an intervention.

There were a total of 78 acupuncture treatments among the 18 women receiving treatment, with minor adverse reactions reported during three (3.8%) of these
treatments. One involved discomfort while needling, which was resolved with the removal of the needle. Another involved a bruise on the leg following treatment and one woman reported sensations in her abdomen, which she described as uncomfortable (although not painful or cramping), and which was resolved shortly following treatment. These events were acceptable to women, with all women continuing to receive acupuncture until exiting the trial at 12 completed gestational weeks. There were no adverse reactions reported for the 21 women receiving the touch intervention.

4.16.2 Summary of trial findings

This study for pregnancy outcomes found that, while there was a reduction in pregnancy loss and complications for women in the acupuncture group, it did not demonstrate statistical significance. However, this pragmatic trial of a modest sample size was not expected to show statistically significant changes.

Of the measurements utilised for quality of life, women in the acupuncture group reported a significant difference for a primary symptom they nominated as being of concern on exiting the trial at 12 completed gestational weeks. However, there were no significant differences reported between the two groups for general wellbeing or pregnancy-related fear. There were no significant differences between the two groups for diet and lifestyle activities on exiting the study or in the support they considered useful. While the majority of women in this study found the diet and lifestyle changes useful, two women reported no changes that were useful and one reported that she did not find bed rest useful. Of the changes that women reported as helpful, implementing dietary advice and taking appropriate rest were seen as the most beneficial changes.

A manualised acupuncture protocol was successfully used to deliver a range of acupuncture diagnoses and interventions, with only minor adverse reactions that were tolerated well by women in the trial.

This concludes the reporting of the outcomes for the randomised trial. The following section reports on the thematic analysis of women exiting from the trial and their perceptions of what they found beneficial.
4.17 Thematic analysis

This section presents the findings of analysis of 11 interviews with women with a diagnosis of threatened miscarriage following their participation in an RCT. Of the 11 women interviewed, seven received the acupuncture treatment, six had experienced a previous miscarriage, five had one or more living children and two had conceived using fertility treatment.

The aim of these interviews was to explore participants’ experiences of threatened miscarriage and the care they received in the trial. The research question was: What were women’s experiences of threatened miscarriage?

An overarching theme emerged from the data of ‘finding something you can do’, which encompassed three main themes: ‘they said there was nothing they could do’, ‘managing while marking time’ and ‘feeling the benefits’. Together, these themes reflect the experiences of women with threatened miscarriage and their experiences participating in this trial. This chapter discusses the main themes and then presents each theme in more detail, along with their associated subthemes.

4.17.1 Overview of themes

‘Finding something you can do’ was the central unifying theme in these interviews. Three major themes and several subthemes are presented in Table 4.17 and Figure 4.3. The first theme ‘they said there was nothing they could do’ captures what women were told about their treatment options and their reaction to this which included feeling that they are left to cope on their own and their use of the Internet for further information.

The second theme, ‘managing while marking time’, captures how women saw themselves as having to cope until they reached 12/13 gestation weeks. Reaching this second trimester was perceived as a safe, or safer, time. This theme describes how women managed and what they considered helpful while they waited for this time to pass.
The final theme, ‘feeling the benefits’, illustrates what women saw as the benefits of being involved in the trial. This included the overall feeling of control by all women—that they had actively taken action to try and achieve a positive pregnancy outcome—and how they perceived this as reducing their stress, as well as the specific physiological and psychological benefits they felt they had received from acupuncture or touch.

**Table 4.17: Themes from the interviews of women participating in a pilot randomised trial**

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<th>Finding something you can do</th>
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<td><strong>Themes</strong></td>
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<td><strong>Sub-themes</strong></td>
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<td>They said there was nothing they could do</td>
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<td>Managing while marking time</td>
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4.18 Presentation in the text

The quotations used in this chapter are identified according to fictitious names. All women received the acupuncture or touch by the lead researcher (DB) (who did not undertake the interviews), who is identified using her name (Debra). An ellipsis (…) is inserted where words have been removed from a comment. Square parentheses [ ] are used to maintain anonymity when specific locations or names were used.

4.19 Finding something you can do

This overarching theme of ‘finding something you can do’ is used to capture how women expressed their experience of participating in this trial—that they were taking an active approach to try and help themselves by being involved:
I actually felt like I was actively doing something to try and help my situation, because otherwise you are left in a little bit of a black hole (Shelly).

Women entering the study were told they would not be able to choose which group they would be assigned to. Being placed in the acupuncture or touch group did not appear to affect their perception because they had found something they could do. For these women, participation was described as actively doing something useful:

I think doing nothing feels quite helpless really. It’s all outside of your control anyway but at least trying acupuncture or acupressure it makes you feel like you’re actually doing something to try and stop it (Janice).

It’s because you felt like you were doing something to minimise things, I did feel more relaxed (Susie).

‘Finding something you can do’ was considered important by all participants because it offered women the possibility that they could do something that had the potential to make a difference to their pregnancy outcomes:

I had to wait for another week, week and a half until I had a scan where there was a heartbeat until I could actually enter the study. But I wanted to do it immediately because I felt like I could do something, and if there was any potential that it was going to help save the pregnancy then that’s what you’d like to do (Shelly).

[The treatment] was comfortable and quite reassuring really that I was trying to do something to help myself (Susie).

This overarching theme of ‘finding something you can do’ is interwoven through all of the main themes presented in this chapter: ‘they said there was nothing they could do’, ‘managing while marking time’ and ‘feeling the benefits’.

4.20 They said there was nothing they could do

A theme that captures women’s reactions to the care they received from their Western-trained medical practitioners is ‘they said there was nothing they could do’. This was not easy for women to accept, and there was disbelief for one woman that with all of the health care that Western medicine could offer, there was no treatment for threatened miscarriage:
It just boggles the mind really that pregnancy is the oldest condition surely and yet going to the hospital they say there nothing we can do—it’s astounding that’s there nothing they can do (Jill).

For all women, there was an expectation that even if there was no medical treatment available, they would receive advice and support from their practitioners. For one woman with a nursing background, it came as a shock to find that she was offered no further support—not even the opportunity to talk to someone:

The fact that when you ring up somebody who’s meant to be there—the clinic who’s helped you conceive and they’re meant to be a bit more supportive and all they say, well just put your feet up, there’s not much you can do about it. It’s kind of like oh, you know a bit of a shock. You sort of think golly if I’m feeling like this and I’ve got a bit of a medical background and am quite sensible, imagine how other people must be feeling, it must be absolutely horrific not to have any support there, or anybody you can just ring and talk to (Rachel).

Women discussed the lack of support they received in terms of staff not spending time with them and the lack of information they received. For one woman, this was especially distressing because it occurred several times when seeking emergency assistance in a hospital for severe bleeding and pain, including an episode where she had collapsed and was brought into the Accident and Emergency department by an ambulance. Her impression was that, although she was bleeding heavily and distressed, hospital staff left her alone, in part because they did not have any medical treatment to discuss or offer her:

I’ve had five bleeds in 16 weeks and we’re talking a lot of blood. The second to last one was very, very painful as well and yeah my experience with the hospital hasn’t been very positive. I think it’s simply that they don’t have time—they’re really, really busy and they don’t have anything they can do, so that’s it really (Jill).

All women interviewed were offered, and received, appointments for ultrasound follow-ups. While all women expressed how reassuring this was, they also expressed that their health practitioners offered limited advice, support and information other than planning appointments for these ultrasounds:

All that happened is every time I had a bleed I’d ring my doctor and I had to go in and have my bloods taken and go for a scan and that was all really that happened each time. There wasn’t really anything else. It was just you’ve got to wait and see, there is nothing we can do (Shelly).
While there was no reference to the information and advice they had received from their health practitioners for three women—other than that they had informed the women about the study—the remaining women expressed dissatisfaction with the advice and information they had received, although they were not specifically asked this question. The overwhelming dissatisfaction was with the advice that there was ‘nothing they could do’ and to ‘try not to worry’:

> It’s not enough to have your midwife tell you oh don’t worry—there’s nothing we can do at the moment. I just don’t think it’s fair to leave women like that, because it’s a really traumatic thing that you’re going through you know, just to be told to pretty much not worry and just wait and see, I don’t know—I just don’t really think that really cuts it really (Kelly).

> I guess what really chimed with me was about being told to go home and try not to worry about it…and it’s impossible. You know it’s utterly impossible to try not to worry about it (Annie).

> So I’m so stressful at that time because my midwife told me just all we can do is to wait and see how it goes. So I went to the hospital and then I asked my midwife to refer me to the doctor. Then the doctor told me that they can’t find anything that’s causing this bleeding (Gina).

One woman was told that three miscarriages were normal. This was something she did not accept, and she associated it with abortion being legal in New Zealand:

> Here they said three miscarriages were considered normal…I was thinking maybe because abortion is legal here in New Zealand maybe they consider three miscarriage is normal, but I don’t think it’s normal (Gina).

Women felt that by being told there was ‘nothing they could do’, their practitioners were in effect saying that they were leaving them to cope on their own:

> It’s just wait and hope you get to 12 weeks kind of thing…you are just sort of left to deal with it (Shelly).

In contrast, it was perceived that by participating in the trial, they had found someone who was offering them care—that someone was trying to help them at this time when they were seeking support:

> I think it was just—like having someone trying to help me was really beneficial because I’d been told otherwise just go home, there’s nothing we can do (Lucy).

Women’s dissatisfaction with their care and their reluctance to accept that there was nothing that could be done to assist these at-risk pregnancies, either by Western medical
practitioners or through their own efforts, is further expanded in the subthemes ‘I know they are just doing their job but…’ and ‘nowhere to go but the Internet’.

4.20.1 ‘I know they are just doing their job but…’

In this subtheme, women expressed their dissatisfaction with the care they received. It was not seen that practitioners were being neglectful or deliberately unkind—just that, as part of their job, they were treating threatened miscarriage as a common situation for which nothing could be done. However, for the women, it was distressing and not helpful to be told that this was common and there was nothing they could do but wait and see:

I know they’re just doing their job but I think they need to find a way to help these mothers. I know there are mothers out there probably going through the same thing as me, but it’s not easy (Tina).

Because you do to the doctor and the doctors like, well there is nothing you can do. There’s no information given to me so that was really all I thought would happen. I think I would be more proactive if someone said that to me now, I’d be like, well that’s actually not true. Go and try this or go and see this person. Because it’s horrible to just go home and be told well, wait and see (Lucy).

Women also saw the language being used around a threatened miscarriage as difficult to cope with; for women, this was their pregnancy and their baby rather than a viable pregnancy:

Some of the medical staff and I mean even down at the pregnancy unit was quite difficult, the language they used. Like they have rung me up and they are like come down and we’ll check if your pregnancy is viable. I dislike that word intensely, it’s like, I realise that this is your job and you deal with it every day but this is a person to me (Lucy).

4.20.2 Nowhere to go but the Internet

This subtheme captures how women were unable to accept that there was nothing they could do, and they sought further information from the Internet, such as diet and lifestyle advice. While they acknowledged that this was not ideal, they saw that they had nowhere else to go:

I hadn’t really got anywhere to go for that kind of stuff except the Internet which is you know 99 per cent rubbish (Annie).
Three women specifically mentioned the Internet as a useful source of information, although they also expressed that they did not trust the Internet to always provide accurate information. While aware that the Internet may be providing biased information, they expressed how difficult it was to determine the accuracy of information. This was something they undertook themselves, although they found it difficult:

There was—like some useful information on them. Like a lot of them were saying not all bleeding’s serious. But there’s still—it wasn’t exact like, scientific sort of research. A lot of it people had written themselves. So you kind of have to pick out what you choose to believe. I think when you’ve had a fright like that, you read everything as if it might be fact (Rachel).

Working out which bits are the rubbish and which bits actually are the kinds of things you should be listening to is quite hard (Annie).

4.21 Managing while marking time

The second theme, ‘managing while marking time’, illustrates how all women saw themselves as having to manage until they achieved safety by reaching their second trimester—that each week that went by offered more hope and reassurance until they were able to ‘get to that three months and everything would be OK’ (Susie). The following subthemes capture what they perceived to be helpful while making it to this milestone: ‘someone to talk to’, ‘support that was relevant’, ‘time to reflect’ and ‘physical reassurance’.

4.21.1 Someone to talk to

This subtheme illustrates how important it was for women to be able to talk to someone: ‘It’s the need to talk about it. I don’t think you can manage without talking about it’ (Annie). This included talking about feelings of guilt—that they may have done something to cause the bleeding or that they were still doing something that was detrimental:

You feel like you might have done something wrong or you might have caused it to happen. So it was just nice having someone come in and give you that reassurance. Just to be able to sort of talk about things really (Rachel).

That first session was really kind of dealing with a whole bunch of stuff that had been swimming round my head. A bit about kind of blame—did I do something wrong and what do I do going on from here as well? (Annie).
Women also wanted to talk about how their reactions to the reality of a possibility of a miscarriage were not always what they would have expected:

I think if I’m being objective, my objective self recognises that often you miscarry because something not quite right. But I think when it’s actually happening to you, you feel quite differently about it to the rational side of your brain (Annie).

Being able to talk to someone was viewed as something constructive that women could do—both when it was available on a regular basis and as something extra they could initiate if they wanted to talk about an event that had occurred between visits:

I think that is what sticks out, just being able to talk to someone, I looked forward to her coming each week and it was nice to know if I really wanted to I could ring Debra if something happened (Shelly).

Being able to talk to someone about their concerns went beyond something that they perceived as an extra benefit of participating in the trial. It was seen by the women as having a very real therapeutic effect in addition to the intervention being offered by assisting them to deal with stress:

It's not even just the acupuncture to be honest, it’s more the just having someone to talk to and go through you know, just talk about—well who knows where you’re at sort of thing (Rachel).

If you're feeling a little bit stressed, it's very, very important to relax and have someone to talk to about your feelings. Because after you voice out what you feel, it makes you feel better (Gina).

Women expressed that while it was helpful to talk to family and friends, there was a difference in having access to someone who was knowledgeable about threatened miscarriage. This was perceived as important to women in terms of being able to express any negative feelings they were experiencing and in reducing the pressure for their partners and families to be the sole providers of support:

You go into work and the ladies at work are all really lovely and they’d be like how are you feeling today and this, that. You’d be like awful. But you didn’t want to be like that every day. So it was quite nice to have somebody else you could say, I am feeling rotten and don’t expect me to be feeling flash or anything like that (Rachel).

It was quite difficult for my partner to be that person, like that’s quite difficult because I think he just worries too much about me being stressed to be able to be that listening person around some of those things (Annie).
Debra acknowledged how I was feeling and told me what I was feeling was normal, and that made me feel a lot better. Also, she was not my family. She wasn’t my friend. She was someone that knew a lot about it (Kelly).

4.21.2 Support that was relevant

This subtheme captures the types of support that women regarded as relevant, including providing reassurance and information that they perceived as valid for them. It was not seen that this reassurance required a guarantee of a positive pregnancy outcome; rather, being provided with realistic reassurance that offered some hope of a positive outcome was supportive in itself:

It’s just that feeling of helplessness. I think that for me was the hardest thing, so just having someone to talk to and to kind of reassure and say well look, that sounds positive, just try and keep positive. You can never guarantee that that’s going to be the outcome because in some cases it won’t be, but just, I think, providing that support (Shelly).

This included having someone that validated their feelings and acknowledged that a range of feelings was possible during an at-risk pregnancy:

Because when I talk to Debra about how I was feeling, she’s put it into perspective and she made me feel like I wasn’t the only person that was feeling like that, and I wasn’t a crazy person for feeling the feelings that I was feeling (Kelly).

A range of concerns was expressed, including their partners’ reactions to the pregnancy, their workplace environment and concerns about telling people they were pregnant. However, the majority of concerns centred on coping with their emotional reactions to the pregnancy and consuming foods that might be detrimental to the pregnancy:

It definitely gave me peace of mind. There were things that I was worried about. I’d just been feeling quite down about it, and not really believing it, and I think during those few weeks I definitely felt—well obviously I came to realise that I really was pregnant and happy about it, and also just not to be so stressed out about types of food that you can and can’t eat, because she gave me the facts and the figures…I think the mental attitude that I managed to overcome worked, more significant maybe than the physical (Ellen).

I was freaking out as well, because I was stressed, that you’re not supposed to stress when you’re pregnant. So then I was like oh no is that going to do something to the baby as well? (Kelly).

It just felt like there was this endless list of stuff I couldn’t eat and I said well what can I eat? You know all that stuff where there is this advice and it’s
conflicting and you can’t tell what’s people being paranoid and what’s common sense…I guess was kind of an overriding feature for me of that first session. A relief from having had some kind of sensible, pragmatic answers (Annie).

Providing information that women regarded as reliable was also seen as important support. In particular, women spoke about how useful it was to receive information that was personally relevant to them from people they trusted:

[Debra] spent quite a good chunk of time helping me unpack the kinds of things that were at the top of my list of things that were causing me stress and anxiety. A lot of that was around I don’t know where to get good information from (Annie).

[I] went to the emergency doctor who was absolutely fantastic and gave me loads of information and sent me on my way (Ellen).

In addition to receiving appropriate reassurance and information, women viewed useful support as discussions in which their main concerns were identified and they had an opportunity to discuss what they could do to assist themselves. This was expressed as being given time to work out what was achievable and important for them rather than receiving a list of instructions:

I quite like the way that Debra was very good at making it, helping me to self-direct that rather than directing what she thought I should be doing. She’s very good at framing all of that in the context of helping you to work out what is going to work for you (Annie).

4.21.3 Time to reflect and rest

A further benefit that women considered helpful was the physical time spent receiving acupuncture or touch. Women saw these sessions as a ‘time to reflect’. It was used as a space to relax and a time to self-evaluate how they were coping and to discuss any changes they wanted to make:

I liked having a space to go and just be and having that space every week was extremely helpful…I suppose it was a reflective opportunity to kind of go what is stressing me out this week? (Annie).

Every week they gave me a list to answer what I’m feeling. So I noticed that from week to week my stress levels getting down (Gina).

…I was trying to build meditation into my week and I found having the on-going appointments really good because it made me really think about well when am I going to find time, how am I going to fit this into my week and then take
time and do it. I have actually noticed that I have been worse about doing that since I’ve finished having sessions (Annie).

It was also seen as helpful time out, in that it was a time to physically rest:

It was a bit of a rest for me, which was nice. It was kind of compulsory. You had to take it easy (Janice).

Together, this support was expressed as being valuable and contributing to a more positive experience of this time, even if women did not think it would have influenced their pregnancy outcomes:

Yeah, I think my experience would have been extremely different. I don’t know whether the outcome would have been different or not, but I think my experience during that period would have been extremely different without the support that [Debra] provided (Annie).

### 4.21.4 Physical reassurance

Women also spoke of obtaining reassurance through the passage of time—experiencing changes in symptoms they associated with miscarriage, such as cramping and bleeding, and having physical proof that the pregnancy was continuing through medical monitoring:

Just passing the little milestones like having a 12-week scan and seeing that it was all Ok and not bleeding and things like that. They’re the things that put my mind at ease really. Those actual physical milestones (Janice).

Because I’m A negative blood type I had to go into the hospital and have anti-D injections and all those bits and pieces, but at the same time I was scanned so it was also comforting to see that the baby still had a heartbeat and things were okay (Susie).

Although ultrasounds were spoken of as powerful reassurance, women did not necessarily see them as a guarantee that the pregnancy would continue with no further problems. Several women expressed concerns that there would be ongoing problems with their pregnancy:

Even after seeing the scan I kept thinking oh no, something’s going to go wrong. I’m not sure why (Ellen).

A further reassuring sign for some women was the presence of nausea, which was taken as a positive sign by all women who experienced it. Women discussed how the presence
of nausea was a reassurance that the pregnancy was continuing, and there was a correlation between the level of nausea and the likelihood of the pregnancy remaining viable:

I felt really sick, a lot of nausea and things like that, so that was also quite comforting to know that things were still going on as they should and it was quite a strong pregnancy (Susie).

4.22 Feeling the benefits

This theme illustrates why women saw their participation in the study as useful to them. For the purpose of clarity, the group assignment (acupuncture or touch) is placed in parentheses following the name for the following section. These beneficial effects are captured in the following subthemes: ‘a sense of control’ and ‘helpful for relaxation and symptom management’.

4.22.1 A sense of control

The overwhelming majority of women spoke of feeling less helpless and gaining a sense of control by entering the trial—that the process of being involved offered them the opportunity to do something proactive:

I felt like I was actually able to have a little bit more control over the situation. That I was able to do something a little bit more proactive and I did. I felt more hopeful that maybe if I did these things it would have a better outcome than if I just sat at home and did nothing (Lucy, acupuncture).

I know there’s not too much control that you do have. I just felt I had more control this time whereas last time I don’t think I did (Susie, touch).

…so that coming away with some control—a feeling of control over some of that I guess was kind of an overriding feature for me of that first session (Annie, touch).

4.22.2 Helpful for relaxation and symptom management

The majority of the women expressed that they experienced a sense of relaxation following their sessions, with the exception of one woman in the touch group who reported feeling no different after her treatment sessions. Those who reported feeling more relaxed specifically mentioned positive emotional aspects such as feeling less
anxious and less stressed, as well as sleeping better as a result of receiving acupuncture or touch. For the majority of women in the acupuncture group, there was a reluctance to attribute this directly to the acupuncture they were receiving. These women moderated their responses to allow for the possibility that these positive effects may have resulted from the support they received from the researcher:

I know that I felt better after each session and whether that was a combination of the acupuncture itself or being able to talk through my fears and concerns with Debra, I can’t really probably put it down to one specific thing (Shelly, acupuncture).

However, one woman directly identified the acupuncture treatment she received as specifically contributing to this relaxation effect:

[Debra] also taught me about relaxation techniques as well to do, but I just think acupuncture is the way to go (Kelly, acupuncture).

However, it was evident that while the women receiving touch spoke of relaxation in general terms—‘just a lot more relaxed’ (Susie, touch)—women in the acupuncture group gave examples of specific effects that were related to the timing of the treatment they received:

I fell asleep at something ridiculous—6:30 or something that evening. I was just so relaxed and slept like a log…it wasn’t like I hadn’t been sleeping, but I slept so deeply (Ellen, acupuncture).

After the first treatment, I felt so relaxed and almost sort of relieved. It’s kind of like you’re just—like she asked me to lie down for about 20 minutes and I just thought I could have just stayed there all night sort of thing. Just you know, you stop worrying about everything (Rachel, acupuncture).

Interviewer: Did it stay with you?

It did for at least 24 hours. Then you’re sort of back at work and back to normal sort of everyday things (Rachel, acupuncture).

Emotional aspects relating to feeling less irritable and angry following the treatment featured in the relaxation responses of two women in the acupuncture group. One participant’s mother, who was living with her daughter and present during the interview, observed this change during and immediately following the first treatment session:

So to see her noticeably calm down over that hour and a half, whereas I’d had quite a few weeks where it was constantly walking on tender—you know, sort
of tenderhooks, really for Kelly there was a noticeable change in her demeanour (Kelly’s mother, acupuncture).

Women receiving acupuncture treatment also described beneficial physical effects related to changes in bleeding, cramping and back pain following treatment, which were not discussed by women in the touch group. For two women in the acupuncture group who had been experiencing heavy bleeding and abdominal cramping for several weeks, acupuncture was perceived as being beneficial due to direct effects noticed following treatment:

The next day my bleeding stopped…yeah, I was shocked and I was really happy. I was a little bit sceptical, and I kind of was thinking oh is it all just — this acupuncture stuff, is it all just in people’s heads kind of thing, but no. I know now that it works (Kelly, acupuncture).

I was going through quite a lot of cramping and I had a treatment and that went away straight away, which was brilliant. Since I finished the treatment I get quite a lot of cramps (Jill, acupuncture).

For the remaining women, where the bleeding and cramping was no longer present or intermittent, the focus was on symptoms such as back pain and constipation. Interestingly, despite several women experiencing nausea and all women in the acupuncture group being offered treatment for their nausea, only one woman requested treatment:

Actually when Debra was doing the Moxa treatment I found that quite good because I was quite cold, I’d been having a quite cold back. So I felt better physically after those treatments (Janice, acupuncture).

I was also suffering from constipation, which she gave me treatment to help with that, which did actually help quite a lot (Rachel, acupuncture).

I had quite a bit of reflux and nausea as well and that certainly settled for a couple of days (Lucy, acupuncture).

For women receiving touch, there were no physical benefits related to pregnancy symptoms other than the nausea improving over time. For the two women in the touch group who were actively bleeding when they entered the trial, there were no reported changes in their bleeding or cramping symptoms following treatment. However, they reported feeling less stressed about these bleeds, and the reduced concern about these symptoms was perceived as positive:
Yes I think less anxiety because before when I first noticed that there is some bleeding, I always cry and then I can start to cry. But now I became relaxed and think about positive sides (Gina, touch).

I just wasn’t so stressed about it. I knew there was nothing I could do, but that was something that, I don’t know. It just made me feel a lot more relaxed about it and I wasn’t too uptight about it (Susie, touch).

4.23 Integration of the RCT and semi-structured interview findings

The RCT pilot demonstrated that acupuncture was a feasible intervention to offer women, with approximately 50% of the eligible women who presented with threatened miscarriage consenting to randomisation. It emerged from the semi-structured interviews that women entered the trial because they viewed that receiving either intervention was being proactive compared to the ‘there is nothing you can do’ advice they received from their Western health practitioners.

For women receiving acupuncture, there was a statistically significant reduction in the threatened miscarriage symptom that they self-selected as a primary concern (p=0.04), with these symptoms relating to women’s anxiety over vaginal bleeding as well as abdominal cramping and back pain. However, there was no corresponding significant difference for general wellbeing in the MYMOP questionnaire or pregnancy-related fear questionnaire between the two groups on exiting the trial. This finding was captured in the interviews, where women from both groups expressed feeling less stressed and more in control by being involved in the study. The women discussed this control—through ‘finding something they could do’—as a major reason for feeling less stressed; women in the acupuncture group did not directly attribute it to the acupuncture treatment. However, the interviews captured differences between the groups in the way that women perceived themselves as less stressed. Women in the touch group reported less anxiety about abdominal bleeding and cramping, while women in the acupuncture group discussed the relief they felt from specific reductions in symptom in terms of abdominal bleeding, cramping and back pain.

In the RCT, 29 women (93.5%) nominated beneficial changes that had occurred from being involved in the trial, with all women who received acupuncture nominating these beneficial changes. Of these changes, implementing the dietary advice they had been
given and taking appropriate rest was seen as the most beneficial change. In the interviews, it emerged that, in addition to the advice they perceived as being relevant, women valued the therapeutic relationship with the researcher, discussing how helpful it was to talk to someone who was knowledgeable about threatened miscarriage.

Only one-third of the women reported the support they received from a Western-trained health professional as useful, with dissatisfaction expressed by the majority of women interviewed because they expected more support than medical monitoring from their health practitioners.

This concludes the integration of the quantitative and qualitative data from the online acupuncture practitioner survey and the pilot RCT. Chapter 7 presents the integration of these research findings with the findings in the other chapters in this thesis.

4.24 Summary

In conclusion, acupuncture was a feasible intervention to deliver to women presenting with threatened miscarriage. Recruiting through an MAU was the most successful method of referral; however, the finding that fewer women than expected presented with viable pregnancies and that women presented at a gestational age past 11 completed weeks requires consideration when recruiting in future research.

There were eight (20.5%) pregnancy losses throughout the study. Five (12.8%) occurred before 12 completed gestational weeks and three (7.7%) were late pregnancy losses. Five women experienced a pregnancy loss in the touch group compared to three women in the acupuncture group. This difference was not statistically significant (RR 0.70; 95% CI, 0.19–2.13, p=0.58). However, statistically significant differences in pregnancy loss between the groups were not expected, as this was a pilot study.

An unexpected finding was that early pregnancy loss was similar for women who reported their initial bleeding as lighter than a period and as heavier than a period. The late pregnancy losses in this study all occurred with women initially reporting their bleeding as lighter than a period.
Acupuncture was a safe treatment intervention that provided an additional benefit for women in terms of less concern relating to threatened miscarriage symptoms on exiting the trial compared to those receiving touch as an intervention. The use of a manualised acupuncture protocol in this study allowed for a range of diagnoses without restricting clinical practice, and it provided information on the main diagnostic patterns, which may be useful for consideration in any further research.

Both groups of women reported supportive care as being useful. This was reported as an overall theme of ‘finding something to do’, and it included having access to someone they could talk to and receiving diet and lifestyle advice that was relevant to them. Only one-third of the women in this study reported that the support they received from Western-trained health professionals was useful to them, with dissatisfaction expressed by the majority of women interviewed, as they expected more support than medical monitoring.

This concludes the findings for this chapter. Chapter 5 explores how Western-trained medical practitioners perceive the care they offer to women presenting with threatened miscarriage.
Chapter 5: Western-trained Health Practitioner Interviews: Considerations of Optimal Practice for Threatened Miscarriage

5.1 Introduction

This chapter presents the findings of the analysis of 12 interviews with Western-trained health practitioners working with women presenting with threatened miscarriage in the Wellington and Hutt Valley regions of New Zealand. These practitioners included three nursing staff and a medical doctor from a fertility unit, two midwives and a medical doctor from an MAU at Hutt Valley Hospital, one nurse from a Women’s Health Assessment Unit at Wellington Hospital, three LMC midwives and one GP.

The aim of this research was to explore practitioners’ considerations of optimal clinical practice for women presenting with threatened miscarriage. The research question was: What do Western health practitioners consider optimal clinical practice for the treatment of threatened miscarriage, including dietary and lifestyle advice in clinical practice?

An overarching theme emerged from the data of ‘walking a fine line between hope, reality and professional responsibility’, which encompassed four main themes: ‘realistic reassurance’, ‘feeling in the dark to give reassurance and advice’, ‘preventing blame’ and ‘support useful, but limited’. Together, these themes capture how practitioners viewed themselves as health professionals providing care for women with threatened miscarriage. This chapter first discusses these main themes before presenting each theme in more detail. Chapter 7 presents an integrated discussion of the findings of this chapter.

5.2 Overview of Themes

‘Walking a fine line between hope, reality and professional responsibility’ was the central unifying theme in the interviews. Four themes and several subthemes are
presented in Table 5.1 and Figure 5.1. The first theme, ‘realistic reassurance’, captures practitioners’ concerns about wanting to give women hope and optimism for a continuing healthy pregnancy while simultaneously maintaining a professional responsibility to inform women about the risks of bleeding during pregnancy. This professional responsibility included ensuring that they did not provide women with ‘false hope’. Practitioners felt that it was appropriate that medical results from blood tests and ultrasounds were used to provide reassurance; however, when these medical results were not positive or when the cause of the bleeding was unknown, it became more difficult to offer realistic hope and reassurance. An ultrasound was seen as the ultimate reassurance for women, although concern was expressed that women may not understand that it was not a guarantee of a continuing pregnancy.

The second theme, ‘feeling in the dark to give reassurance and advice’, illustrates practitioners’ view that a limited information base is available to them to provide women with accurate advice, including medical advice and diet and lifestyle advice. The Internet was seen as an information source used by practitioners in different ways. While all practitioners viewed the Internet as something that women accessed, for most practitioners, it was important to caution women against using the Internet due to potentially inaccurate information. However, for two practitioners, the Internet was seen as a positive source of information that was useful for directing women to specific information sites. In their clinical practice, the lack of an evidence base was discussed with women before practitioners gave advice, with the majority taking into consideration the women’s circumstances and preferences when giving self-care advice.

The third theme, ‘preventing blame’, focuses on how practitioners felt that it was important to prevent women from incurring self-blame in the event of a subsequent miscarriage. This included ensuring that any advice they gave was practical to follow and that women understood the reality of miscarriage as a natural and often medically unexplainable event.

The final theme, ‘support useful, but limited’, captures how practitioners viewed themselves providing support by offering relevant medical information to women. However, there was a perception that, while any support that helped women reduce their anxiety may be useful, it was unlikely to have any effects that would alter the final
pregnancy outcome. Supportive care was also limited due to the fragmented nature of maternity care in early pregnancy, with not all women able to access supportive care through their health-care providers.

**Table 5.1: Themes from Western health practitioner interviews**

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-themes</th>
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<tr>
<td><strong>Realistic reassurance</strong></td>
<td>Hope but not false hope</td>
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<td></td>
<td>Using medical knowledge to justify reassurance</td>
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<td>• ultrasounds—the ultimate reassurance, but only at this moment in time</td>
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<td></td>
<td>The uncertainty principal</td>
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<tr>
<td><strong>Feeling in the dark to give reassurance and advice</strong></td>
<td>A limited evidence base</td>
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<td>Dr Google—unreliable but widely used</td>
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<td>Remaining flexible—a woman’s preference</td>
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<tr>
<td><strong>Preventing blame</strong></td>
<td>Advice that women can follow</td>
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<td></td>
<td>In nature’s hands</td>
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<tr>
<td><strong>Support useful but limited, ‘what will be will be’</strong></td>
<td>Acupuncture limited to relaxation</td>
</tr>
<tr>
<td></td>
<td>An access gap</td>
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5.3 Presentation in the text

The quotations used in this chapter are identified according to a number assigned to the practitioner (e.g. P1 for practitioner one), followed by a brief description of their role as health practitioners. An ellipsis (…) is inserted where words have been removed from a comment, and square parentheses [ ] are used to maintain anonymity when specific locations or names were used.

5.4 Walking a fine line between hope, reality and professional responsibility

All practitioners perceived that women sought reassurance from them and expressed how difficult it was to provide women with reassurance that all would be well with their pregnancy:
Well they’re seeking reassurance that everything is going to be all right. Of course, no health professional will give them that (P1, midwife).

While acknowledging that women were anxious and that providing information and reassurance was helpful, this needed to be balanced with the medical knowledge that a diagnosis of threatened miscarriage indicated potential risk factors for miscarriage:

…no bleeding is good bleeding. But some bleeding doesn’t mean the pregnancy is going to end. I think it’s just about being honest and upfront with people…you need to be honest, but not brutally honest and that is a bit of a fine line sometimes (P9, medical doctor).

This central theme of ‘walking a fine line between hope, reality and professional responsibility’ encompasses how practitioners viewed themselves as health professionals providing women with hope while maintaining the reality that this was an at-risk pregnancy. This overarching theme ran through the interviews and is organised into the following themes and sub-themes, which illustrate how practitioners dealt with this ‘fine line’ in their clinical practice.

5.5 **Realistic reassurance**

This theme illustrates that practitioners felt it was important for women to receive accurate information regarding potential risks for pregnancy loss. This was expressed in terms of being honest as an expectation of professional practice, and as being necessary to provide trust in building future relationships with the women:

…there is an expectation that you would tell them if there was anything that was going to be detrimental. Because they look up to you as somebody who should be able to guide them in that way (P7, independent midwife).

…they’re always going to be upset…but you still have to be honest, because otherwise it comes back to—once they have a scan, if it’s not right, the nurse told me it was all right and this shouldn’t have happened and why (P8, nurse).

So, you kind of have to be careful, because then you’ve got to maintain the trust relationship with patients as well. So, you can’t over-reassure if you’re not sure (P2, nurse).

Honesty was seen as important not only because it was an expectation of professional practice, but also because practitioners viewed honesty about potential problems as beneficial for women. There was a perception that providing accurate information
would be advantageous, because being fully informed would give women time to prepare for any subsequent pregnancy loss:

I think in terms of managing what is many times going to end up being a traumatic experience for them, they’ll get through it a hell of a lot better if they’d had a chance to get to terms of what might not be a good outcome (P9, medical doctor).

It was considered possible to remain honest and professional by delivering reassurance that was realistic. This is captured in the following three subthemes: ‘hope but not false hope’, ‘using medical knowledge to justify reassurance’ and ‘the uncertainly principal’.

5.5.1 Hope but not false hope

Being able to give women hope was considered valuable; however, optimism should be balanced with information about the risk of potential pregnancy loss to ensure that women understood this was a possibility:

…you can’t tell them what the outcome is going to be. But you can try and be optimistic, because I think in this case, being optimistic helps (P5, medical doctor).

…it’s really hard. You don’t want to obliterate all hope but you want to prepare the women that this isn’t good (P11, nurse).

While being optimistic when possible was considered appropriate, all practitioners believed that it was inappropriate to be too optimistic, to over-reassure or to encourage ‘false hope’. While some hope was useful to women, there was a perception that being too reassuring without medical justification encouraged unrealistic hope, which would be unhelpful:

So, giving them a little bit of hope, but also the reality is that this may not be a viable pregnancy, keeping it real, making sure that you’re not giving them too much hope of it (P8, nurse).

I’d be very careful, and word it very carefully not to ensure false hope. That’s dangerous. I wouldn’t do that (P3, nurse).

…we are, at least I think, by and large as honest as we can be with people about what the likely prognosis is going to be. Now, I think sometimes it would be very tempting to give people false hope and say well, there is a heartbeat there, so you never know, it might be okay (P9, medical doctor).
5.5.2 Using medical knowledge to justify the level of reassurance

Being able to use medical test results was one way that practitioners could ensure that they provided women with ‘realistic hope’ rather than ‘false hope’. By focusing on the specifics of the hormone levels in the blood tests, as well as the results of an ultrasound and any known causes of bleeding, it was possible for practitioners to provide a level of reassurance while maintaining a note of caution in any information given:

I reassure them that they are bleeding but it may not be from where the embryo has attached or where the foetus is growing from. We look at the levels and we say, ‘look, they should be there but they are here, so we are quite realistic (P3, nurse).

If it’s not looking right, for example if the size is smaller than it should be, like more than a week, or if the heartbeat is slow, I’ll say so to the patients. I’ll say there is a heartbeat there, which is great. But I do have some concerns and I’ll spell them out (P9, medical doctor).

There is the one group of women who have the ultrasound which comes back showing the subchorionic hematoma. For those people, you can explain that there’s been seen this little bleed behind the placenta and it depends on - you talk them through that and it kind of—if they’ve got a small one I really try and reassure them and say this is really small and should go through really at the stages of like a bruise and that probably the body will reabsorb this blood and hopefully it will all settle down (P5, medical doctor).

In this subtheme, ultrasound scanning was discussed as providing the ultimate reassurance that women sought. This was captured in the concept of ‘ultrasounds—the ultimate reassurance, but only at this moment in time’. An ultrasound was considered powerful and as offering women absolute ‘proof’ that their baby was viable. This form of reassurance was actively sought by women and was viewed by practitioners as possibly more reassuring than anything else that they were able to offer:

I think it’s the scan, I think there’s nothing you can say, can really reassure more than actually seeing that the baby is okay. So I think if they can, I think the scanning is really important. I think nothing else really (P2, nurse).

I think for a huge majority of women, the important thing is the scan and that you can get a woman to come to an appointment if there’s a scan…but if they’re just going to see a doctor, often they’re not so interested in coming to the appointment. I don’t know how useful we are to these women (P5, medical doctor).

Despite acknowledging the positive aspects of ultrasound technology, there were concerns that not all women understood the transient nature of the results—that is, the
reality of the ultrasound was that it did not offer a guarantee for a continuing viable pregnancy. While it was a powerful reassurance to see that they were still pregnant, it only showed women their pregnancy at that specific point in time:

- Whether they understand the concept of the—now if we scan you here and now, this is only here and now. I do think that that’s a hard concept to grasp for some women, because the reassurance is, oh yeah, my baby’s okay, not my baby’s okay here and now in this very point in time (P1, midwife).
- Yes there’s a baby, yes there’s a heartbeat, but it doesn’t mean it’s going to stay that way (P6, midwife).

5.5.3 The uncertainty principal

The third subtheme identified was that, although practitioners used medical knowledge to provide reassurance, their ability to provide realistic reassurance became less straightforward when there was uncertainty regarding why the bleeding was occurring:

- If we can’t say well, look, you’ve got a hematoma or erosion on your cervix or you’ve got a big fibroid that’s degenerating and that’s why you’re bleeding. So if you can’t give them a reason or they haven’t had post-coital bleeding and things like that then it’s well, difficult (P11, nurse).

Practitioners also discussed the uncertainty that came from the medical assessments they used and acknowledged that this information may not always provide an accurate prognosis. Practitioners discussed how the assessments they used—the hormonal blood tests and scanning to assess the size of hematomas—were not always reliable indicators of a pregnancy outcome. Practitioners also discussed how symptoms relating to the amount of bleeding or pain women were experiencing could not accurately predict a miscarriage:

- There are instances where the blood results look like it’s never going to end in a baby and it has, so we have a bit of experience to call on…we’ve also had women with very light spotting, which is nothing really, that have had a miscarriage (P8, nurse).

This uncertainty was discussed as personal experiences that resulted in practitioners acknowledging that they would not always be able to predict outcomes, even when the prognosis was considered very poor in terms of medical information or a diagnosis from another practitioner:
I would never call it. We have been so wrong in some cases where people have had this and they’ve virtually been told, well—and I think one case was the doctor didn’t even bother with a follow-up scan. It was a viable pregnancy (P11, nurse).

It is a really tricky one to tell because some women have had really significant bleeding in early pregnancy and then carried on to have a full term baby. I had a client a while ago who had contacted me late because her GP had said this is definitely going to be a miscarriage (P4, independent midwife).

The nausea goes, the back ache starts, period cramping, clotting, flooding and you think this isn’t going to survive and they do sometimes. Then others, they just don’t…I don’t think their demise is inevitable, I just think the outcome is unknown (P11, nurse).

5.6 Feeling in the dark to give accurate advice

The second theme of the practitioner interviews relates to difficulties in giving women accurate health information, including diet and lifestyle advice. This encompassed three subthemes: ‘a limited evidence base’, ‘Dr Google, unreliable but widely used’ and ‘remaining flexible—a woman’s preference’.

5.6.1 A limited evidence base

All practitioners discussed the lack of medically accepted evidence that would allow them to provide women with accurate advice about beneficial self-care activities:

I would say initially, how do you get that advice? Where is that source of information for us to learn from to then pass on to the women? (P8, nurse).

There is not a lot of evidence that shows if you have bed rest or you don’t have sex or if you don’t do this or if you don’t garden it’s going to make a difference (P11, nurse).

Practitioners also identified that they tended not to talk to each other about how they offered advice to women with threatened miscarriage, and they expressed how helpful they thought discussions about this would be:

I’d be very interested to know what the other doctors say to these people. Because it’s not something we often discuss, it’s around more acute crises type problems generally, than this... I would be interested to hear what they say. We certainly don’t have any guidelines on it (P5, medical doctor).
This limited evidence base included specific medical information as well as general diet and lifestyle advice, with practitioners expressing uncertainty about being able to answer specific medical questions due to a lack of accurate information:

I had someone recently she had lots and lots of questions around the taking of iodine which was new to this pregnancy…she’d also had the flu injection. She just had lots of questions for me. I mean I couldn’t really answer (P7, independent midwife).

There was also awareness that women were being given different medical information by different practitioners, especially in relation to whether bleeding in pregnancy was abnormal and the use of frequent ultrasounds:

Recently somebody said to me, oh their GP had said if you bleed at this point, this is quite common because this is when your period was normally due. But I’m not actually sure that’s correct information (P7, independent midwife).

You often hear the term oh, that was just an implantation bleed or just this whole normalisation of bleeding in early pregnancy. I don’t think that’s helpful. There is no such thing as implantation bleeding. It’s just something that people have made up to try and calm down patients’ anxieties when they’ve had a little bit of bleeding. But no bleeding is good bleeding (P9, medical doctor).

Some of my colleagues have strong feelings about scanning and the heat that it produces and exposing the baby to that at an early age (P7, independent midwife).

This lack of an accepted evidence base resulted in a variety of advice being given to the women by different practitioners, even when they worked in the same clinical environment:

…their [the doctors’] advice would be completely arbitrary as to who was on, as well. So one would say definitely no sex, take a few days off, take it easy, don’t go lifting heavy cartons and things like that. Then somebody else would say, well, nothing that’s been proven to help so let’s not tell it (P11, nurse).

I don’t tend to say bed rest. I tend to say, take it easy, because bed rest kind of occurs its own anxiety and then trying to get people off bed rest is quite difficult as well—sometimes [name of doctor] will tell somebody to have bed rest for three or four days, but that’s kind of—I don’t know that it’s helpful, really (P8, nurse).

All practitioners expressed how health information and diet and lifestyle advice was based on first acknowledging the lack of evidence that was currently available. While specific aspects such as alcohol consumption, cigarette smoking and avoiding certain
foods that may contain listeria or salmonella remained identical to advice they would provide to all pregnant women, they were uncertain about advice related specifically to threatened miscarriage, such as the safety of frequent scanning, taking time off work and restricting women from their usual physical or sexual activities. The following subthemes examine how practitioners positioned their advice as a result of the lack of an evidence base.

5.6.2 Dr Google—unreliable but widely used

For the majority of practitioners, information obtained from the Internet was considered unreliable, although the Internet was perceived by practitioners as being widely used by women:

A phrase that we quote a bit is, beware of Dr Google. Because the problem with the Internet is that it is such an unedited source of knowledge and a lot of what is on the Internet is just either wrong or incorrect…But we know women get on the net—but we try to say the advice that we give you, one of our sort of principles here is to say we practice evidence-based medicine (P9, medical doctor).

I don’t think our patients really admit how much they are on the Internet. I think they all keep quiet about it, I have a feeling (P2, nurse).

Although the majority of practitioners cautioned women from seeking Internet-based information, there were exceptions. In these cases, the Internet was incorporated into the practitioners’ discussion to illustrate the lack of credible evidence or to provide a trustworthy site for women to seek information from. One GP used a desktop computer to show women sites where they could access information and to demonstrate how little medical evidence there was for any medical treatment:

They come in saying I need to be on progesterone, I read it on the net, you need to be giving me Provera tablets et cetera, et cetera…you can’t say not to go on the Internet; people will. So my attitude is to say right go on the net but look at the right stuff and I’ll give them addresses to look at, reputable stuff to look at, yeah (P12, GP).

The other practitioner who discussed using the Internet in a positive way was a midwife who recommended an information site to ensure that women were able to access information about the use of ultrasounds in pregnancy:
I do initially give them the information or the website on the scan and just say that we don’t actually know whether it could be harmful (P7, independent midwife).

5.6.3 Remaining flexible—a woman’s preference

This subtheme reflects how the majority of practitioners discussed the diet and lifestyle advice they gave by focusing on what they considered important for the individual woman. In these instances, it was the woman’s preferences rather than any personal recommendations that influenced the advice they gave:

If giving up work is something that’s going to help that woman psychologically, because she feels like she’s doing something to help herself, then I would say that to her. I would say, look, if you feel that that’s the right thing for you to be doing, I’m happy to support you and give you work certificates…if they say, look, I’d like to go to work. Is that okay? I’d say, if you feel okay to go to work, great, yes (P1, midwife).

Practitioners also discussed how they made their own judgements at times regarding what they thought the women wanted to hear from them, and they adjusted the self-care advice they gave accordingly:

I think you have to judge who it is suitable for and you can kind of gauge that by the degree of anxiety that’s been mirrored to you. There are some women who are just very philosophical about it and they really do come at it from the well, what will be, will be and they will just carry on life as per normal and then you’ll have others who really do want to put themselves to bed for seven days or what have you (P9, medical doctor).

This concept of allowing women to decide what they would prefer included supporting women even when practitioners felt that the women’s concerns were medically irrelevant:

Sometimes you just don’t know what to say really. You have to bring it back to, okay, well, if you feel better not eating pineapple, by all means, don’t (P8, nurse).

Even when women asked practitioners to provide specific self-care advice, there was a continuing emphasis from the practitioners that they tried to remain flexible. Their preference was to make recommendations after they had tried to determine what they thought would be preferred by the woman:
Oftentimes you’ve got a woman who doesn’t quite really know one way or the other, she’s just looking for advice and guidance. Whilst I’m trying hard not to be too directive about it, if a woman is looking for advice and guidance then I’ll try and fish for which way in that kind of dichotomy her priorities might lie, or her anxieties might lie and then support what seems to be a management plan that will make her feel the safest (P12, GP).

Exceptions to this flexible advice occurred when a practitioner interpreted specific types of bleeding as requiring lifestyle changes that could be justified using a medical rationale:

…if you’ve seen a large hematoma. That’s where I’d say maybe you don’t want to be doing those really heavy lifting or impact exercises…if you haven’t seen a reason for that bleeding, I don’t know that I would want to give them time off (P5, medical doctor).

The only other exception to seeking a woman’s preferences came from the personal experiences of one midwife. This midwife, who had experienced a threatened miscarriage herself, encouraged women to take time off work to rest, just as they would be required to do if they had another medical problem during a pregnancy:

There’s a lot of information out there that says if the pregnancy is challenged or not going well, going to work will not affect the outcome. But I’m not convinced that that’s the right advice. I mean if you broke your leg or if you had a sprain or you had a chest infection, if you were otherwise unwell with other medical conditions, you definitely would take time off work. I think the same should be applied (P10, independent midwife).

5.7 Preventing blame

The third theme reflected practitioners’ concerns that women would use any information or advice they received from them as health professionals to blame themselves if they subsequently experienced a miscarriage:

One of the most tricky things I think, and one of the things that I personally spend most of my talking about, is talking to women and their partners about not apportioning blame, causation or responsibility (P12, GP).

The way that practitioners attempted to ensure that women did not blame themselves is captured in the following subthemes: ‘advice that women can follow’ and ‘in nature’s hands’.
5.7.1 Advice that women can follow

One of the major concerns expressed by all practitioners was that it was difficult to recommend self-care advice without ‘evidence’ because of the potential that, in the event of a miscarriage, any advice unable to be complied with may result in a woman blaming herself. Practitioners perceived that many women would seek reasons for pregnancy loss and there was a desire to provide advice that would prevent them from feeling guilty for something that practitioners considered inevitable:

I would tread a bit cautiously in that I don’t want them to feel responsible for miscarrying a baby that was going to miscarry anyway (P5, medical doctor).

I think that’s really important that they’re not riddled with I shouldn’t have done that run, I shouldn’t have had sex last night, I shouldn’t have drunk a bottle of wine with my mates two weeks ago—that sort of stuff. I think that is really important because they feel really guilty regardless (P12, GP).

This was particularly relevant to any advice concerning women taking time off work, where it was perceived that taking time off work was difficult for many women and that either complying with this advice or being unable to comply would only create extra stress:

They get stressed if they can’t take time off work, that it’s their fault they miscarried because they didn’t take time off work. So I think there’s definitely that (P2, nurse).

5.7.2 In nature’s hands

Practitioners also tried to reduce the potential for women to blame themselves in the event of pregnancy loss by discussing pregnancy loss. Practitioners expressed how they tried to present miscarriage as a natural event that was not anyone’s fault, and that miscarriage was a common occurrence in early pregnancy and a cause could not always be identified. In this context, nature was spoken of as an external force that could not be controlled:

This isn’t anyone’s fault and there are no magic bullets or necessarily therapies that are going to necessarily minimise whether the pregnancy becomes viable or not. I think the key concept that I try to get across is that by that stage, to a certain degree, the outcome of the pregnancy is going to be in nature’s hands (P9, medical doctor).
Nature is a wasteful system, and sometimes in hindsight you can see that there are reasons why a pregnancy fails. We talk a little bit about sometimes there are genetic problems and talk a little bit about poor implantations and that sort of thing, but also acknowledge that oftentimes in any one individual case there’s no way that we can actually confirm or rule out those sorts of influences (P12, GP).

5.8 Support is useful, but limited—‘what will be will be’

This final theme captures practitioners’ views on providing women with support when they present with threatened miscarriage. Providing women with supportive care was considered important and beneficial; however, these benefits were limited. While practitioners spoke of providing support, and this was expressed by all practitioners as having positive benefits for the women, it was expressed only as benefiting women emotionally—that is, by creating a sense of control and assisting them to cope with the pregnancy outcome. This supportive care was not considered an active treatment that could influence pregnancy outcomes:

The support that I offer is more emotional. I don’t think my being there’s going to make a difference to whether that pregnancy’s going to go on or not (P6, midwife).

Well just acknowledging that it is scary for them and not just to be brushed aside. So yes, but I mean really I wouldn’t know how—I don’t think that the level of support would change the outcome (P7, independent midwife).

I think bed rest or cutting down on exercise, that sort of thing, I think it’s a good thing to do from the point of view at least the woman feels like she’s doing everything she can. That’s what’s really hard for a lot of women to take, is that this is so much beyond their control. So at least they can control whether they choose to keep running around madly or exercise or whatever, if they can have the opportunity of just resting up, then I think that, at least on a psychological level does some benefit. But I’m certainly not advocating people who have had a threatened miscarriage take themselves to bed for the week, because I don’t believe it makes any difference. What will be, will be. (P9, medical doctor).

It was also suggested that, for some practitioners, advice was given because they felt pressured to offer women something to do, even if the practitioners did not perceive that the advice they were giving would make a difference:

They [other medical practitioners] just want to say something, not particularly because they believe it but they just want to—because people are looking at you with these eyes of just tell me what to do to make my baby stay…I think it’s a bit like that (P11, nurse).
Even when acknowledging evidence that showed that providing supportive care had improved outcomes for women with unexplained recurrent miscarriage, this was considered an anomaly. How could emotional support alter pregnancy outcomes when no active treatment had been administered?

…for people who have recurrent miscarriages, giving them serial scans throughout the first trimester is very, very useful for them and has been shown to improve outcomes. So what is it that’s doing that, because you’re not actually intervening? You’re just—you’re showing the woman that the little embryo is still there (P5, medical doctor).

The exception to the view that supportive care was unable to influence pregnancy outcomes was one midwife who expressed an opinion that it may be possible for women to improve pregnancy outcomes by reducing stress levels:

I think it could make a difference because they just slow down. I think that makes a difference and gives the body a chance to perhaps heal itself and readjust from the very stressful fast lives that we have these days…it just readjusts your body and puts it back on an even keel (P10, independent midwife).

In the context of supportive care providing emotional benefits, any form of therapy that assisted women was considered beneficial, including meditation, relaxation techniques, counselling and referral to alternative health practitioners such as acupuncturists:

If a woman wants to go to an acupuncturist, great. If she wants to go to an osteopath, great. If she wants to go and meditate on the beach because that’s mentally going to help her, fabulous (P1, midwife).

5.8.1 Acupuncture—limited to relaxation

Acupuncture was regarded as a possible treatment by all practitioners, and it was associated with other therapies that offered women relaxation. Practitioners were open to women receiving acupuncture, even if it was something they were unfamiliar with or would not personally promote:

…if we’re talking about acupuncture just on the basis of producing some general relaxation I think that’s not a bad idea, and although I’m not going to go out of my way to strongly promote it, I would be happy just to offer general moral support for it (P12, GP).
Practitioners viewed acupuncture as a supportive therapy and were prepared to recommend it as a relaxation treatment without expressing a need to understand the rationale behind the treatment. However, all practitioners expressed concern regarding the use of Chinese herbal medicine, except one who was familiar with its use. The concerns for the remaining practitioners focused on herbal medicine being potentially unsafe. Practitioners stated that they would require further information that they could understand from a pharmacology viewpoint before they would feel comfortable recommending it as a safe treatment:

The problem I have with some of the Chinese herbs or herbs in general is that I just don’t know what they are….and you just wonder about things like dose control and just generally what the effects might be (P9, medical doctor).

Although all practitioners were supportive of women undertaking self-help therapies under the rationale that they may assist women to cope with stress, there was no provision in any of the areas that these practitioners worked in to directly refer women to self-help therapy. While counselling was provided in the fertility unit, other therapies were seen as something that women would have to seek out for themselves:

We basically leave patients to self-source that sort of stuff, I suppose. It’s certainly not something we provide in-house (P9, medical doctor).

The supportive care offered by medical practitioners included providing medical information and open access for women to seek out this support as needed. Further support that was considered helpful in terms of helping women to relax was also considered beneficial, and acupuncture, although not Chinese herbal medicine, was seen as belonging to these beneficial therapies. However, specific recommendations or access to these therapies were not provided; this was viewed as something that women could access themselves. While supportive care was considered useful in providing women with psychological benefits, with the exception of one practitioner, offering supportive care was not seen as something that would physiologically have an effect as a treatment to improve pregnancy outcomes.

5.8.2 An access gap

A further limitation of supportive care was the availability of practitioners to provide this for women in early pregnancy. Practitioners were aware that there was a gap in care
for many women until they accessed their LMC, which may not happen until late in the first trimester or early in the second trimester. This occurred for all women, including those receiving fertility treatment. Women undertaking fertility treatment may receive support at the fertility unit until they have contact with their LMC, but this was at the discretion of the staff at the unit:

Well there isn’t [an official follow up policy] on a clinic level but we do just because we are human beings and we need to keep in contact. I often book people with a counselling phone call but then also ring them so that they have got a contact initially on those few days…Ten weeks seems to be a good mark to get people to and then they are picked up by their midwives (P3, nurse).

For women in the community, their first contact following bleeding in early pregnancy may be with their GP, a hospital emergency department (ED), the MAU or an independent midwife. For women who presented at the hospital ED or MAU, there is no pathway for further follow-up unless they present with further bleeding or miscarry. For the GP interviewed, support was offered through an open-door policy, where women were able to contact his practice to seek further information and advice:

…we always make sure that they understand very clearly that it’s an open access, pick up the telephone, call us here anytime—I’ll call you back or you can talk to my practice nurse if you’ve got concerns or anxieties, or things are changing, or you need some advice or feedback, or we need to see you again (P12, GP).

However, the follow-up for women presenting to their GP or independent midwife was dependent on the individual practitioner’s perspective on providing supportive care. For those with an independent midwife, there is presently no funding to claim for threatened miscarriage support. There may also be a time lag between when a woman first makes contact with a midwife and when that midwife officially becomes her LMC. This limited access to a midwife in early pregnancy was considered difficult because it left women in a ‘grey zone’:

…a woman might have made contact with a midwife. You know, been to see my GP today. He’s giving me scan forms. Great, I’ll see you in a couple of weeks. She’s not going to get funded for this…she hasn’t signed this woman on yet. She’s not legally responsible for her care yet. So there is a time-lag between when they first make contact with someone and when they actually see them. So they’re in a grey area. Because they have a midwife, but they haven’t met her yet (P1, midwife).
It was suggested that in an ideal world women would receive follow-up supportive care through a seven-day-a-week support centre through an MAU:

I think we need a one-stop shop, where women can come, eight in the morning to eight at night, Monday to Sunday, as a walk-in situation where we have rooms, we have doctors, we have facilities to be able to scan there and then, to be able to do bloods, to be able to link them in to who they need and offer them what they need. If they need follow-up in a week, we need to be able to organise that. We need to have the facility to do that. It might not change an outcome of a pregnancy at all. But if we can make that pathway and that journey easier for that woman and her family, then yeah. That’s an ideal world (P1, midwife).

5.9 Summary

This chapter reported the findings from 12 interviews with Western health practitioners about their perceptions of optimal care for women presenting with threatened miscarriage. The practitioners wanted to support women presenting with threatened miscarriage, and they considered that offering women realistic hope and diet and lifestyle advice was supportive. However, the overarching theme of ‘walking a fine line between hope, reality and professional responsibility’ illustrates that, while Western health practitioners perceived that they play a role in supporting these women, they also perceived that there are boundaries and lines that are unprofessional to cross. Information should be realistic, and providing hope should be based on medical information. Further, diet and lifestyle advice was only considered useful if it supported a woman’s preferences and was framed in a way that would avoid the woman blaming herself in the event of a miscarriage.

While practitioners discussed these as measures that they could take to be supportive, these were perceived as having beneficial effects for the women rather than as active treatments that they were recommending that would affect pregnancy outcomes. It was also acknowledged that it was not always possible for women to access this support due to the realities of early pregnancy care in New Zealand at present. In the context of providing support, acupuncture was perceived as a safe and relaxing CAM treatment that may help women reduce anxiety, but that it would be unlikely to reduce the risk of pregnancy loss.
This concludes the findings of the interviews with Western health practitioners. These findings are discussed further in Chapter 7. Chapter 6 will present the findings of the data collected from online threatened miscarriage forums.
Chapter 6: Findings from Threatened Miscarriage Internet Forums

6.1 Introduction

This chapter presents the findings from the analysis of the data collected from threatened miscarriage Internet forums during April to November 2011. The aim of this research was to explore women’s experiences of threatened miscarriage. The specific research question was: What are women’s experiences of threatened miscarriage? An Internet alert from the Google search engine was used to collect the data using thematic analysis, as outlined in Chapter 2. The overarching theme of this analysis was ‘a search for hope and understanding’, with the themes ‘a reason for hope: stories and real life experiences’, ‘becoming the expert’, ‘a safe place to share’ and ‘a connection to empathic support’ capturing women’s experiences of posting online. This chapter discusses these main themes before presenting each theme in more detail, along with their associated subthemes. An integrated discussion of the findings is presented in Chapter 7.

6.2 Overview of themes

‘A search for hope and understanding’ was a central unifying theme of the online postings. It involved both the initial posting, where specific requests were made to other forum members, and the replies received. Four major themes have been used to structure the data, with each theme generating several subthemes (see Table 6.1 and Figure 6.1). The theme ‘a reason for hope: stories and real life experiences’ illustrates the search for, and receipt of, hope through the stories and experiences of others, including where women with a very poor prognosis proceeded to have a viable pregnancy. Positive stories were exchanged among those posting as a rationale for encouraging hope, including hope after a pregnancy loss for another successful pregnancy.
The second theme, ‘becoming the expert’, captures how participants used their experiences to provide medical advice that at times challenged the medical information women had been given by their health-care practitioners. Women’s opinions were stated as medical knowledge at times, and women were encouraged to demand further diagnoses and medical treatment.

The third theme, ‘a safe place to share’, captures how women used Internet postings to share a range of complex feelings and experiences with each other. These included women expressing their feelings about pregnancies that they now perceived as being at risk of pregnancy loss, reactions from their family and friends, and dissatisfaction and anger at the medical care received during their current and past experiences.

The fourth theme, ‘a connection to empathic support’, focuses on the support offered and received through the long-distance Internet medium. This theme captures the use of positive thoughts and prayers, practical and emotional self-help advice, and the need for caution to seek further medical advice for potential medical problems.

**Table 6.1: Themes from Internet forums on threatened miscarriage**

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<th>A search for hope and understanding</th>
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<td><strong>Themes</strong></td>
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6.3 Presentation in the text

The quotations used in this chapter are identified according the initial(s) given by the person posting. This is followed by a number created for each of the discussion threads and then a page number. Thus, a comment made by ‘worried mumma’ that was collected as the third discussion thread where the comment appeared on the second page is represented as (WM/3/2). Although the initial postings were usually made by a woman, there were two postings made by men whose partners had received a threatened miscarriage diagnosis.

Although some grammatical and syntactical changes have been made to the quoted passages to assist the reader, these changes are minor. As these were Internet postings, some spelling and grammar errors remain, which reflects the reality of the medium used. An ellipsis (…) is inserted where words have been removed from a comment.
Square parentheses [ ] are used to maintain anonymity when specific locations or names were used and to explain the abbreviations used in the forums.

6.4 A search for hope and understanding

A consistent concept running through the forum postings was that women experiencing threatened miscarriage were seeking hope for a positive pregnancy outcome and the understanding of others who had experienced a similar situation. At times, this desire for hope was expressed overtly by those asking for positive stories and experiences:

I thought I would ask you ladies if any of you had this happen and still went on with a healthy pregnancy? Thanks in advance…I’m an emotional wreck (TK/1/1).

This search for hope was acknowledged in reply postings that urged women to remain hopeful and that advised that, until there was definite proof that they were miscarrying, no matter what the medical prognosis, they were still pregnant:

Please don’t listen to the doctors, follow your gut! If a miscarriage is meant to be it will happen on its own you do not need a D&C [Dilation and Curettage]. Get another opinion; get more if you need it (E/40/2).

The search for understanding by women experiencing a threatened miscarriage was also evident in the postings, with women expressing their desire to connect with others experiencing a similar situation and showing gratitude when receiving practical empathic support and advice from those who had been in a similar situation. This empathic approach was woven throughout the postings, with women discussing their personal stories and experiences, how they had coped with being in a similar situation and non-judgmental postings expressing concern and offering advice:

I’ve had it twice and both of my girls are healthy little women (3 and almost 8). I also continued to bleed and/or spot throughout my entire pregnancies with both girls. It’s a terrible place to be in, because you’re even more worried all the time. But, hang in there. If you pray, then give it to God and just take it easy (P/3/2).

I’m so sorry. This happened to me and I was devastated but if I hadn’t of lost that bean I wouldn’t now be pregnant with this baby boy, who I love so much already. For me it was just meant to be (BF179/12/1).
The central theme of these forum postings illustrates women’s search for hope and understanding following a diagnosis of threatened miscarriage, and how this was received through the reply postings. This overarching theme ran throughout the postings and is organised into the following themes and subthemes.

6.5 A reason for hope: stories and lived experiences

A forum posting typically commenced with the personal details of a bleeding episode in a pregnancy that resulted in a Western medical practitioner giving the woman a diagnosis of threatened miscarriage. The majority of these posts asked if others in similar circumstances had gone on to have a successful pregnancy: ‘please anyone give me your stories if u had one like mine and your baby was healthy’ (E/73/1). While it was not always possible to obtain a detailed picture of the precise circumstances of all postings, it was evident that for some, the search for hope was in the face of medical caution to prepare for a potential miscarriage:

The midwife basically told me that the baby is unlikely to survive as there is too much blood and to expect a miscarriage, so I’m here at home waiting, I’m still bleeding but haven’t passed anything, has this happened to anyone and they have gone on to have a successful pregnancy? (M/25/1).

Although these postings encouraged others to respond with positive replies, some requests also deliberately asked for positive replies that were realistic:

I would appreciate honest responses or feedback as to what it sounds like to you, no sugar coating (R/35/1).

They said the numbers increased—which is good—but because they did not increase a lot they are concerned. I don’t want to have false hope—but I am also not prepared to give up (H/39/1).

Has anyone gone through a threatened miscarriage with heavy bleeding and clotting and still had a healthy baby? Or am I just grasping at straws? (J/71/1).

While a direct appeal was made for positive stories, real-life experiences were also sought, as these were seen as having a credibility that was different from the factual information available through searching Internet sites or from their health-care practitioners:

I am trying to get other people’s experience on these issues because I just want to know more information and I already Googled all I can. I am not asking for
medical advice because I am already talking with my OB/GYN I just want your experiences (T/2/1).

A reason for hope was typically given in the postings from women sharing their experiences of receiving a diagnosis of threatened miscarriage and how they continued with a healthy pregnancy:

I bled 3 separate times with my son. Each lasting a couple of weeks with flow much like a period. It was absolute terrifying each time because I have a hx [history] of miscarriages. There was no known cause for my bleeding but everything turned out fine and I have a healthy 2 year old. (B09/11/3)

Further reasons for hope are captured in the following subthemes: ‘the medics are not always right’ and ‘hope following pregnancy loss’.

6.5.1 The medics are not always right

This subtheme illustrates how a reason for hope was also gained through the stories and experiences of women who went on to have viable pregnancies after being told that they had lost their pregnancies. These postings urged other women to remain hopeful, even in the face of a medical diagnosis of pregnancy loss. These stories were discussed as triumphs in the face of health-care practitioners’ advice that there was no hope, and clearly challenged the medical expertise of these practitioners:

I had bleeding at 5, 8 and 10 weeks of varying levels. Each time I was told a miscarriage was inevitable and on one case was told to go to the hospital to get some medication to finish the miscarriage off. Well good thing I didn’t as my ‘miscarriage’ is now 2! (HM/92/3).

I had bleeding at 10 weeks with my daughter and when I say bleeding I mean my bed looked like a crime scene. The ER told me my baby was a loss…I went to the doctor and she was still there and she will be 3 in November (P/72/2).

These stories of hope were not limited to subjective accounts of bleeding; they also gave details of specific medical tests such as hCG levels and ultrasound results that diagnosed a non-viable pregnancy. The medical terminology used in these postings by women and their partners assumed an expertise in both interpreting and understanding this information and the right of women to dispute whether the diagnosis of pregnancy loss they had been given was correct:
…went to the ER a week later for bleeding & cramping. Told my HGC levels were only at 460 and needed to be in the 10,000’s. They said my ultrasound showed NOTHING in my uterus. So I had ‘miscarried’. 6 weeks go by, no period. So I thought something was wrong and made a gyno apt [gynaecological appointment] to make sure my insides were ok. Well he told me I was pregnant. Had an ultrasound 2 days later and I was 11 wks pregnant. I never miscarried. Now I’m almost 30 wks pregnant. So in a nutshell get a second opinion. Doctors don’t always know everything (NB/111/2).

One woman was told on two separate occasions by a doctor (based on ultrasound results) that she needed to have a Dilation and Curettage (D&C) and that by waiting she was ‘only prolonging the inevitable’. Subsequently, she had a viable pregnancy confirmed:

I went to see another doctor. That doctor did another u/s [ultrasound] and to our surprise, we saw a baby with a very strong heart beat!!! I just started crying then she started crying and we were both crying for 15 min. She gave me 7 u/s pictures. I went straight to my husband’s work and without saying a word I just gave him the pictures. He just dropped to the floor and started crying. Please don’t listen to the doctors (E/40/2).

6.5.2 Hope following pregnancy loss

In addition to stories of pregnancies continuing following a diagnosis of threatened miscarriage and the experiences of ‘miracle’ pregnancies that continued despite women being told they were miscarrying, hope was also offered regarding the potential for future successful pregnancies. These stories were told with an understanding of what it meant to experience miscarriage, while offering hope for future healthy pregnancies. However, these stories were less common than the ‘miracles’ told or the ‘against-all-odds experiences’ put forward:

I’m sorry you have to go through this. FWIW [for what it’s worth], my miscarriage was with my first pregnancy. Second pregnancy is now a beautiful 22-month old and third pregnancy is looking OK so far (A/51/3).

6.6 Becoming the expert

The second theme of ‘becoming the expert’ captures how women sought and gave each other what can be considered medical diagnostic information online. Medical terminology was used with an assumption that others would not only be able to understand these terms and their meanings, but also be able to respond to offer their
own opinion on the diagnosis they had been given. A clear challenge to medical authority was evident, with both the postings and responses using medical language, and with some women actively requesting specific advice relating to medication, further medical treatment or diagnostic tests they should seeking:

3/5: last period
3/20: ovulation
4/19: 1st vaginal ultrasound, 6 weeks sac, yolk sac, no foetal pole
4/25: 2nd vaginal ultrasound, 7 weeks + 2 sac, large yolk sac, still no foetal pole. I am on prometrium now, do I still have hope or just stop the Prometrium?
4/19: HCG at 29,000, Progesterone at 16
Anyone? Please help! (LB/4/1).

In other cases, women gave their opinions as unprompted advice. By asking for, or accepting, this advice, it was evident that women were seeking and attempting to give hope through these diagnostic postings as an alternative to medical authority. There was an acceptance of a credible expertise through having shared the experience of threatened miscarriage. These responses are captured as concepts under the following headings: ‘I would say—opinions as medical facts’, ‘self-diagnosis’ and ‘your right to demand best possible care’.

6.6.1 ‘I would say’—opinions and advice as medical facts

At times, women expressed their opinions and advice as medical facts and took on the role of an expert. There were some clear inaccuracies in some of this information, which was stated with authority and remained unchallenged by others. These lay medical opinions offered reassurance about diagnostic procedures, explained medical terms and the likely cause of bleeding, and made a prognosis from the information posted:

…yeah very normal usually you don’t hear it (a heartbeat) until 9 weeks I believe so nothing to worry about there (AM/18/5).

…all you can do drink a TON of water and rest as much as physically possible. 50% of miscarriages are due to dehydration (MB/79/1).

Some women have a subchorionic bleed. It’s nothing major usually just a tear in the lining causing bleeding (M13/22/2).

Mostly if the blood is brown then it is old blood and not usually cause for worry. Red blood is a different story (BR/37/2).
Spotting is also very normal at almost any point in pregnancy. As long as it does not turn into a ‘period’ type bleed then you are OK (PG2/65/2).

Women in these postings were assuming medical knowledge and giving what can only be considered advice from their own experiences or understanding in order to offer hope to other women. At times, this advice was given with an authority that actively dismissed the medical information that the woman had received. Again, this assumption of expertise is very evident, and their authority stems from having experienced miscarriage and having had previous cause to doubt the medical profession:

Really?? he said it could be a complete miscarriage?? That’s ridiculous because a small amount of bleeding as you’ve described with I’m assuming not much pain if any? That’s all normal!! You know what honey the more I read/think about it, the more I believe you’re fine!! Honestly if you were in a lot more pain with a lot more blood then yeah I’d say be worried but seriously these doc’s should know what normal pregnancy symptoms are (LA/86/2).

You most likely have some sort of infection an you will be just fine. Honestly anytime you go to the ER with any ‘problem’ during pregnancy they label it threatened miscarriage- honestly. I had the same exact thing ended up being an infection and was treated with antibiotics—all is fine and my threatened mc [miscarriage] is now my almost 22 week old baby girl (well in the womb) (FS/52/1).

Women also suggested changes to lifestyle that might assist in preventing miscarriage, stating that there were diet and lifestyle activities that would make a difference. This was presented as experience-based knowledge to counter the medical advice that there was nothing that women could actively do except wait and see:

actually there are many ways to prevent a miscarriage…first you need to eat a lot of healthy foods cut back on the chips and drink a lot of fluids and drink light soda do not take a extremely hot shower yes they are lovely but that is a no no…and a miscarriage may happen but if you eat right get enough sleep and take prenatal vitamins for 6 months you will be fine (K/95/2).

6.6.2 Self-diagnosis

Examples of how women had undertaken proactive research and diagnosed themselves with something other than a threatened miscarriage were also used to provide women with hope. These postings implied that if women’s bleeding was related to another cause—such as cervical polyps, a vanishing twin pregnancy or thrush—the pregnancy outcomes were more positive. Once again, this was presented from the perspective of
personal experiences and was a powerful contradiction to the information women had been given by their medical practitioners:

I was labelled with a threatened miscarriage two times but I didn’t believe it. I was just bleeding with no cramping at all. I did some research and found some information on Cervical Polyps and for sure that’s what I had (HH/11/2).

Some would say this was a threatened miscarriage, but after doing research…I realized this was most likely the loss of my daughter’s twin. Three weeks of not knowing whether my baby was alive or dead, and it turns out she lost (what I believe) was her little brother…I have very little doubt that my threatened miscarriage was really a miscarriage of my vanishing twin (M/109/1).

Today I went and got thrush/yeast cream. Goggled miscarriage, spotting, twins and yeast infection. Found hb [heartbeat] on Doppler and spoke to midwife. Half diagnosed myself (D/60/1).

6.6.3 Your right to demand best possible care

It was seen that there were possible treatments for threatened miscarriage—such as progesterone supplementation—and that it was possible to prevent miscarriage through accessing this care. There was a sense in the postings that if women had not been offered this treatment, it was due to a deficiency in the medical care they had received and they needed encouragement to fight to access the potential treatments or to change caregivers. There was a clear sense that it was not acceptable to ‘do nothing’:

What was your doctor’s response after u mentioned progesterone? It’s so frustrating with times like this when they say, ‘it’s no one’s fault’ or ‘there’s nothing that can prevent it!’ There is something that can be done and you should demand it. Don’t worry about pissing anyone off at the doc’s office. I would be on the phone with them as soon as they open (BC/63/1).

Have they tested your progesterone? I had 4 miscarriages and switched Drs. I am on progesterone now and have made it to 8 weeks problem free. I have known 2 other women who started to bleed and it was their progesterone preventing implantation. They were given some progesterone and both of their babies went full term and are now healthy (JH/76/2).

As discussed above, receiving an alternative diagnosis to threatened miscarriage was seen as positive, including that of a subchorionic haemorrhage. It was seen that women needed to be proactive and ask for this extra testing themselves:

Did they check you for a sub-chronic haemorrhage? I had extreme bleeding and clots and went to ER twice and they called it a threatened miscarriage. It was all caused by the SCH [subchorionic haemorrhage]. When you go back …definitely have them check for it (H/44/1)
6.7 A safe place to share

The third theme found was ‘a safe place to share’, which illustrates how the Internet forum was viewed as a safe place to share their thoughts and feelings with others who would be accepting. Three subthemes are discussed under this theme: ‘complex experiences and feelings’, ‘dissatisfaction with medical care’ and ‘if you stay within the rules’.

6.7.1 Complex experiences and feelings

Using a forum when experiencing bleeding in early pregnancy was not always about women seeking reassurance for positive pregnancy outcomes. For some women, the forum was used to seek support and understanding for the feelings they were experiencing following a diagnosis of threatened miscarriage, including how difficult it was to feel excited about being pregnant:

I don’t know how to feel anymore. I’m afraid to be happy to find out in a few weeks that my LO [Little One] has passed (SC/48/1).

Women also expressed concerns that the stress and anxiety they were feeling would negatively affect their pregnancy. They also discussed problems with being on bed rest when they had other children to care for and that they might somehow be responsible for the bleeding. Guilt was also a factor:

I took the morning after pill a few weeks ago after a condom mishap not knowing I was PG [pregnant] and I feel so guilty knowing that I may have done this to my poor baby (C/58/1).

As well as sharing their concerns, the forum was a place to discuss their partners’ reactions. The anonymous nature of the Internet and the ability to use pseudonyms made this highly public medium also feel private and safe for women. Abbreviations were also used to describe their partners, as though this added to the anonymity:

DH [Dear Husband] seems to be fine with everything, acting like I shouldn’t be worried. I’m super worried. How can he be so calm (J/69/2).
Women described feeling very alone in their experience, with some unable to share their thoughts with their partners. Sometimes this was in order to protect their partners, while at other times, it was due to inadequate support received from their partners:

…don’t want to tell him I’m pregnant but I might be miscarrying because he would just be shocked and relieved whereas I am now devastated at the thought of losing this baby I just don’t know I think I just needed to write this down just to prove that this baby does exist even if it’s only me that knows about it. I feel completely alone (S/92/1).

OH [other half] doesn’t seem to care about anything apart from work. Doesn’t seem to care about what’s happening. Been home 10 minutes and he’s not asked any questions (L/104/1).

Forums were also seen as a place to discuss concerns when they had told no one else about their pregnancy:

I could really use some support as most of my friends don’t even know about this pregnancy. I’m 7w4d [seven weeks and four days] with my first child (AK/38/1).

### 6.7.2 Dissatisfaction with medical care

For many women, the forum was a place to express their dissatisfaction with medical care, including the care being offered to the women making a posting or their own experiences in the past. Women discussed what they perceived as substandard care that had affected their pregnancy, as well as a lack of adequate medical monitoring:

…the midwife nicked my womb and now I’m bleeding a lot as a result. I’m now worried about baby as they only checked heartbeat on Doppler but I have a Doppler and so knew the hb [heart beat] was there. I wanted a scan for reassurance (T/74/1).

…my dr knows my history with my son, the miscarriages after him and that my first child was still born, but he hasn’t ordered any test to check my progesterone levels even though I keep bringing it up to him. Twice Monday I mentioned it and have all the symptoms…very sore breast, bleeding, cramping, lower back ache and low hcg levels!! To be honest I’m very pissed also bc [because] I could lose my child n feel like he’s not doing all that he should!! (AH/63/1).

The language and manner used by some health professionals was also perceived as insensitive, ‘dr. said I will probably pass my baby in the toilet (how sympathetic?)’ (MH2/21/1), and lacking respect for a woman’s ability to understand what was happening:
...the rudeness of professionals these days are bit much. No bedside manner or respect. Like they don’t want to be bothered with questions or because you aren’t a doc you don’t know anything (M/35/2).

This insensitivity included unnecessary painful examinations:

...I’ve had one women that DUG around in there till I was like OK you have to stop your hurting me and I KNOW from past U/S [Ultrasound] this should not hurt this bad...I sat back moved away from the probe and looked at her and said perhaps you did not hear me you are HURTING me and I’m DONE with you get me someone else or I’ll go somewhere else this is MY baby MY body...They got me someone new that was MUCH better saw things easier and she said the other girl was a student and they had other complaints on her being rough with others. I mean REALLY you are dealing with a human life in there!!!! (LR/6/3).

6.7.3 If you stay within the rules

The perception that the forum was a safe place to share a range of feelings without receiving criticism remained true as long as women obeyed the forum protocols. In two instances, women were criticised for their postings. One occurred when a woman posted a photo of the bleeding in her underwear. This was seen by some women as unnecessary and led to some unsupportive postings:

People don’t want to see your bloody panties, simple as that. There was no paragraph leading up to the picture, no warning, no nothing. It’s gross...What feedback & advice do you smurfing want? Oh no your undies don’t look like they have blood on them and you’re not miscarrying?? (BF/18/6).

This was countered with a reminder from another woman that this criticism was unnecessary and that the forum existed to provide positive and supportive comments:

...others need to mind their own business if they don’t like what they see...it’s just as easy to close the post as it was to open it...especially if they don’t have anything positive or supportive to say (LM/18/8).

The other comment that received criticism concerned a woman with threatened miscarriage who posted on a pregnancy loss forum. She was firmly reminded that this was not the appropriate place to post because she was still pregnant:

This is not an appropriate place for questions like this. This is for grieving mothers who have experienced a miscarriage, still birth, or infant loss...Please read the rules before you post in the future. If you do miscarry, you are very much welcome to return, but until then you are violating the board rules...we
are in a tremendous amount of pain from suffering a real loss…you have to understand that (A/29/1).

6.8 A connection to empathic support

The final theme captures how these Internet forums provide an opportunity for women with threatened miscarriage to receive long-distance support and empathic advice from those who understand their experiences. The focus of these postings was to provide an empathic response to others in the forum. The theme, ‘a connection to empathic support’, is discussed in the following subthemes: ‘thought support: positive thoughts and prayers’, ‘doing all you can’ and ‘cautionary tales’.

6.8.1 Thought support: positive thoughts and prayers

For many of those posting, it was important that others sent them positive thoughts and prayers. There were specific requests for this type of support:

I’m hoping that any people who view this can send some positive thoughts/prayers our way I’m a firm believer in ‘mind over matter’ (JO4/5/1).

If you pray could you pleeeeeease say a quick prayer for me and LO [little one] or if you don’t send good vibes or positive thoughts my way. I’m not one to ask for things but I really really want this baby more than anything and any t&p [thoughts and prayers] from whoever can spare them would make me feel a little better (CT/81/1).

This long-distance ‘thought support’ was seen as something that would be helpful, and there were numerous messages referring to positive thoughts and prayers being sent to those making the initial posting. While some were directly religious and referred specifically to God and prayers, the majority referred to general good wishes using concepts such as ‘sticky babies’ and ‘sticky dust’. These references to the medical terminology for implantation and viability dominated the forums, as women reframed medical terms into language they could relate to:

I’m sending you good thoughts that this baby sticks and that what you are facing is just a small speed bump in this pregnancy. We are here for you (K/70/2).
6.8.2 Doing what you can

The support given in these forum postings contained practical advice for physical and emotional actions that women could take, with an emphasis on providing personal experiences that encompassed how difficult it was at times to follow the usual advice given about resting and trying not to worry. There was an emphasis on taking all action possible, but this advice was delivered with an understanding of how difficult this could be. Specific efforts were made to moderate any advice to suit women who had circumstances that made it difficult to follow optimal advice, such as those caring for other children:

I understand about not being able to fully take it easy. My OB [obstetrician] told me it take it easy and I laughed. I have a 3 year old and a 20 month old. I tried not to pick them up when I didn’t need to, when I would clean I would take several breaks and during nap time I would relax and watch a movie or read a book (A1330/13/2).

The advice that women gave each other included resting as much as possible, refraining from having sex, drinking plenty of water and purchasing a Doppler so they could listen to the heartbeat for extra reassurance:

I also bought a home Doppler so I can listen to baby’s HB [heart beat] and get some reassurance between OB apt (MG/8/1).

Emotional advice included honouring the pregnancy and accepting that they may not be able to control the eventual outcome:

Today, in this moment, I’m pregnant and love my baby. If something were to happen I would mourn it and remember it always (PM/10/1).

I talk to my baby constantly, rubbing my belly and telling my ‘bump’ that no matter what they hear in there about what’s going on outside their ‘home’ that Mommy loves you and you will always have a special place in my heart (LH/10/1).

The best advice I have is you have to at some point let it go. WE don’t have control is what it comes down to. We can do our best and take care of our bodies but beyond that there is nothing to do. I prayed and focused on those things I could control. It was so much better! (HJ/33/1).
6.8.3 Cautionary tales

While the majority of postings involved positive stories, some postings warned women that pregnancy loss was a possibility. Postings that mentioned pregnancy loss in a factual way—without a personal or empathic connection—were scarce. They either mentioned pregnancy loss as statistics, without any personal input: ‘There are 4.4 million confirmed pregnancies in the US every year. 900,000 to 1 million of these end in pregnancy losses EVERY year’ (J/27/1), or they gave an opinion that the pregnancy loss was because the baby was not healthy:

I’ve always felt that if a foetus isn’t strong enough to withstand basic daily activity (walking, doing laundry, cleaning) then it probably isn’t going to be strong enough when it’s born, miscarriage is our body’s way of letting us know that our baby isn’t healthy enough to survive…it is the way life works (MP/15/1).

These postings prompted no responses from other forum members; perhaps they were deemed irrelevant. The majority of postings that mentioned pregnancy loss were posted with empathy, discussing the possible reality with a background of personal experience and deep empathy. These postings inevitably held a glimmer of hope as well as empathy:

I know how terrifying that can be. Sadly this early it’s really tough to say. I had a threatened miscarriage…the doctor said there was a 50/50 chance it would sort itself out, unfortunately I lost my little one. This time around I had the same spotting and was terrified the same thing was happening…scan showed a very strong heartbeat and no reason for the bleed. The fact that your cervix is still closed and there has been no tissue lost is a good sign but only time will tell how things will turn out (LB/1/1).

I have had it go both ways. During my current pregnancy I have been bleeding and clotting through the whole thing. I am 30 weeks now so I think everything will be fine. My first pregnancy I had the same symptoms in the 4th month and wound up miscarrying (M/13/3).

While the majority of the interactions questioned medical authority and knowledge, some women expressed their concern that women should seek further medical attention. This advice was again based on past experience and given with great empathy:

My sister spotted through her whole pregnancy…she ended up in labour at 23 weeks…he lived one month So if this is something that keeps happening get to a specialist (B4/13/2).
I would go and get the bloods done, I had the same thing happen at 7.5 weeks I was so happy when I saw scan and heartbeat…I was unlucky and mc [miscarriage] at 11 weeks…promise ull [you will] rest heaps and go and get bloods done (MB/38/2).

Even when the outcome described in the post was adverse, it was done in a way that balanced hope with reality and caution:

I feel I need to tell my story here as I really think you should go to the Hospital hun. I didn’t know I was pregnant until I started getting a niggle in my right side (it wasn’t a pain, just a niggle but every now and then it did shoot up my back). A hot water bottle did relieve it so I wasn’t too worried but I went to the Dr…I was sent straight to hospital where they did a scan and they couldn’t see anything. I need to point out I had no bleeding just a bit of discharge and not all the time…2 days later I woke with a severe pain in my right side—I was rushed into surgery an hour later where they removed my right tube. The recovery wasn’t nice emotionally or physically. I’m not telling you this to scare you, I’m telling you this so that you don’t go through what I did…if I had I would have asked for the tablet and I may still have both my tubes. As you can see from my ticker despite what has happened I have gone on to have a healthy pregnancy, however, I still kick myself every day…I’m only telling you this as a precaution and I really do wish you the best and that you are just too early on to see bubba (T/104/3).

6.9 Summary

This chapter examined 121 online forum postings made by members of the public on the topic of threatened miscarriage during April to November 2011. The overarching theme that emerged was one of ‘a search for hope and understanding’. Within this, four themes illustrated this search: ‘a reason for hope: stories and real life experiences’ ‘becoming the expert’, ‘a safe place to share’ and ‘connecting to empathic support’.

These findings highlight the proactive search undertaken by those faced with bleeding in early pregnancy within an online community allowing a connection to others in an attempt to gain hope and support. This provided an opportunity for women to gain a different perspective from the one they received from their health provider or by searching online information sites—a perspective that allowed and actively encouraged hope. It was also apparent that in responding to these postings, women gave empathic support to women and their partners, as well as information and advice that they felt that was important. There was acceptance by both those asking for advice and those
giving advice, of an expertise came from experiencing threatened miscarriage and that this expertise could be used to challenge medical expertise.

This concludes the findings for this chapter. Chapter 7 presents a discussion that integrates the research findings in this thesis.
Chapter 7: Integration of Findings

7.1 Introduction

This chapter integrates the research findings of this thesis. The initial analysis of the multiple data sets generated in this MMR study was undertaken using the appropriate quantitative or qualitative techniques and then reported on in the individual chapters pertaining to each study (Chapters 3–6). This chapter integrates the key findings of these chapters. This has been undertaken as outlined in Chapter 2 by using the ‘following a thread’ technique to discuss the data. This technique involves identifying a key theme and/or analytical question from one data set to follow through to the remaining data sets. For this chapter, both a key theme and a question have been identified. The ‘the value of hope’ theme is first examined in online threatened miscarriage forum data, where it emerged most strongly, before being used to integrate the findings across the remaining relevant data sets. Similarly, the research question ‘how was acupuncture perceived as a treatment for threatened miscarriage?’ is first examined in the data from the survey of acupuncture practitioners before being used to integrate the findings across the remaining relevant data sets.

7.2 ‘The value of hope’—a discussion thread

The concept of hope featured across all data sets; ‘a search for hope and understanding’ was a central unifying theme for women discussing threatened miscarriage on the Internet forum threads, with various aspects of receiving and providing hope present as a finding in the other data sets for this study. Hope has been described as a human response associated with a beneficial therapeutic value for those coping with stressful life experiences (Folkman 2010; Kylmä & Vehviläinen-Julkunen 1997; Stephenson 1991; Valle et al. 2006). While there is difficulty in achieving one definition that encapsulates all aspects of hope relating to health (Cutcliffe & Herth 2002a), consequences of hope that have been identified involve the ability to cope with stressful stimuli (Benzein & Saveman 1998), providing a time of protection or buffering when adapting to a stressful event (Valle et al. 2006) and feelings of empowerment that can
assist self-care (Benzein & Saveman 1998). These beneficial consequences of hope have been identified for individuals coping with a variety of health-related situations, including women during pregnancy and postpartum (Evans et al. 2012; McKechnie & Pridham 2012; Hess et al. 2010), parents of neonates and children with medical problems (Amendolia 2010; Charchuk & Simpson 2005; Jones & Lewis 2001; Reder & Serwint 2009; Roscigno et al. 2012) and chronic health conditions for adults with cancer and heart disease (Dickerson et al. 2006; Klemm & Wheeler 2005; Rideout & Montemuro 1986). The value of hope as a finding in this study is first discussed using the data from the Internet threatened miscarriage forums, where it emerged most strongly.

The search for hope in terms of a continuing healthy pregnancy ran throughout the threads posted on threatened miscarriage forums. At times, this was expressed overtly by women and their partners by asking others for positive stories and experiences, as well as those stating that they were trying to stay positive and the reply postings urging women to remain positive. At other times, it was implied that until there was definite proof of a miscarriage, the women were still pregnant. Hope through positive stories of successful pregnancies following threatened miscarriage was also expressed on these discussion threads. The use of Internet discussion threads as an online space to seek and maintain hope through personal stories and experiences is also a finding for women with postnatal depression (Evans et al. 2012), complicated pregnancies (Hess et al. 2010), caregivers of those with a cancer diagnosis (Klemm & Wheeler 2005) and parents of children with Down syndrome (Jones & Lewis 2001).

Due to the nature of online discussion, it was not possible to adequately assess the effects of seeking hope through this medium, although women provided feedback in the threatened miscarriage forums about how valuable these stories and experiences were to them, even when posting about a subsequent pregnancy loss. It has been suggested that hope may serve as a protective coping strategy for parents facing preterm delivery and of neonatal infants (Amendolia 2010; McKechnie & Pridham 2012). It is possible that hope also acted as a coping mechanism that provided women and their partners with beneficial time as they sought to understand the diagnosis of threatened miscarriage and to place this in the context of what this may mean for their pregnancy.
However, in the findings from the threatened miscarriage Internet discussion, it was noticeable that for some women, this hope involved not only the positive stories of others, but also challenging medical authority. This challenge was evident in postings that suggested that the diagnosis and information women had been given by their health professionals was incorrect or that there was beneficial treatment that they had not yet been offered. These postings challenged the hormonal blood tests and ultrasounds indicating a failing or non-viable pregnancy through stories and experiences of ‘miracle’ pregnancies. They urged women not to give up, to seek out further tests and second medical opinions. Symptoms were also discussed using medical terminology and diagnosis and advice given according to the ‘expert lay opinion’ in the discussion threads. This search for hope through challenging the information and advice received from health professionals illustrates how the Internet is utilised by women and how it may have the potential to influence the way they view and interact with their health-care practitioners.

7.3 Hope through viability misdiagnosis

The ‘against all odds’ and ‘miracle’ stories offered by women to give others hope that a pregnancy may still be viable despite medical advice of a non-viable pregnancy or impending miscarriage were usually presented in forum threads as mistakes and errors by the Western health practitioners involved. These stories suggested that advice to proceed with medical or surgical management could not always be trusted, and women were urged to remain hopeful and to seek another opinion. This advice reflects the reporting that can be found in public media, where newspaper articles and websites report cases of miscarriage misdiagnosis and urge women to have a second scan to ensure any pregnancy is non-viable before taking any further medical treatment (Cari 2013; Corderoy 2012). While women in the threatened miscarriage discussion threads perceived a misdiagnosis of early pregnancy viability as demonstrating the incompetence of health practitioners, the reality for health practitioners is that it is not always possible to provide an accurate diagnosis through a single blood test or ultrasound reading in early pregnancy.
Although early pregnancy literature focuses on the need for more accurate diagnostic information to reduce stressful waiting for women with a probable miscarriage (Adam et al. 2011; Bottomley et al. 2013), women in the threatened miscarriage discussion threads appeared to welcome any diagnostic uncertainty as potential for hope. The stories reported in the threads reflected the difficulties of establishing an accurate diagnosis for early pregnancy viability. Although it is possible to establish viability before cardiac activity develops by measuring mean gestation sac diameter (MSD) and embryo CRL, these may be measured differently by sonographers, thus reducing their diagnostic reliability (Pexsters et al. 2011). It has also been reported that pregnancies presenting with ultrasound measurements that were previously thought to indicate impending miscarriage—including minimal or no growth over several days—do not always predict a failing pregnancy (Abdallah et al. 2011). These findings have resulted in revised guidelines for determining foetal demise, with a recommendation for repeat scans and the use of more conservative ultrasound measurement cut-off values (Royal College of Obstetricians and Gynaecologists 2011b). However, even with revised guidelines, it may be that a single diagnostic test will inevitably produce inaccurate findings. Therefore, it has been suggested that the approach for establishing a non-viable diagnosis in early pregnancy involves cautious waiting—one that does not rely on a single consultation (Jurkovic 2012).

Acknowledging the possibility of hope by discussing diagnostic uncertainty may be beneficial to both women and practitioners in providing a time period that permits hope until diagnostic certainty is established for women, while minimising the potential for medical misdiagnosis for practitioners.

7.4 Hope through challenging medical authority

A further finding of the postings from the miscarriage threads was that women sought hope by finding an alternative diagnosis to that of threatened miscarriage. Postings suggested that women had a more hopeful prognosis if their symptoms were not those of a threatened miscarriage. This was expressed as advice that minimal light-red bleeding and light abdominal cramping were normal in early pregnancy, or that symptoms may be the result of another pregnancy problem, with a diagnosis of a
subchorionic hematoma, a vanishing twin pregnancy or vaginal infection expressed as preferable to that of a diagnosis of threatened miscarriage. This diagnosis of symptoms came from women challenging the medical information that others had been given. This usually resulted either from their own experience, where they had self-diagnosed their threatened miscarriage as something else, or from expressing their doubts that the symptoms presented in the thread postings did not match their definition of threatened miscarriage.

The advice and suggestions posted on the threatened miscarriage forums urged women to be cautious of the information and advice they received from their health professionals. This does not mirror research findings, which have observed that Internet forum advice is beneficial through encouraging contact with health practitioners (Evans et al. 2012; Dickerson et al. 2006; van Uden-Kraan et al. 2009). While some postings urged women to seek further medical advice in case they required further assessment and intervention, the majority of the lay expert opinions challenged medical information by urging women to seek another opinion regarding their diagnosis of a non-viable pregnancy, their diagnosis of threatened miscarriage or the medical advice that ‘there was nothing they could do’.

This ‘expert lay opinion’ remained unchallenged despite being clearly inaccurate at times. The potential for online information to lead to misunderstandings and miscommunications has been raised by Western health practitioners, who are concerned that this could affect the therapeutic relationship between practitioners and their patients (Blumenthal 2002; Taub 2006). It is unknown how the information and advice presented on the threatened miscarriage forums was perceived and used. While no actions were recommended that would be physically harmful to a pregnancy, it is possible that emotional repercussions could result from these discussions, which would require further discussion with health-care practitioners to prevent misunderstandings. For example, if women perceived that their health provider was providing inadequate care or if they grieved for the loss of a vanishing twin when this was not the case.
7.5 Realistic hope

The findings from the interviews with Western health care practitioners illustrated their awareness that women sought hope from them for a healthy, viable pregnancy, and that they wanted to provide hope but were concerned about offering false hope. This ‘walking a fine line’ between wanting to provide hope and their ethical responsibility to avoid providing false hope was expressed by all practitioners.

This ethical concern can also be seen in the medical literature for threatened miscarriage, which recommends that despite the diagnostic uncertainties that presently exist, evidence-based practice includes ensuring that ‘physicians must avoid giving false assurance regarding a pregnancy that is in fact likely to fail’ (Bottomley et al. 2013, p. 69). In nursing and midwifery literature, hope is discussed as providing holistic care—as an important coping strategy with beneficial effects to reduce stressful experiences for patients and their families (Amendolia 2010; Kylmä & Vehviläinen-Julkunen 1997; Stephenson 1991), with discussions on hope for speciality areas of practice (Cutcliffe & Herth 2002b, 2002c; Herth & Cutcliffe 2002a, 2002b). However, the specifics of how hope is provided, enhanced or maintained by practitioners is an area in which many questions remain unanswered (Herth & Cutcliffe 2002c).

In the interviews with the Western-trained health practitioners, the ability to use medical diagnostic tests was used to provide ‘realistic’ hope, which was seen as ethically responsible in contrast to providing false hope. This was attempted by using available medical information, including hormone levels and ultrasound results, with the ultrasound considered the ultimate reassurance they could provide for women. However, it was also acknowledged that there was a level of uncertainty with the current ability of these diagnostic tests to provide an accurate prognosis. Although practitioners recalled personal experiences where they had been involved with pregnancies that had continued despite a poor prognosis, they expressed that it was important to remain honest and avoid any encouragement of false hope through these ‘exceptions’ so that women were prepared for potential pregnancy loss. There was a majority view that the outcome of the pregnancy was in nature’s hands—that there was nothing women could do to increase their chances of a positive outcome other than
adopt a ‘wait and see’ approach. While women could take proactive measures to assist with relaxation, this would have no effect on the eventual pregnancy outcome.

All practitioners shared the perception of hope as something that women sought but that required cautious expression from health practitioners unless they had a medical rationale. The practitioners’ focus on the ethical concerns of false hope is in accordance with findings reporting that Western health practitioners view minimising false hope as a way of helping their patients to prepare for the potential problems that may lie ahead and as a way of ensuring that people fully understood the nature of the medical problems they may face (Reder 2009; Roscigno et al. 2012).

The literature has identified divergent views between practitioners and their patients concerning the value of hope. In qualitative interviews with parents awaiting premature delivery, there was an emphasis on the importance of having and maintaining hope, while interviews with health practitioners emphasised maintaining objectivity and avoiding ‘false hope’ to ensure that parents remained realistic (Grobman et al. 2010; Roscigno et al. 2012). However, Roscigno et al. (2012) suggested that it is possible to have both a realistic understanding of a poor prognosis and to maintain hope as a beneficial coping mechanism. Their findings reported that patients value practitioners who balance the delivery of medical information with hope, and that this provided parents with increased feelings of trust in their practitioner, enhanced the communication between parents and practitioners, and resulted in a greater willingness from parents to accept or follow medical advice. This inclusion of hope was achieved by balancing negative prognostic information with the possibility of hope (including a willingness to share success stories), ensuring that parents understood that all realistic treatment options were being considered, and through practitioners including themselves as having a shared goal for a successful outcome with the parents. While no parents discussed negative aspects of their practitioner expressing hope, they expressed that they did not want to receive false hope, which included information that was too optimistic or that was only given to make them feel better at the time.

Although women in the RCT all received diagnostic confirmation of a viable pregnancy and this was seen as important and reassuring, they also expressed dissatisfaction with their practitioners’ responses that there was ‘nothing they could do’. The advice that the
outcome was in nature’s hands was seen as practitioners leaving women to cope on their own. In contrast, entering the trial was considered positive and something that offered hope because it was ‘finding something they could do’.

7.5.1 Hope through self-care activities

For women interviewed when exiting the RCT, ‘finding something they could do’ was a key motivation for joining the trial. It was the opportunity to be proactive rather than the opportunity to receive acupuncture or touch as a specific therapy that women cited as being the reason they originally agreed to participate in the study. Personal empowerment has been identified as a beneficial outcome of hope, with hope involving a process of setting future-oriented goals, engaging in hopeful behaviour and relating to feelings of control (Farran et al. 1992; Stephenson 1991). These aspects of hope were present for women interviewed on exiting the RCT, with women expressing how beneficial it was to have access to relevant self-care advice as they attempted to remain positive until they reached what they perceived as a time of safety at 12–13 gestational weeks.

Women also reported experiencing an overall feeling of control as a result of participating in the trial, which contributed to feeling less stressed. Data collected from all women exiting the trial suggested that the most useful information women received was dietary information and advice about appropriate rest. While Western medical practitioners expressed concern that diet and lifestyle advice could create stress for women—especially if they were unable to follow this advice and then miscarried—women exiting the RCT appreciated the option to take some control and engage in diet and lifestyle activities that they found useful and relevant to them personally.

7.5.2 Seeking hope through acupuncture treatment

It was evident from the interviews with acupuncture practitioners that they appreciated that women sought out acupuncture treatment with the hope that it would lead to a viable pregnancy outcome. Seeking hope through acupuncture treatment was a finding of Bishop and Lewith (2013), who examined the decision-making processes of how people initiated acupuncture treatment for a wide variety of health conditions. They
reported that for some people it was not TCM ideology that attracted them; rather, they were dissatisfied with their current medical care and seeking personal control through treatment that provided hope in preference to being told there was nothing that conventional medicine could offer them.

Acupuncture practitioners spoke of ‘a balancing act’ in which they aimed to deliver a treatment they considered both safe and therapeutic. As part of this balancing act, there was an awareness of managing treatment expectations for unrealistic hope. This was achieved by discussing with women how they would be using the treatment in an attempt to achieve an ongoing pregnancy, but also explaining that there were limitations. Acupuncturists spoke of framing self-care advice so that this was achievable in order to prevent women from blaming themselves if they were unable to follow this advice and subsequently miscarried. This approach reflects discussions by Roscigno et al. (2012), in which hope was delivered therapeutically by discussing negative prognostic information while including the potential for hope in the discussion.

Although both Western health practitioners and acupuncture practitioners aimed to provide realistic hope, there was a difference in the way they approached this advice. While Western health practitioners used diagnostic information from medical tests and considered hope useful for women but irrelevant to the pregnancy outcome, acupuncturists used TCM theories of the pregnant body to explain and design their treatment. This involved the view that hope was an important emotional aspect to maintain an optimal environment in early pregnancy. Acupuncturists viewed themselves as providing hope for women that they were not receiving from their Western health practitioners—both through offering acupuncture as a treatment and through offering women self-care advice which was individualised to their TCM diagnosis.

7.5.3 Summary—the value of hope

In conclusion, hope was actively sought after, and valued by, women on Internet discussion threads for threatened miscarriage and in the interviews conducted with women on exiting the RCT. Seeking hope through discussion threads focused on the positive stories and experiences of others, including those of a successful pregnancy following pregnancy loss from threatened miscarriage. Hope was also provided through
the experiences and advice of others who challenged the medical information and advice women had been given. In the interviews, women expressed that they found hope by being able to engage in self-care activities. ‘Finding something they could do’ provided hope that they were being proactive, which resulted in feeling more in control and less stressed. These beneficial effects involved not only receiving the treatment offered in the trial, but also utilising the self-care advice they received, with dietary suggestions and advice about appropriate rest rated as the most beneficial.

The Western health practitioners who were interviewed about the care they provided to women presenting with threatened miscarriage acknowledged that women sought hope from them, and they attempted to provide realistic hope using medical diagnostic tests. While acknowledging that hope was emotionally important for women, it was not perceived as a factor that could influence the pregnancy outcome, as a miscarriage was seen to be ‘what will be will be’ and a matter of adapting a ‘wait and see’ approach.

The acupuncturists’ perspective highlighted how they provided women with support by maintaining hope and filling a need that was absent from Western health care. This hope was offered through an active treatment that was based on theory concepts within TCM, as well as diet and lifestyle advice for women to follow, which was individualised to their TCM diagnosis. Together, the treatment and self-care activities were considered important because they assisted women to achieve the maximum health benefits possible in an attempt to maintain and enhance the intrauterine environment.

### 7.6 Acupuncture as a treatment for threatened miscarriage

Acupuncture as a treatment for threatened miscarriage will now be examined by exploring the question: How was acupuncture perceived as a treatment for threatened miscarriage? This is first explored among acupuncturists participating in the survey, as well as interview data, before exploring this across the remaining relevant data sets.
7.7 Acupuncture as a safe treatment

Acupuncture was viewed as an active treatment; however, there were concerns about acupuncture being a safe treatment. Practitioners who were not actively treating women were concerned that they might be held responsible for any subsequent miscarriage, while practitioners who were treating women were concerned that other practitioners may cause a miscarriage through incorrect treatment. These concerns over safety were also reflected in the practitioners’ interviews, where all acupuncturists, despite using diverse acupuncture points and treatments, justified themselves as providing safe treatment.

7.7.1 Contraindicated acupuncture points in pregnancy

Different points in acupuncture texts are labelled as forbidden or to be used only with caution during pregnancy. While some of these points are listed as contraindicated or forbidden with no rationale, others are specifically contraindicated, as these points may be used to induce labour, and there are concerns that they may also stimulate early labour or miscarriage (Betts 2006; Lyttleton 2004; Maciocia 1998; West 2001). Acupuncturists participating in the online survey were given a list of all points listed as forbidden or contraindicated in current obstetric acupuncture textbooks and asked which they would personally avoid when treating threatened miscarriage. It was an unexpected finding that practitioners did not select points used to induce labour as acupuncture points they would avoid when treating threatened miscarriage. A small minority (5.3%) considered that there were no contraindicated points, while others did not select specific contraindicated points. This ranged from 21 practitioners (12.8%) who would not avoid LI 4 to 83 practitioners (50.6%) who would not avoid BL 67. Acupuncture practitioner characteristics identified that those trained as medical acupuncturists were more likely to use GB 21 (p=0.002) and practitioners with 10 or more years of clinical practice were also more likely to use acupuncture points LI 4 (p=0.002), SP 6 (p=0.001), GB 21 (p=0.012) and BL 60 (p=0.001); however, these observations were based on small numbers.
There may be several reasons why practitioners did not select contraindicated points as points to avoid when treating threatened miscarriage. An argument was made in recent acupuncture literature that there are no contraindicated acupuncture points in pregnancy. The authors argued that studies on pregnant rats demonstrate no adverse effects and that acupuncture is self-regulating in effect (Guerreiro da Silva et al. 2011, 2013). In addition, it has been argued that fears of detrimental effects are merely theoretical concepts from historical texts and that warnings concerning contraindicated points during pregnancy could be dismissed as unnecessary (Cummings 2011; Roemer 2005).

However, those promoting the use of a ‘no contraindicated points approach’ did not discuss that rat studies may not be applicable to early pregnancy in humans. While rat and mice models can be useful for studying genetic expression, they are not useful for examining human implantation due the different physiological process involved in rodent early pregnancy compared to human pregnancy (Lee & DeMayo 2004). Authors making an argument for the use of these contraindicated points also do not examine any articles from within China, where these points are used as a treatment to stimulate abortion in the first trimester. Although these treatments are usually administered with strong stimulation over several consecutive days, which may not reflect clinical practice in a Western setting, a 75.5% success rate of inducing spontaneous abortion has been reported (Jin & Zhu 2005). A role for acupuncture use as a treatment to assist artificial abortion and drug-induced abortion has been reported in the literature from China, with acupuncture reported to accelerate cervix dilatation and foetal sac release, resulting in an increased completed abortion rate compared to medical abortion alone (Yuan et al. 2012). Although the articles from China lack rigor, they may indicate that these points are not self-regulating.

A further consideration that may influence acupuncturists when making treatment decisions in early pregnancy is that contraindicated points have been used in studies of pregnant women, with LI 4, BL 32, BL 33 and BL 60 used for back pain (Elden et al. 2005), LI 4 for heartburn (da Silva et al. 2009), GB 21 for insomnia (da Silva et al. 2005) and LI 4 and GB 21 for headache (da Silva et al. 2012). However, in these studies, the points were only administered to women when they reached their second trimester. It has been suggested that the potential action of these contraindicated points
may be different during the first trimester because of the different physiological process of pregnancy at this time (Betts & Budd 2011).

Acupuncturists may also consider points LI 4, SP 6 and local abdominal points safe to use in early pregnancy following their use as part of fertility treatment protocols associated with improved clinical and ongoing pregnancy rates (Dieterle et al. 2006; Westergaard et al. 2006; Paulus et al. 2002). However, in these circumstances, the acupuncture treatment was administered before implantation had occurred, thus, the application of these points to early pregnancy may not be appropriate.

The purposive selection of practitioners for the interviews was used to explore why some acupuncturists did not select contraindicated points to avoid when treating. These practitioners spoke of being able to safely use specific points such as LI 4, SP 6, BL 32, GB 21 and BL 60. These points were used as powerful calming points and points to relieve back pain. These are common presentations for women experiencing threatened miscarriage, with anxiety over vaginal bleeding and back pain nominated as symptoms of concern by women and treated in the RCT of this thesis (although different point selection was utilised). BL 67 was also a point that the surveyed practitioners would not avoid in the treatment of threatened miscarriage. This is a point principally used in Chinese medicine to promote the optimal positioning of a baby with moxibustion, to induce labour, to assist with a difficult delivery and to promote the expulsion of the placenta following childbirth (Deadman et al. 2001). It is possible that it was not selected as a point they would avoid simply because it was seen as irrelevant.

In the in-depth interviews, practitioners discussed the contraindicated points they used as being therapeutic and safe for a variety of reasons, including the needling technique and point combinations, interpretation of point function from a Western medical perspective, the opinions of those they trusted and their own personal experiences of using these points. Although practitioners discussed why they thought points were safe to use, their reasoning was based on their personal opinions and clinical experience rather than evidence-based rationale from TCM theory or Western medicine.

While acupuncturists who were prepared to use contraindicated points questioned the information in historical texts, practitioners who did not use contraindicated points
discussed how they respected the knowledge presented in historical texts. They were also concerned that if a woman subsequently miscarried, it would be difficult to maintain that they had used safe practice if they had used points identified as contraindicated in acupuncture texts. Similar to practitioners who chose to use contraindicated points, some practitioners’ clinical experiences reinforced their decision not to use these points.

To date, the use of the acupuncture points identified as contraindicated in pregnancy have not been explored in clinical practice. The findings from the survey and interviews identify diversity in clinical practice to use or not use these points. While acupuncturists were concerned about the safety of the points in terms of the possibility of stimulating a miscarriage, there was no consideration from practitioners that if they were treating a small number of women any miscarriage effect following treatment would be difficult to detect. This was concerning in view of practitioners using treatments that texts and other practitioner’s considered unsafe. There was also no wider safety concerns expressed that women may need medical referral if presenting with other conditions involving vaginal bleeding such as ectopic or molar pregnancies. It was interesting that while acupuncturists did have some concerns about the possibility of acupuncture stimulating miscarriage the Western health practitioners interviewed cited no concerns and placed acupuncture in the context of a therapy that assisted women to relax and cope with stressful situations.

The use of Chinese herbal medicine can be seen as a separate branch of TCM. Chinese herbal medicine has been discussed as a treatment for threatened miscarriage in various texts (Lyttleton 2004; Maciocia 1998; Marchment 2007; Flaws 2002). Findings from the survey of practitioners identified that two-thirds (67%) of practitioners would use Chinese herbal medicine as a treatment modality. However, this may not reflect the reality of clinical practice; it was evident from the interviews that there were circumstances in which practitioners chose not to use herbs in clinical practice.

Refraining from the use of herbal medicine was undertaken in order to maintain practitioners’ relationships with Western health practitioners who they felt did not approve of the use of Chinese herbal medicine, and as an acknowledgement of women’s concerns regarding safe use in early pregnancy. This approach was not universal; for
one practitioner, it was considered important to promote herbal medicine as part of treatment. She discussed her advice with women and explained why she thought herbal medicine was safe. However, for the majority of acupuncture practitioners interviewed, there was an adaption of practice around their use of Chinese herbal medicine.

The perception that Western health practitioners had reservations about Chinese herbal medicine was reinforced in the interviews with Western health practitioners, who viewed acupuncture as a separate therapy and wanted further information regarding the safety of Chinese herbs before recommending their use. Their concerns reflect the recommendations in the literature that further research is required to establish the safety of using Chinese herbal medicine for threatened miscarriage (Li et al. 2012a; Li et al. 2011).

7.8 Acupuncture as an active physiological treatment

For the acupuncturists interviewed, justifications about delivering a safe treatment were linked to delivering an active treatment with physiological consequences. Practitioners discussed how they aimed to affect a woman’s qi, Blood and Shen to stimulate appropriate responses using acupuncture points and techniques without initiating a physiological reaction that would stimulate miscarriage. This concern over a practitioner’s understanding of qi, Blood and Shen in a pregnant body and the appropriate acupuncture treatment for pregnancy was a feature of practitioners’ concerns both in the acupuncture survey and interviews. Acupuncturists responding to the survey were concerned about the potential strength of acupuncture to bring on a miscarriage by over-stimulating this qi response, while practitioners who participated in both the survey and interview were concerned about other practitioners inadvertently stimulating these responses. This discussion concerning the differences in a pregnant woman and how to treat them by stimulating qi responses is a feature of early TCM writings and can still be found today in acupuncture texts and journal articles discussing contraindicated points.

Early writings describing the application of TCM to care during pregnancy can be found in the Mawanghui manuscripts, which were discovered in 1973 and predate 168 BCE.
One of these texts, the ‘Book of Gestation and Birth’, contains a month-by-month description of foetal development, with prescriptions for a woman’s behaviour, food and desired environment throughout pregnancy (Wilms 2007). These writings suggest the ideal maternal behaviour, food consumption and environment for each month of pregnancy. These factors are seen as influencing maternal qi and thus influencing the developing foetus. The writings refer to TCM theories regarding how foetal qi forms in early pregnancy and how the qi from the mother affects foetal development. This interest in influencing health in pregnancy continues in historical writings with meridians that correspond to each month of gestation supporting a pregnancy and further diet and lifestyle advice expanded on by various authors throughout TCM history (Wilms 2007; Rochat de la Vallee 2007).

In terms of threatened miscarriage, Sun Simiao’s writings (581–682 CE) details treatment for women’s health, with a focus on how special treatment is required for women, including herbal recommendations for bleeding during pregnancy, commencing from the first month (Wilms 2002). In later historical texts, differential diagnoses were given to vaginal bleeding in pregnancy, where ‘restless foetus’ refers to bleeding in a pregnancy at risk, while ‘falling foetus’ refers to a miscarriage before three months and ‘small labour’ and ‘half labour’ foetal loss after this time (Maciocia 1998). There are also treatment recommendations made in historical case histories by physicians that discuss treatment to preserve a pregnancy perceived as viable and to assist miscarriage, with warnings of incorrect treatment leading to miscarriage (Furth 1999). These historical considerations referring to the meridians nourishing different gestational months and the incorrect stimulation of qi through inappropriate herbs and incorrect acupuncture treatment continue through to modern textbooks’ discussions of treating threatened miscarriage (Maciocia 1998).

The interviews with the practitioners referred to this historical link to treatment, with different practitioners questioning this historical authority or accepting these concepts. However, while practitioners differed in their opinions about how acupuncture points and techniques could be utilised, all spoke of qi concepts in their treatment. Practitioners discussed the importance of using treatment that would support the specific meridians and organs that support early pregnancy in TCM, as well as TCM theory concepts relating to qi, Shen and Blood. The finding that practitioners consider qi
a fundamental aspect of the treatment mirrors the findings of Schroer et al. (2012), who identified that acupuncture practitioners regarded qi as their number one guiding treatment principle. All beneficial aspects of their treatment, including how the patient followed through on diet and lifestyle self-care, were ultimately a result of the effect on a person’s qi. This concept was evident in the acupuncture practitioners’ interviews, where the rationale for offering treatment, including diet and lifestyle advice, related to TCM theories on how qi influences the body in early pregnancy.

Data from the online survey identified that the majority of practitioners (62.8%) gave lifestyle advice related to traditional Chinese concepts and half (51.2%) gave dietary advice related to traditional Chinese concepts as part of their clinical practice. In the interviews, practitioners spoke of how this self-care advice was an important consideration for treatment success in terms of specific TCM concepts of calming Shen and nourishing the qi of TCM organs associated with early pregnancy. Practitioners also discussed how they individualised any advice for the TCM diagnosis and how they framed this advice to make it achievable for women to follow.

This importance of using diet and lifestyle advice from a TCM perceptive as an important component of treatment is supported by research relating to a variety of other treatment conditions (MacPherson & Thomas 2008; MacPherson et al. 2006; Paterson & Britten 2008; Paterson et al. 2012). The practitioners that were interviewed identified self-care not as an optional component of treatment, but as specific advice that was individualised to the patient’s diagnosis, that differed in content from medical advice and that contributed to treatment outcomes. This emphasis on using self-care advice could also be seen when acupuncturists emphasised the non-needling aspects of their treatment, and decisions made by the patients themselves were a key aspect to the treatment they provided (Hughes et al. 2007; MacPherson & Thomas 2008; MacPherson et al. 2006; Schroer et al. 2012). This finding is in contrast to research in which Western-trained acupuncturists were interviewed about the treatment they provided and discussed these non-needling aspects of treatment as having an effect, but as separate to their acupuncture treatment (Hughes et al. 2007).

While the acupuncturists interviewed in this thesis discussed that miscarriage would be inevitable for certain women due to genetic abnormalities, there was also a perception
that it was possible to stimulate qi for some women to produce beneficial responses. Stimulated through acupuncture and self-care, these responses could assist the body to maintain a viable pregnancy when genetic abnormalities were not present. This was viewed as a key to how practitioners saw themselves as offering care that was not available in Western medicine, where women were told that there is ‘nothing you can do’.

In contrast to the acupuncture practitioners’ views that they were providing care that had the potential to stimulate beneficial responses to influence pregnancy outcomes, the majority of Western-trained health care practitioners viewed acupuncture differently. They discussed acupuncture treatment as useful to assist with relaxation and deal with stressful events. In this context, although considered useful for the women, acupuncture was not viewed as a treatment that would affect the pregnancy outcome. Therefore, this was seen as something that women had the option to seek out for themselves if they chose to. The perception amongst the majority of practitioners that nothing could be done to the influence pregnancy outcome except ‘watchful waiting’ is interesting in view of the literature discussing the potential for supportive care to reduce stress and positively affect pregnancy outcomes (Brigham et al. 1999; Liddell et al. 1991). When research on the usefulness of providing care to reduce anxiety among women with an unexplained miscarriage was mentioned, it was queried how this could have been beneficial to pregnancy outcomes when there was no active treatment provided.

The RCT found that there were both emotional and physical benefits for women in the acupuncture group, with a significant difference for threatened miscarriage symptoms, including those of anxiety over vaginal bleeding, abdominal cramping and back pain (MD 1.36; 95% CI, 0.07 to 2.66, p=0.04). Women from both groups reported beneficial effects relating to feelings of hope provided through the emotional support and self-care advice they received and how this resulted in feeling more in control and less stressed. The majority of women discussed the possibility that this support and advice was responsible for reducing their anxiety rather than the acupuncture. However, beneficial changes in their physical symptoms of bleeding, cramping and back pain were directly attributed to the acupuncture treatment. In comparison, women in the touch group reported no changes in physical symptoms, although they reported that they felt less stressed and concerned about these symptoms when they occurred.
Acupuncturists identified changes to women’s anxiety and general stress levels as being a primary aim of treatment, although treatment success was also evaluated through specific changes to the physical symptoms of vaginal bleeding, abdominal cramping and back pain. While these changes were not seen as a guarantee that the pregnancy would continue, they were seen as providing feedback of the beneficial treatment effects that had resulted in physiological changes, and these were used by practitioners as a rationale for continuing to use specific treatment modalities.

7.9 Acupuncture as supportive care

Providing information and support to women as care during pregnancy has been discussed as a beneficial concept in the research, although the details of the specific care provided varied. Supportive care has been defined as providing emotional support (which could include counselling and reassurance), information and advice, and practical support (Hodnett & Fredericks 2010). In research examining the use of supportive care for pregnant women with unexplained recurrent miscarriage, support included providing medical monitoring through blood tests and ultrasounds (Brigham et al. 1999; Clifford et al. 1997; Liddell et al. 1991; Stray-Pedersen & Stray-Pedersen 1984). A further aspect to supportive care was illustrated by Musters et al. (2011, 2013), where women with unexplained recurrent miscarriage discussed supportive care involving a relationship with their practitioner where they felt they were being listened to and understood and that their concerns were being taken seriously. Musters et al. (2013) described these empathic practitioner-related communications as ‘soft skills’ in order to differentiate this support from that of medical monitoring.

These findings reflect the findings discussed in the thread for ‘the value of hope’, where providing empathy was seen by both the women in the discussion threads and the RCT interviews as supportive and working with them towards a positive outcome. All women from the RCT reported that they had received useful support from the researcher, while useful support from a health professional was nominated by only one-third of the women. This perception of a lack of support was a further finding in the interviews, where the majority of women spontaneously reported feeling dissatisfied with the information and support they received from their Western health practitioner.
This was a surprising finding considering that their health practitioner had originally referred these women into the study and all women had continued to receive medical monitoring that included follow-up ultrasounds. The dissatisfaction expressed by women focused on being told that there was ‘nothing they could do’. This was perceived as health practitioners who, although not being deliberately unkind (they were ‘only doing their job’), were leaving them to cope on their own until they reached a time of safety at 12–13 gestational weeks. Support received from the researcher that was expressed as beneficial related to having someone knowledgeable to talk to, someone who was available on a regular basis, and receiving information and advice about diet and lifestyle. Together, women described this support as decreasing their anxiety about their symptoms and offering them choices and a feeling of control while they were ‘marking time’. While women expressed that they found medical monitoring and ultrasounds reassuring, the majority also discussed that they were expecting more information and emotional support from their health practitioner.

Acupuncture was discussed by Western health practitioners as having the potential to provide support to women presenting with threatened miscarriage because it was seen as a therapy that may help women relax. However, it was not perceived by these practitioners that acupuncture provided women with information or support that they would not receive through Western medical care. While practitioners discussed how difficult it was to provide evidence-based information to these women for self-care, they perceived that it was useful to base any diet and lifestyle advice on what was acceptable or achievable to the women. In this way, diet or lifestyle activities were centred on the women’s situation or their personal preferences. The only exception was an independent midwife who encouraged all women under her care to rest, even if this meant taking time off work. A flexible approach to giving diet and lifestyle advice was considered supportive by the majority of Western health practitioners, who expressed how important it was that women did not blame themselves in the event of a subsequent miscarriage. However, this did not appear to be the effect that this advice had on the women interviewed in this thesis, where they discussed how they proactively sought out self-care activities to help maintain the pregnancy at risk of miscarriage. Practitioners acknowledged that women sought information from the Internet, despite their concerns that this information was incorrect. This perception was demonstrated by women entering the RCT, with 53.8% of women reporting activity using the Internet in
the week of entering the study. Several women discussed that, although they were uncertain about the accuracy of the information they were receiving, they had ‘nowhere else to go’. The use of the Internet by pregnant women to seek out pregnancy health-related information due to a perception that they have not received adequate information has been reported previously by Lagan et al. (2010), who found that close to half of the women seeking pregnancy-related health information did so because they were dissatisfied with the information given to them by their health practitioner.

Support identified by Western-trained health practitioners as useful for women related to information conveyed through medical monitoring, particularly through the use of ultrasound. Practitioners expressed reservations that women perceived these ultrasound results as a guarantee of a continuing pregnancy instead of a snapshot that the baby was viable at this point in time. Ultrasounds were perceived as the most useful reassurance they could offer women. In contrast to this perception, when women have been asked about the frequency of receiving ultrasounds for at-risk pregnancies, they have indicated a preference for fortnightly scans or scans when new bleeding occurs rather than twice-weekly or weekly scans (Musters et al. 2011; Musters et al. 2013). While women may appreciate the value of ultrasound scanning, they may also consider frequent scanning unnecessary and look to their health practitioner to support them in relation to uncertainty and questions they may have between scanning appointments.

Empathic practitioner relationships and providing supportive care are acknowledged as important in the practice of Western medicine, as can be seen in the unexplained recurrent miscarriage literature (Brigham et al. 1999; Clifford et al. 1997; Liddell et al. 1991; Musters et al. 2011, 2013; Stray-Pedersen & Stray-Pedersen 1984). However, these aspects may also be perceived as incidental factors that are placebo-related and independent from an active treatment (Paterson & Dieppe 2005). Certainly, the use of the term ‘soft skills’ by Musters et al. (2013) to describe practitioner empathy and supportive care is interesting. This approach to providing supportive care was also found in the practitioner interviews. Where supportive care was not discussed in terms of providing a therapeutic relationship that included on-going emotional support for women but in terms of medical monitoring and preparing women for potential pregnancy loss.
In contrast, the acupuncturists interviewed believed that providing emotional support was an important part of their treatment. This was discussed as relevant to the TCM theories of physiological functioning in early pregnancy. Providing TCM explanations of why specific self-care was important was perceived by practitioners as part of this support and as providing an alternative view to the information given by Western health practitioners.

In the qualitative interviews of the pilot RCT, women discussed receiving advice that was relevant for them and delivered in a way that made the advice achievable. This emphasis on delivering individualised advice in a manner that is not practitioner-directed, but rather a process of active participation between the practitioner and the patient, has been discussed as an important component of treatment in acupuncture research (Evans et al. 2011). Through the analysis of treatment sessions, Evans et al. (2011) noted that that diet and lifestyle advice was ‘interwoven’ throughout a treatment session, initiated by the practitioner or patient, that the advice was likely to be related to the TCM diagnosis, and that it was usually framed in a manner that supported patients as active participants in their own care. Acupuncturists in the interviews described how they supported women by being available to listen to them, by providing them with TCM information that was framed to be supportive, and by working with them towards the aim of a viable pregnancy. By providing these aspects of care, acupuncturists offered women both hope and support that they were not receiving in the current Western medical care system. The supportive care aspect of providing acupuncture treatment may be an important contribution in providing care for women presenting with threatened miscarriage.

7.9.1 Summary—acupuncture as a treatment for threatened miscarriage

Acupuncture was seen as an active treatment by acupuncturists with the potential to enhance beneficial physiological and psychological effects in early pregnancy by stimulating TCM responses that may influence pregnancy outcomes. Due to the effects involving qi, Blood and Shen, there was concern among acupuncturists who were not treating women with threatened miscarriage that there was potential for incorrect treatment that could stimulate a miscarriage. However, acupuncturists treating women saw themselves as delivering safe therapeutic treatment despite using diverse and often
conflicting treatment rationales. They perceived the diet and lifestyle advice they offered as part of their treatment and saw themselves as offering emotional support, including hope, through the framework of TCM that was not currently available to women in Western medical care.

Western health practitioners viewed acupuncture as a safe treatment that may be useful in assisting women with relaxation and reducing stress, but concerns were expressed over the safety of using Chinese herbal medicine. Although practitioners all discussed acupuncture as being potentially beneficial to women, it was discussed as belonging under the umbrella of CAM care, which assists with relaxation, and was therefore something that women could access as an optional extra. Thus, acupuncture was viewed as providing emotional support to women, but not as having any physiological effect on pregnancy outcomes.

Women in the RCT acupuncture group demonstrated a reduction in the symptoms that they had nominated as their primary symptom of concern. However, the majority of women in the interviews were reluctant to attribute any relaxation and stress-reducing effects directly to the acupuncture treatment—perhaps because of the value of the emotional support they received from being part of the study. However, they explained that there were beneficial effects for their bleeding, cramping and back pain symptoms, which they perceived as being directly due the treatment.

7.10 Summary of integration findings

A ‘following the thread’ technique was used to integrate the findings in this thesis by identifying the key theme (‘the value of hope’) and the question (‘how was acupuncture perceived as a treatment for threatened miscarriage?’). The value of hope was a theme across all data sets, with different meanings and perspectives from the women experiencing threatened miscarriage, Western health practitioners and acupuncturists. Hope was actively sought and received through the stories and experiences shared on Internet discussion forums, and this was perceived as a way of offering useful support. The ability to access self-care advice was also seen as providing women with hope that they were doing all they possibly could for their pregnancy. However, for Western
health practitioners, caution was required to ensure that women received realistic hope rather than false hope, which was perceived as unprofessional and unhelpful to women. While acupuncturists were aware of the potential to give women false hope if women did not understand the limitations of their treatment, they perceived they were providing hope that was not available to women through Western medicine by using their treatment to encourage beneficial qi responses in early pregnancy. For women interviewed on exiting the RCT, joining the trial provided hope that they were doing all they possibly could for a positive pregnancy outcome, which was their main reason for participating.

Acupuncture was perceived by Western health professionals as one of many potentially relaxing CAM therapies, but not as a treatment that had the potential to influence pregnancy outcomes. For acupuncturists, acupuncture was capable of stimulating specific beneficial early pregnancy responses according to TCM theory, although they were also concerned that acupuncture could stimulate miscarriage if not used correctly. In addition to the use of needles and TCM modalities, including that of individualised diet and lifestyle advice, a supportive therapeutic relationship was perceived as an important part of the care they offered. Women in the RCT reported that they found acupuncture helpful for relaxation, but they felt this may have been part of the support they received through the therapeutic relationship they experienced from being part of the trial. However, they attributed acupuncture to assisting physical symptoms due to the improvements observed following treatment. The RCT found beneficial effects reaching statistical significance for the symptom that women nominated as their primary concern, with these including both emotional aspects relating to anxiety due to the vaginal bleeding, and symptoms such as abdominal cramping and back pain.

This concludes the integration of the findings. Chapter 8 presents a discussion on these findings, the study’s limitations and implications for practice and future research before presenting the final conclusion of this thesis.
Chapter 8: Discussion and Conclusion

8.1 Introduction

The overall aim of this thesis was to explore the role of acupuncture in providing care for women presenting with threatened miscarriage. To achieve this, four studies were carried out using MMR. These studies examined the current use of acupuncture among acupuncturists, the use of acupuncture compared to an active control group in a Western clinical setting, the perception of providing care from Western health practitioners treating threatened miscarriage and the experiences of women with threatened miscarriage in Internet discussion forums.

This thesis makes a significant contribution to the body of knowledge concerning the treatment and experiences of women presenting with threatened miscarriage. Women sought emotional support from their Western health practitioners and were prepared to challenge medical authority if this was not received. This emotional support involved offering hope for a viable pregnancy, receiving self-care advice and gaining access to someone knowledgeable to talk to. This emotional support was met for the women participating in the RCT, with additional benefits for those receiving acupuncture for threatened miscarriage symptoms, including reduced anxiety associated with vaginal bleeding and reduced abdominal cramping and back pain. This finding provides new knowledge for both acupuncturists and Western health practitioners responding to women presenting with threatened miscarriage. Prior to undertaking this series of studies, information that guided acupuncture practice was restricted to textbook opinions and one poorly designed randomised trial.

This is the first study to specifically examine the experiences of women presenting to acupuncturists and Western medical practitioners with threatened miscarriage. This is a common complication of early pregnancy and an identified gap in understanding women’s experiences of threatened miscarriage. Women clearly demonstrated a need to find a safe place to seek hope and support. While ultrasound assessments were expected care from their Western health practitioners, the current Western medical advice that
there was nothing they could do to positively influence their pregnancy outcome was challenged by women. Findings from the Internet forums illustrated how women challenged Western health practitioners’ knowledge and diagnosis, with women seeking and providing lay expertise to give each other hope and support. Interviews with women participating in the RCT illustrated that, by entering the RCT, they were challenging Western health practitioners’ advice that there was nothing they could do. Their main reason for joining the RCT was the need to do something rather than an interest in receiving acupuncture as a specific treatment.

The findings showed that Western health practitioners were aware that women sought hope and that practitioners offered this hope using medical assessments. However, it was important for the practitioners to offer only what they considered realistic hope based on Western medical rationale. This involved a professional responsibility to use medical knowledge and diagnostic tests to ensure that women did not receive false hope, with practitioners discussing how it was helpful for women to have realistic information to assist them in preparation for possible pregnancy loss. The study also found that practitioners perceived ultrasound assessment as the most useful support they could offer women. In the absence of evidence demonstrating that self-care activities positively influenced pregnancy outcomes, practitioners attempted to adapt any diet and lifestyle advice to ensure that women did not blame themselves in the event of a miscarriage. While the majority of Western health practitioners were concerned about the safety of Chinese herbal medicine, they perceived acupuncture as a safe and potentially relaxing treatment for women. However, they did not consider acupuncture an active treatment with the potential to positively influence pregnancy outcomes.

There was concern among acupuncturists about the safety of using acupuncture for threatened miscarriage because acupuncture was capable of stimulating qi responses that had the potential to stimulate miscarriage if used incorrectly. In the interviews, all acupuncturists treating threatened miscarriage saw themselves as practicing safely and justified their practice by challenging or accepting historical knowledge, the opinion of other experienced practitioners and their own clinical experiences. The treatment strategies and modalities used in clinical practice were diverse when using acupuncture and moxibustion, with the majority of practitioners also using diet and lifestyle advice according to TCM principles. Self-care advice relevant to the TCM diagnosis was
discussed by practitioners in the interviews as offering women care and support that was not currently available through Western health practitioners. Together with acupuncture, this care was seen as supporting specific TCM qi responses in early pregnancy that had the potential to be beneficial and to influence pregnancy outcomes. Acupuncturists were aware that, by offering women treatment, there was a potential to create false hope. Thus, they undertook a responsibility to manage unrealistic treatment expectations by framing any self-care advice to be achievable and by discussing treatment aims while acknowledging the potential for miscarriage.

8.2 Discussion of findings in terms of existing research

There is an absence of any new evidence to offer women with threatened miscarriage additional treatment options when they present to Western health practitioners. While the use of pharmacological interventions continues to be explored, there is insufficient evidence available to recommend this as a treatment in clinical practice (Carp 2012; Devaseelan et al. 2010; Ahmed et al. 2012). Rather than focusing on providing care for threatened miscarriage, Western medical research has focused on developing miscarriage prediction models for threatened miscarriage with the aim of improving the identification of those who are most likely to require further support when they miscarry (Adam et al. 2011; Bottomley et al. 2013; Hanita et al. 2012). No new research has provided a voice for women to articulate their needs for supportive care. The trial findings identified useful support as advice and emotional support. Interviews with women further identified the advice as self-care advice relating to their diet and appropriate rest, and emotional support as access to someone knowledgeable that they could talk to. These findings mirror research that has explored what women with a history of unexplained recurrent miscarriage regard as supportive care. Musters et al. (2011, 2013) observed that women wanted a therapeutic relationship with their health practitioner that involved someone who listened to their concerns with respect, showed empathy and asked about their emotional needs in addition to offering them information and medical monitoring.

This thesis showed that the Internet was used by women experiencing threatened miscarriage for information and support. Although all Western health practitioners that
were interviewed regarded the Internet as something to warn women against using, women’s use of the Internet was evident through the Internet discussion forums and RCT, where they sought information and support following a diagnosis of threatened miscarriage. Interviews with women highlighted that although they were aware they could receive incorrect information through the Internet, they perceived that they had nowhere else to go. They used the Internet not only to seek out information about a medical diagnosis, but also to receive support through making contact with other women who had similar experiences. This finding is supported by research that has examined discussion forums relating to postnatal depression and following miscarriage (Evans et al. 2012; Gold et al. 2012).

In the RCT, five women (23.8%) experienced a pregnancy loss in the touch group compared to three women (16.7%) in the acupuncture group. This difference was not statistically significant (p=0.58). However, the pilot study was not powered to demonstrate significant differences between the groups. It is difficult to compare miscarriage rates for women in the pilot RCT with other studies due to inconsistent definitions of miscarriage and differing inclusion criteria for reflecting miscarriage risk factors. This inconsistency involves the inclusion of different gestational and maternal ages at presentation, various definitions for the amount of vaginal bleeding and reporting results at different pregnancy gestations rather than birthing outcomes. However, maternal age over 35 years and vaginal bleeding have been reported as important demographic and symptom predicative factors for pregnancy loss (Bottomley et al. 2013). In our pilot RCT, 10 women (25.6%) were aged 35 years or older and 10 women presented with bleeding that they described as heavier than a period. Clearly, the women participating in this trial had acknowledged risk factors for pregnancy loss. In addition, the mean gestational age at which bleeding commenced for women in the study was early: 5.9 gestational weeks for the acupuncture group and 6.5 weeks for the touch group. The pregnancy loss in this pilot RCT before 12 completed gestational weeks at 12.8% (5/39) was lower than the 14–21% pregnancy loss rate reported in other prospective cohort studies for women presenting from six gestational weeks (Adam et al. 2011; Mukri et al. 2008). The pregnancy loss in this study may reflect beneficial effects from the supportive care offered to both groups. However, this remains unknown because it was considered unethical to randomise women to a non-intervention group.
Three women (7.6%) in this study experienced a pregnancy loss following 12 completed gestational weeks. This included a late miscarriage, a stillbirth following an APH and a neonatal death following PPROM. In addition, there were two premature deliveries requiring admission to neonatal special care, with one of these babies defined as IUGR. These pregnancy losses and premature births reflect research findings that women presenting with threatened miscarriage remain at risk for further pregnancy complications in addition to early pregnancy loss (Dadkhah et al. 2010; Saraswat et al. 2010; van Oppenraaij et al. 2009). The follow-up of women in this study to delivery highlights the importance of being able to assess the risk of adverse birthing outcomes such as stillbirth and neonatal death.

In contrast to findings reporting that women with heavy bleeding had an increased risk for pregnancy loss (Poulose et al. 2006; Weiss et al. 2004), findings from the pilot RCT indicated a 20% pregnancy loss both from women who initially reported that their bleeding was lighter than a period and from those reporting it as heavier than a period. The three pregnancy losses after 12 completed gestational weeks were from women who initially reported their vaginal bleeding as lighter than a period. Although the total number of women in this study was small, the vaginal bleeding initially described by women as spotting and ‘lighter than a period’ deserves further attention. It may be that this is an important group of women that might benefit from additional monitoring in the future.

8.3 Discussion of findings using a dialectic approach

It was evident from the qualitative interviews of the Western health practitioners and the survey and interviews of the acupuncturists that paradigm differences existed between these two groups in the knowledge perceived and valued as useful when caring for women presenting with threatened miscarriage. The knowledge that Western health practitioners and acupuncturists considered acceptable evidence to utilise in their clinical practice influenced their perception of how women’s bodies responded to treatment intervention and therefore influenced the care they offered women.
Evidence-based medicine provides levels of evidence that are seen as trustworthy in Western medicine and that provide a basis for making informed quality decisions about patient care. This hierarchy of evidence can be seen as promoting health care based on ‘scientific fact’ rather than relying on ‘medical opinion’ (Jackson & Scambler 2007). In interviews, Western health practitioners spoke of how they used diagnostic information from blood tests and ultrasounds to provide the level of realistic reassurance they were able to give women. With current medical knowledge reporting threatened miscarriage outcomes as unknown and ‘in nature’s hands’, the ability to provide women with medical monitoring using ultrasound was considered among the most important care they could offer. With no evidence that self-care activities could influence pregnancy outcomes, Western health practitioners considered that, while it was beneficial for women to seek support or self-care activities that reduced anxiety, this would not influence pregnancy outcomes. Therefore, any advice about taking time off work to physically rest or seeking out relaxation methods was seen as something that women could choose, and this advice was given according to the practitioners’ assessment of a woman’s situation. Acupuncture was considered one of many possible CAM treatments that may be useful in aiding relaxation, but not as an active treatment for threatened miscarriage. Practitioners therefore focused on providing care by giving women information relating to the possible reason for their vaginal bleeding, supporting them in a professional manner by offering realistic hope and adapting any self-care advice to minimise self-blame if there was a miscarriage.

In comparison to an evidence-based approach, TCM can be considered ‘experience-based’ medicine (Birch & Lewith 2008, p.17). This model of health values practitioners’ experience and knowledge gained through critical reading and historical interpretation of classical texts, historical and current clinical case histories, the synthesis of traditional ideas in current texts, and observations of experienced practitioners and teachers (Kaptchuk 2012). This is also a model of health care that values knowledge obtained through the subjective experiences of patients and where a patient’s experience of health and illness are viewed as being capable of having important effects on their health (Hughes et al. 2007). This emphasis on valuing the ‘whole’ person is a key component of a holistic model of medicine (Cassidy 1998). Indeed, the practice of acupuncture has been referred to as ‘holism in action’ (Gould & MacPherson 2001, p. 261). Study data from acupuncturists described how they valued
and used TCM theories to diagnose and offer treatment with a rationale of being able to stimulate positive qi responses in early pregnancy. Further, in addition to the use of acupuncture, emotional responses and self-care advice were seen as an important part of stimulating these treatment responses. Schroer et al. (2012, p. 321) identified this focus as a ‘qi paradigm’ that was fundamental to the practice of acupuncture for acupuncturists and as the means of achieving improvements in a person’s health, including motivation and compliance with self-care activities. While acupuncture was viewed by Western health practitioners in their interviews as belonging to the practice of a range of CAM therapies, Cassidy (1998) raised the issue that not all acupuncturists would be happy to be under this wide umbrella, where holistic medicine is not always well defined. Certainly, the acupuncturists interviewed in this study saw themselves as offering a therapeutic treatment capable of providing care that went beyond Western health practitioners’ perception of acupuncture as one of many CAM therapies that can be used to reduce anxiety.

The majority of acupuncturists did not consider Western medical information useful for their diagnostic framework. This was interesting in light of how Western medical information has been adapted and written about as a diagnostic tool in acupuncture fertility practice (Lyttleton 2004). Practitioners spoke of how they used information from historical sources, their own clinical experience and the opinions of experienced practitioners in preference to Western diagnostic information. This finding mirrors the findings of others, where acupuncturists cited their own experiences and traditional authority over evidence-based medicine, and where practitioners stated that they did not always see evidence in the Western medical sense as being relevant to their practice (Hansen 2012; Jackson & Scambler 2007). Although it has been suggested that a barrier to acupuncturists communicating with Western health practitioners may be due to inadequate Western biomedical training to adequately express themselves (Sherman et al. 2005), it may be that there are barriers to communication because acupuncturists do not value Western medical evidence as relevant to their practice.

A dialectic approach aims to respect the differences and conflicts in different paradigms. The findings of this thesis illustrate how the knowledge valued by Western health practitioners and acupuncturists influenced their diagnosis of, and treatment for, women presenting with threatened miscarriage. Evidence-based knowledge valued by
Western health practitioners led to care that aimed to support women by providing accurate biomedical information, realistic hope, and diet and lifestyle advice that reflected their understanding that there was nothing women could do to influence their pregnancy outcomes. In contrast, ‘experience-based’ knowledge valued by acupuncturists led to care that aimed to support the body in early pregnancy by stimulating beneficial qi responses. For acupuncturists, their diagnosis took into account women’s physical symptoms and emotional responses, and they promoted self-care activities as part of their treatment. This care reflected their understanding that it was possible to influence pregnancy outcomes. Western-based diagnostic knowledge was not considered essential for these acupuncturists, with a reliance on experience-based knowledge from classic texts, other trusted practitioners and their own clinical practice.

8.4 Implications for research and clinical practice

The findings of this thesis provide direction for future research and implications for researchers in this field. Women presenting with threatened miscarriage can be seen as a vulnerable population with ethical considerations because they have an at-risk pregnancy. This study demonstrated that women were interested in participating in a RCT, accepted randomisation, reported that the intervention was acceptable and that acupuncture was a feasible treatment. Despite recruitment challenges, interest from health practitioners based at the MAU and the fertility unit, as well as from independent midwives, was evident by the number of referrals to the trial. Methodology implications that require further considerations in future research are discussed below.

8.5 Methodology implications

8.5.1 Recruitment

Planning recruitment was a challenge due to the lack of official records on the number of women presenting with threatened miscarriage in hospital departments in the Wellington and Hutt Valley areas, or indeed in New Zealand. There were also no records relating to the incidence of threatened miscarriage collected through midwifery sources, radiology departments or through GP data collection in New Zealand. Rates of recruitment were therefore guided by the literature. International research indicated that
approximately half of the women who presented with threatened miscarriage were found to have a viable pregnancy on ultrasound (Stabile et al. 1987; Tongsong et al. 1995). Therefore, we had an expectation that 40–60% of women presenting with bleeding in early pregnancy through the MAU would have a viable pregnancy on ultrasound. This estimate was supported verbally by the MAU staff. However, recruitment was slower than expected due to the number of women presenting in the MAU with non-viable pregnancies.

As a result of the pilot study, the MAU staff developed an interest in keeping records for the diagnosis of threatened miscarriage. An MAU database recording the diagnosis for all women presenting to the MAU with vaginal bleeding began in March 2012 and is ongoing. These records demonstrate that over the three-month period in which the trial was recruiting (1 March 2012 to 30 June 2012), 67 women presented with vaginal bleeding before 20 gestational weeks. Of these, 17 women (25.3%) had a viable pregnancy on ultrasound assessment. This experience of recruitment was confirmed by MAU data, which found that the number of women eligible for the study was less than anticipated. However, this study contributes new knowledge to guide realistic recruitment for future research.

8.5.2 Suitability of eligibility criteria

Half of the women approached to participate in the trial exceeded the gestational age limit for entry. This was an unexpected finding. It may have been that women were not experiencing bleeding until after 11 gestational weeks, or that they did not seek care when their bleeding originally commenced. However, it may have also been that women initially sought care from practitioners who did not inform them of the trial. Therefore, potential study participants under the care of their GPs may have only become aware of the study later in their pregnancy when they were referred to a hospital unit or seeking a midwife as their LMC. The number of women presenting with a viable pregnancy at this later-than-expected gestational age contributed to slower-than-expected recruitment, and this requires further consideration in future studies.
8.5.3 Recruitment of eligible women

Safety concerns are recognised as a barrier to entering research trials for pregnant women, with concerns over any risks to the baby influencing women’s decisions to participate (Tooher et al. 2008). Potential participants for this trial presented at a time recognised as a risk for pregnancy loss, but also with vaginal bleeding associated with the potential for subsequent miscarriage. Consequently, it was anticipated that safety concerns about their pregnancy would act as a barrier to recruitment. However, recruitment was high, with 56.3% (40/71) of all eligible women agreeing to participate.

One-third of women declined to participate, while the remaining women were either considering a termination of pregnancy or sought acupuncture treatment to avoid being randomised to the touch intervention. The ability of potential participants to access acupuncture treatment privately raises recruitment issues in terms of reduced participation that may not be present in trials offering medical treatment that is new or unavailable in the community. Although Pastore and Dalal (2009) suggested that recruitment may be enhanced for CAM trials due to the opportunity for participants to receive free treatment, when offered a choice to receive acupuncture in a non-randomised group for chronic lower back pain, three out of four participants declined randomisation despite receiving financial advantages if they were randomised (Witt et al. 2006). A consequence of high refusal rates to participate in a trial is that it may result in a non-representative population in acupuncture trials (Sherman et al. 2008). In this study, five of the 31 participants who declined after contact with the researcher (DB) sought acupuncture treatment privately. These women initially received information about the trial through the fertility unit or a midwife. While this was not a high refusal rate, recruitment for this study may have been affected by other potential participants who, after hearing about the trial through these sources, sought acupuncture practitioners rather than contacting the researcher to avoid being randomised to a non-acupuncture group.
Data collection through follow-up telephone calls and accessing ultrasound and hospital birthing records was a successful method to collect pregnancy loss and pregnancy and perinatal outcomes. There was a high compliance rate among participants using the MYMOP questionnaire, the pregnancy-related fear questionnaire and the lifestyle diaries, with all women completing these questionnaires until exiting the trial. However, it should be noted that for the MYMOP questionnaire, the majority of women only wanted to nominate one symptom of concern and two women did not want to nominate any.

It was interesting to note that, while women in the acupuncture group demonstrated a significant difference in the symptom of primary concern compared to the touch group, there was no corresponding significant difference for the outcomes of general wellbeing or pregnancy-related fear. A questionnaire to specifically evaluate anxiety would have been useful to examine the difference between anxiety and the fear of pregnancy loss; this is recommended as a consideration in further research. It was also interesting to note that the women interviewed on exiting the RCT discussed ‘marking time’ until they reached a safety point at 12–13 weeks gestation; this perception of not being safe until this time may have influenced how some women reported their fear relating to miscarriage and general wellbeing in this study.

Although data were collected from women on a weekly basis concerning their diet and lifestyle activities, this frequent data collection did not contribute in a meaningful way to this study. For future research considering the collection of diet and lifestyle information, collection at study entry and when exiting the study would be sufficient to examine the extent of these activities.

Acupuncture protocol

This study involved a pragmatic acupuncture invention with a manualised acupuncture protocol that came from the current recommendations with acupuncture textbooks (Betts 2006; Lyttleton 2004; Maciocia 1998; West 2001). This protocol allowed for the flexibility of an individual diagnosis, delivering what has been termed as
‘representative’ acupuncture (Schnyer et al. 2008, p. 167). This allowed multiple diagnoses and included the use of moxibustion without restricting clinical practice. Of the 29 possible acupuncture patterns of disharmony provided as possible for diagnosis involving threatened miscarriage, 12 were actively used in the study, with no additional patterns of disharmony requiring inclusion. In addition, the documentation concerning predominant diagnostic patterns, although limited to the population in this study, provides further information for acupuncturists to consider beyond that presently accessible in the current textbooks for treatment. Of the 18 women receiving acupuncture, 14 women (77.8%) received an initial diagnosis involving two to three diagnostic patterns. It was also of clinical relevance that of the 12 patterns of disharmony selected at the initial diagnosis, the most frequent pattern (Liver qi stagnation) relates to emotional considerations concerning frustration, depression, anger and emotional stress in TCM (Maciocia 1989). Of the 49 possible acupuncture points listed for use in the study protocol, 28 were used in this study, with one to six points used per treatment.

While the acupuncture diagnosis and point selection in this study reflects the choices made by a single acupuncturist and therefore these 12 pattern of disharmony and 28 points may not be generalisable to clinical practice for other practitioners, they provide a reference point for practitioners that expands on the information currently available to practitioners seeking information on treating women presenting with threatened miscarriage. The range in the acupuncture selection and the number of acupuncture points used for the treatment of threatened miscarriage in this study is comparable with studies examining the diversity of acupuncture for back pain, where various diagnoses were selected and used with a variety of acupuncture points by acupuncturists (Bishop et al. 2011; Kalauokalani et al. 2001). This diversity illustrates the reality in clinical practice and the value of pragmatic acupuncture trials in which acupuncturists have the freedom to choose the acupuncture points they utilise (Thomas et al. 2006; Witt et al. 2006).
8.6 Implications for practice

Interview data from the Western health practitioners’ interviews described that there was a ‘grey zone’ for some women in accessing care once they received a diagnosis of threatened miscarriage. In New Zealand, midwives, GPs with postgraduate training in obstetrics and specialist obstetricians provide care as LMCs. Hospital-based maternity care is also available for women who do not choose an LMC or who are unable to find one. While GPs are funded to diagnose pregnancy and deal with first-trimester complications, once a woman has chosen her LMC, this LMC then assumes responsibility for maternity care with the option to refer as required (Miller et al. 2013). Following confirmation of a viable pregnancy with their GP, the fertility unit or through the MAU, the women in this study were required to find and register with their LMC for ongoing follow-up. Independent midwives stated that, while they were able to receive funding for miscarriage care, any visits or time spent with women specifically for threatened miscarriage was unfunded.

Although all women in the study had access to ultrasound scanning and arranged for an LMC before leaving the study at 12 completed gestational weeks, the study findings suggest there is a potential gap in care. Some women had yet to meet with their LMC or were waiting for an appointment through the hospital because they were unable to find an independent midwife. During this period, there was no official follow-up and no access to personal contact with a health-care practitioner. This time lag may have important emotional consequences for women. Women in the interviews expressed that they felt they were being left to cope on their own until they reached their second trimester. With women identifying important support as having someone knowledgeable to talk to, practitioners who initially see women could consider how they can provide continuing follow-up to support women—perhaps through telephone contact—until they register with their LMC.

The studies using interviews and Internet forums demonstrated that even with personal contact, women with threatened miscarriage may have emotional needs relating to hope and support that are not currently being met by their Western health practitioners. While Western health practitioners were concerned about providing false hope, this study
illustrated how women actively sought hope by finding ‘something they could do’, and they used the Internet to seek hope through the experiences and stories of others. Western health practitioners should consider how hope can act as a coping mechanism for these women. They could then offer interested women support by recommending relevant diet and lifestyle activities that allow women to feel they are doing all that they can through self-care. While this study found that women viewed the Internet as a useful form of support, it may also be relevant for practitioners to recommend relevant Internet sites for women wanting to seek out information and support from others who have experienced threatened miscarriage. As some women challenged medical care and presented inaccurate medical information as facts in these forums, practitioners may also find it useful to initiate a discussion with women about their use of the Internet to discuss any questions and misunderstandings that may arise about the care they are receiving.

The study findings also suggested that acupuncture was viewed as an acceptable treatment among Western health practitioners and was considered by women to provide useful emotional support and relief from physical and emotional symptoms relating to threatened miscarriage. Acupuncturists may have an important role to play in working with Western health practitioners to offer women the care that they perceive as relevant.

The survey of acupuncture practitioners highlighted that they were treating threatened miscarriage and that their main referral base was women that they had previously treated. However, among women entering the RCT, over half (24, 61.5%) had no previous experience of acupuncture, indicating the possibility that women other than those receiving acupuncture treatment may be interested in acupuncture for threatened miscarriage. While Western health practitioners articulated concerns about the safety of Chinese herbal medicine, there was an acceptance of acupuncture as a useful CAM treatment for relaxation. This understanding of the perception of acupuncture by Western health practitioners may provide a useful approach for acupuncturists who are interested in working with Western health practitioners to expand this area of their clinical practice.
8.7 Strengths of this study

This study drew on a range of data sources designed to examine threatened miscarriage from several different perspectives, including that of acupuncturists, Western health practitioners and women experiencing a threatened miscarriage. Technology in the form of an online survey, Skype and an Internet search engine (Google) were used to gather data that would have not otherwise been available in order to fully explore the research questions posed in this thesis. The use of a mixed methods approach allowed for data collection and analysis that resulted in a greater understanding of the research questions than would have been possible if using a quantitative or qualitative approach in isolation.

The use of an online survey made it possible to survey practitioners in New Zealand and Australia without the associated costs of a traditional postal survey. A strength of this survey is the increased validity and reliability achieved through successful piloting and use of a Content Validation Survey undertaken prior to administration. The use of Skype to interview participants provided access to a range of experienced practitioners, which would not have been possible due to cost and time considerations relating to traditional face-to-face interviews. A positive response to using this medium was received from practitioners, with 48 practitioners willing to be interviewed. Collecting data from discussion threads provided a real-time snapshot of women experiencing threatened miscarriage. This avoided the time-lapse difficulties experienced by Warner et al. (2012) where, at the time of the interview, women with problems in early pregnancy had either progressed past the perceived safety of the first trimester or had experienced a miscarriage. This research also contributes to the small but growing body of knowledge that explores how women are using Internet health discussion forums for pregnancy-related issues (Evans et al. 2012; Gold et al. 2012; Hess et al. 2010).

In addition, the pilot RCT in this study demonstrated for the first time that acupuncture may be an acceptable and credible form of treatment for threatened miscarriage in a Western clinical setting. In this RCT, successful treatment allocation was achieved and retention was high in both groups. The use of a pragmatic treatment protocol allowed diagnosis and treatment for underlying TCM patterns of disharmony as well as those
specially addressed within texts for threatened miscarriage, increasing the validity and generalisability for clinical practice. There were 12 TCM patterns of disharmony selected indicating that the range of treatments reflected clinical practice with underlying patterns of disharmony, rather than being limited to the patterns listed within texts for threatened miscarriage. There were no further diagnoses required for the women involved in this trial suggesting this protocol does not need altering for further trials.

A further strength of this study involved the qualitative interviews. These were undertaken with both Western medical and acupuncture practitioners treating threatened miscarriage, as well as with women receiving care for threatened miscarriage; this provided new insights into practitioners’ and women’s experiences of this common complication of early pregnancy.

Finally, it is a strength of this study that a ‘following a thread’ technique was used to integrate the findings. While MMR is becoming more common within health research, the reporting of findings does not always reflect adequate integration (O’Cathain et al. 2008). Dezin (2011) refers to triangulation as using a combination of multiple methodological practices to add rigor and depth to any inquiry. Originally a term to refer to the use of multiple practices within qualitative research, the challenge is now how to define and use triangulation in MMR without creating a hierarchy where qualitative research is used to merely support quantitative findings (Denzin 2012). With complex research designs emerging across different fields, Creswell (2009), comments on how terms such as triangulation may not reflect the future of MMR, with more synergistic approaches where the sum of quantitative and qualitative is greater than either approach alone. The use of a ‘following a thread technique’ is one such method where findings are woven together rather than integrated as qualitative findings adding to the quantitative findings or vice versa.

8.8 Limitations of this study

8.8.1 Acupuncture survey and semi structured interviews
The main limitations of the acupuncture survey related to the low response rate, recall bias and a self-selecting sample. The low response rate may introduce a potential bias reflecting both a non-representative and self-selecting sample. However, the response rate was expected to be low because threatened miscarriage is a very specific aspect of clinical practice for acupuncturists—that of pregnancy-related care. It was unknown what percentage of practitioners in Australia and New Zealand were actively treating women during pregnancy. A 2012 survey of UK acupuncture practices reported that for their 10 most recent patients, 13% of traditionally trained acupuncturists had treated an obstetrics-related condition (Hopton et al. 2012), which suggests that this area of clinical practice may be an area of growth and clinical development. There was also a practical consideration that, in order to preserve confidentiality, the link to the survey was sent out through the professional organisations’ own mailing lists. There is a high probability that some practitioners belong to multiple organisations, resulting in overlapping numbers of members being counted in the final number of online survey invites sent out. In an Australian survey of acupuncture practitioners, tracking and adjusting for these multiple members increased the survey response rate from 15.7% to 25% (Choy et al. 2010).

While there are no published surveys for New Zealand acupuncture practitioners, the demographics for the practitioners responding to the online survey mirrors that of practitioners surveyed in Australia by Choy et al. (2010), with more female than male practitioners, over 50% of practitioners having a bachelor’s qualification and over 50% of practitioners practicing for less than 10 years, suggesting that this survey was representative. The threatened miscarriage survey in this thesis asked practitioners to self-report treatment over the past year; thus, the findings are subject to recall bias. However, despite these limitations, an online survey allowed valuable practitioner information to be collected in this specialised area of practice for the first time.

Acupuncture practitioners may have moderated their interview responses due to awareness that the interviewer was the author of a textbook on the use of acupuncture during pregnancy. This may have influenced participants’ responses regarding the treatments recommended in the textbook. However, due to the findings of these interviews, in which acupuncturists discussed the diversity of practice and the use of
acupuncture points and modalities not recommended in the textbook, these considerations were unlikely to be a source of bias in the study.

A final limitation of this survey and interviews is that it involved practitioners from Australia and New Zealand; therefore, these findings may not be generalisable outside of this geographical area.

8.8.2 Pilot RCT and semi structured participant interviews

A limitation of the RCT was the use of a sole practitioner to deliver the treatment when using a pragmatic protocol allowing for multiple diagnosis and treatment flexibility. This has the potential to introduce a practitioner treatment bias that may not be generalisable to clinical practice for other practitioners. The findings from the survey indicated that there is a wide range of treatment methods used amongst practitioners when treating women presenting with threatened miscarriage. In view of this it may not be acceptable to practitioners to have a strict manualised protocol, however future pragmatic trials involving several acupuncturists would reduce the potential for sole practitioner treatment bias.

The use of an active control group receiving touch was a limitation in that both groups received non-specific effects relating to supportive care. Acupuncture can be considered to be a complex treatment that incorporates non-specific effects. These may involve touch, resting for the treatment time and consultation with a practitioner, all of which occurred in the touch control. This may have impacted negatively on the findings for the acupuncture group. The ideal pragmatic control is one of usual care. However the current care within the Wellington and Hutt area involves no medical treatment or follow up and it was not seen as ethical to randomise women to receive no care when experiencing threatened miscarriage. Future trial designs using a control that offered routine monitoring or telephone follow up would provide a control offering support without the non-specific effects of touch.

In the RCT, there was also lack of direct referral from GP practitioners, which may represent selection bias of a non-representative population of women entering the trial. The delay at baseline for women from both groups between their vaginal bleeding
commencing and their entry into the trial suggested that trial findings cannot be generalisable to a wider group of women presenting with threatened miscarriage.

The methodological limitations and biases arising from the interviews relate to human interaction, which may, even when unintended, influence the interviewer or the research participants. To avoid interviewer bias arising from personal interest through delivering the treatment in the RCT, a researcher who did not deliver the treatment interviewed the participants. However, because the women being interviewed were aware that the researcher who delivered the treatment (DB) would see the interview data, this may have influenced their responses, creating participant responses that were more positive about their experiences. It may have also been that as this researcher had no experience of acupuncture, bias resulted from the interviewer not understanding some of participant’s responses to their acupuncture treatment that may have been explored in greater depth by an acupuncturist. The timing of the interviews may also have been a limitation as participants’ recollections of their experiences may have been positively influenced because they were interviewed as they entered their second trimester with a viable pregnancy. Recall bias was also possible because women were interviewed on leaving the trial several weeks after they received their first treatments.

8.8.3 Western trained health practitioners interviews

When interviewing Western health practitioners, participants’ responses may have been influenced through the awareness that the interviewer (DB) was conducting an RCT involving acupuncture. This could result in participants underreporting responses about any concerns they may have for acupuncture as a treatment for threatened miscarriage. However, due to the findings of these interviews, where acupuncture was regarded as one of many possible CAM treatments that had no effect on pregnancy outcomes, this appears unlikely. With a limited GP voice from the Western health practitioners’ interviews, it is possible that the views of GPs have not been adequately reflected; however, there were no new themes generated by the one GP who was interviewed.
8.8.4 Threatened Miscarriage Internet forums

The use of online forums to collect data also introduces potential bias from a non-represented sample and a self-selecting population. Although theoretically open to any member of the public, those participating required basic computer skills, access to a private or public Internet connection and an appropriate level of English literacy, limiting access to those who were able to post in forums. Possible selection bias may have also been present in the findings because only open-access forums were used. Different experiences, information and opinions may be expressed in discussion groups that require members to join and use a password before postings can be made or read. The data collected in these forums were made by those who actively posted; thus, the experiences, information and opinions of those prepared to post may be different to those who only read the postings. Due to the nature of posting in these forums, threads are abandoned rather than completed. Therefore, the effect or usefulness of the postings to those in the thread was not always apparent. In addition, in this type of media, experiences, information and opinions that were not considered acceptable or relevant in the thread may have been ignored rather than commented on. This may have distorted the effect of certain postings, reflecting the nature of Internet postings rather than the experiences of women with threatened miscarriage. However, despite these limitations, the use of Internet forum discussion groups provides a window of opportunity to examine how women experience threatened miscarriage from a different perspective than that provided when directly questioning women about their experiences through surveys, interviews or focus groups.

8.9 Recommendations for future research

1. Women identified a need to receive emotional support, including that of hope, from health-care practitioners. Future research could explore the type of care that women presenting with threatened miscarriage consider supportive. As women used the Internet for support, further exploration of possible support provided through web-based Internet sites is required.

2. Acupuncture treatment benefited women by meeting their emotional needs for hope and support and demonstrating changes to symptoms that related to threatened miscarriage. Determining the effect of supportive care and
acupuncture for women is particularly relevant in the current absence of any recommended pharmacological or non-pharmacological interventions and the dissatisfaction women expressed within this study concerning the care and support they received. It may be that women’s emotional needs may be met through providing emotional support alone. A consideration for future research is that women participating in the RCT identified having someone to talk to as important. Counselling would be a suitable comparison and has been identified in recent research as suitable to evaluate the clinical and economic impact of acupuncture care within depression (MacPherson et al, 2013). Further research is also needed to determine if the symptom changes relating to threatened miscarriage found within the acupuncture group are generalisable to other populations, and if this symptom reduction affects miscarriage rates. The pilot study suggests a future study focusing primary outcomes on threatened miscarriage symptoms using acupuncture plus a supportive care intervention versus a supportive care intervention alone would be acceptable. Based on pilot data a medium size effect is expected, and allowing for a 30% loss, it is estimated that a total sample size of 170 women is required. To determine acupuncture specific effects future research could focus on women receiving usual care rather than touch, for example in a population of women receiving fertility treatment with usual care in the form of ultrasound monitoring.

3. The acupuncture survey demonstrated an interest in treating threatened miscarriage. Although this survey and the practitioner interviews also identified safety concerns that acupuncture may stimulate a miscarriage and concerns over locating quality treatment information. Practitioners also identified that although they may consider Chinese herbal medicine useful, there was concern over the medical and public perception of these as safe to take. These are valid concerns that should be addressed within future research through monitoring and reporting on treatments delivered as well as further qualitative exploration on how safety is understood within clinical practice. Practitioner concerns over safety may also act as a barrier to acupuncturists providing treatment. Although acupuncturists treating threatened miscarriage justified their treatment as safe, diverse treatments were used without an evidence-based rationale. Practitioners also identified the difficulties in obtaining treatment knowledge that they trusted in this specialised area of practice, with a preference for historical sources, their
own clinical experience and those of experienced practitioners over Western diagnostic information. Future research that would be useful to acupuncturists could explore experience-based knowledge, such as the use of a Delphi consultation process with experienced practitioners. This type of research could be used to explore these practice concerns and make recommendations that would be viewed as valuable by acupuncturists in clinical practice.

8.10 Conclusion

Threatened miscarriage is a common complication of early pregnancy, with risk factors for miscarriage and pregnancy complications that include premature delivery. Currently, there is limited recognised pharmacological management and self-care advice in Western medicine to offer as treatment to women, which has resulted in medical monitoring with a ‘watchful waiting’ approach.

The overarching aim of this study was to explore supportive care, with a specific focus on the role of acupuncture in the treatment of threatened miscarriage. This was undertaken by examining the current use of acupuncture among acupuncturists and the use of acupuncture compared to an active control group receiving touch in a Western clinical setting. In addition, the experiences of acupuncturists and Western medical practitioners treating women were explored, as well as the experiences of women with threatened miscarriage. The findings can be summarised as follows:

- Women expressed that Western health practitioners did not meet their emotional needs and that they were seeking care beyond that of medical monitoring. They expressed the need for hope, to feel more in control through diet and lifestyle activities, and that it was useful to have someone to talk to while they waited for the perceived safety of the second trimester.

- Acupuncture was a feasible treatment to offer in a Western clinical setting and demonstrated a statistically significant improvement for threatened miscarriage symptoms rated by women as a concern.

- Acupuncture was used by acupuncturists in clinical practice as a treatment for threatened miscarriage, with diverse treatment approaches. The potential for treatment to stimulate a miscarriage if used incorrectly was an important
concern, with practitioners justifying the safety of their treatment through the interpretation of historical knowledge and personal experiences rather than a rationale from evidence-based practice.

- Western health practitioners saw themselves as providing medical monitoring that was useful to provide women with realistic reassurance or to prepare them for possible miscarriage. Care was focused on providing accurate medical information and achievable lifestyle advice so that women would not blame themselves in the event of a miscarriage.

- Acupuncture was perceived by acupuncturists as a qi-based treatment with the potential to stimulate positive pregnancy responses according to TCM theory through the use of needles, diet and lifestyle activities, and by providing therapeutic practitioner support. In contrast, Western medical practitioners viewed acupuncture as a safe CAM treatment that could be used to reduce women’s anxiety, but one that was optional to offer women because it would not affect pregnancy outcomes.

These findings provide information for both Western health practitioners and acupuncturists concerning the use of acupuncture and supportive care for women presenting with this common pregnancy complication. In addition, these findings can provide direction for future research in this area, for which there are currently no recommended treatment interventions.
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Appendices

Appendix A  Acupuncture as a therapeutic treatment option for threatened miscarriage
Appendix B  Survey on the use of acupuncture in the treatment of threatened miscarriage
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DIET AND LIFESTYLE SHEET FOR THREATENED MISCARRIAGE

The following information represents the best evidence medicine advice currently available and is intended as a guide to assist you in making dietary and lifestyle choices at this time in your pregnancy.

**Alcohol:** Alcohol crosses placental barrier which means that any alcohol you drink passes through to your baby. At present it is not known if alcohol is safe during pregnancy or how much alcohol you need to drink before it becomes a problem for your baby. The New Zealand Ministry of Health guidelines recommend the safest approach is to choose not to drink at all while pregnant.


If you would like further information, are worried about the amount the alcohol you are drinking or unable to stop drinking, you can speak to your doctor or midwife for support and advice or phone 0800 787 797 for a free support helpline.

**Bed rest:** There is no evidence that being on complete bed rest, either at home or in a hospital reduces your risk of miscarriage.

**Caffeine:** Caffeine crosses the placental barrier. High levels of caffeine during pregnancy may increase the risk of miscarriage or having a baby with a low birth weight. Although high levels are found in coffee, caffeine can also be found naturally in tea and cola drinks. The recommendation is to reduce the amount of caffeine you drink during pregnancy to a maximum of the 300mg per day.

The following is a list of the average caffeine content that can be found in:

- 1 regular long black coffee 211 mg
- 1 cappuccino 105 mg
- 1 cup plunger coffee 66 mg
- 1 cup of instant style coffee 51 mg
- 1 cup of tea (loose leaves) 57 mg
- 1 cup of tea (tea bag) 47 mg
- 1 regular cola drink 35 mg

Energy drinks may also contain caffeine which has been added. These drinks may also contain other ingredients not recommended for pregnant women. Swapping regular coffee for decaffeinated varieties which will reduce caffeine intake, however safe levels of decaffeinated products for pregnant women are as yet unknown.

For further information about the caffeine content in food and drink
Cigarette smoking: The detrimental effects of cigarette smoking are well documented and show an increased risk factor for miscarriage as well as problems later in pregnancy such as babies that are born prematurely, low birth weight babies and stillbirth. If you are interested in stopping or reducing your smoking your doctor or midwife can give advice about the options there are to help you while you are pregnant. Further advice is also available at: Quitline http://www.quit.org.nz or phone 0800 778 778 to speak to a Quitline Advisor for free telephone support.

Exercise: There is no evidence to show a link between exercise in early pregnancy and miscarriage, however if you are have vaginal bleeding it is advised that you seek the medical advice from your doctor or midwife before commencing or continuing with an exercise programme.

Multivitamin supplements: For most women, with the exception of a pregnancy folate supplement, vitamins are not recommended during early pregnancy. There is the concern that supplements not designed for pregnancy may be associated with excessive doses of certain nutrients, such as Vitamin A. A healthily diet is recommended as the best way to obtain the vitamins and minerals required in early pregnancy. However women with vegetarian and vegan diets may require additional supplementation and will need to discuss this with their doctor or midwife. For further information on eating a healthy diet in pregnancy: http://www.nhmrc.gov.au/publications/synopses/ds10syn.htm

Sexual Intercourse: This is a personal choice for couples as there is no evidence that sexual intercourse increases your risk of a miscarriage.

For further advice about any of the diet and lifestyle information in this leaflet please consult your doctor or midwife.

If you have any questions or concerns about the information provided in this leaflet please contact:
Debra Betts
Phone 04 479 4054
Mobile 021 151 0714.
E Mail: 16910687@student.uws.edu.au
Interview Schedule

This schedule will remain flexible to focus on aspects participants deem to be important.

**Aim:** To identify what practitioners consider key aspects of acupuncture treatment for women experiencing threatened miscarriage. Participants will be engaged in semi-structured interviews to explore their experiences of providing care. In particular, practitioners will be invited to share stories that illustrate the treatment modalities they use and identify any specific treatment issues they may have around determining best practice and their expectation of treatment within a clinical environment.

The following questions will all be covered during the interview, although the interviewer will not necessarily ask each question in any set order, instead following the participant’s conversation flow, seeking further clarification as required using open-ended questions such as ‘Can you tell me more about that?’ or ‘What is your opinion on this?’

**Introduction**

I have some questions to ask you about your expectations and what you consider the key aspects in the treatment of threatened miscarriage. Please feel free to bring up any comments as they come into your mind—these questions do not need to be answered in any special order. If you feel uncomfortable with any of the questions, please tell me. I can stop the interview and halt the recording at any time.

**Questions**

1) It would be helpful if you could tell about your experience in treating threatened miscarriage.

   A) How did you start to treat women for threatened miscarriage?
Appendix D. Interview Schedule for Acupuncture practitioners

B) What, if any, are the differences in the way you approach treatment today from when you first began treating?

2) There are different opinions expressed in the textbooks concerning the use of abdominal points in the treatment of threatened miscarriage
   A) What specific needling and/or moxa techniques do you use with these points and why?
   B) Are there any situations where you would choose not to use these points?

3) A TCM diagnosis of ‘blood stagnation’ is referred to in textbooks as an uncommon reason for threatened miscarriage or as only occurring in association with trauma.
   A) Does this opinion reflect your experience in clinical practice?
   B) What presenting diagnostic factors do you consider crucial for a TCM diagnosis of blood stagnation?
   C) What, if any, influence does an ultrasound scan report detailing a hematoma have on your TCM diagnosis?
   D) When treating blood stagnation, what specific needling and/or moxa techniques do you use and why?

4) There are different opinions expressed in the textbooks concerning points said to be forbidden or contraindicated during pregnancy. Can you tell me about any points you do not use and why you do not use these in the treatment of threatened miscarriage?

5) When choosing the acupuncture points for treatment, do you have any specific considerations around the number of acupuncture points or needling techniques you use for women presenting for threatened miscarriage?

4) Acupuncture treatment can also involve a variety of treatment modalities such as the use of moxibustion, cupping, electrical stimulation, dietary and lifestyle advice and herbal medicine.

   A) What treatment modalities’ do you consider the most useful when treating threatened miscarriage?
   B) Do you have concerns about any treatment modalities that you feel should not be used?
   C) What are your views on the use of Chinese herbs for the treatment of threatened miscarriage?
   D) Is there any particular diet and lifestyle advice (TCM or medical) that you feel women should be aware of?
Appendix D. Interview Schedule for Acupuncture practitioners

5) In your opinion, what are the possible benefits that a woman gains from having acupuncture treatment at this time?

6) What criteria do you use for determining if the acupuncture treatment the woman receives has been useful?

7) Is there anything else that you would like to say about the treatment of threatened miscarriage?
The Role of Acupuncture Treatment with the Management of Threatened Miscarriage: An exploratory study

Acupuncture treatment

This involves receiving an acupuncture treatment that may include: needles, moxibustion therapy, cupping, dietary and lifestyle advice that is specific to the acupuncture diagnosis made by the acupuncturist.

Treatment consists of two treatments in the first week of entering the trial followed by a weekly visit until participants reach 12 completed weeks of gestation.

Treatment protocols include:

1. treatment based on an eight-principals TCM diagnosis
2. a selection of acupuncture points for each TCM diagnosis along with the appropriate indications for the use of moxibustion and/or cupping
3. recommendations for dietary and lifestyle advice that are specific for each TCM diagnosis
4. needling specifications for needling depths according to a recognised acupuncture text (Deadman, Al-Khafaji & Baker 2001)
5. needling, moxibustion and cupping techniques for early pregnancy according to recognised acupuncture obstetric texts (Betts 2006; Maciocia 1998; West 2001)
6. needling technique for obtaining deqi for each point and needle retention time of 20–30 minutes at each session
7. number of acupuncture points pre-treatment to be chosen by acupuncturist as required through acupuncture diagnosis, with the minimum number of acupuncture points being one and six being the maximum number of acupuncture points to be used in any one treatment.

All acupuncture treatment to be carried out in accordance with the ethical and skin penetration guidelines issued by the New Zealand Register of Acupuncture.
A written sheet detailing dietary and lifestyle risk factors is to be given to women receiving acupuncture care. These diet and lifestyle sheets are based on the TCM diagnosis women receive.

**Acupuncture diagnosis**

Diagnosis will include pattern differentiation based on a TCM paradigm and a treatment documented within a recognised acupuncture obstetric text (Betts 2006; Maciocia 1998; West 2001). Terminology of TCM terms and meridians based on WHO International Standard Terminologies (WHO 2007).

**Lung Disharmonies**
- Lung qi deficiency
  LU 9, BL 13, BL 43
- Lung yin deficiency
  LU 9, BL 13, BL 43

**Kidney Disharmonies**
- Kidney qi deficiency
  KI 3, CV 4, GV 4, BL 23, GV 20
- Kidney yin deficiency
  KI 3, CV 4, GV 4, BL 23, GV 20, CV 4
- Kidney yang deficiency
  KI 7, CV 4, GV 4, BL 23, GV 20, CV 4

**Spleen Disharmonies**
- Spleen qi deficiency
  GV 20, BL 20, BL 21, BL 43, CV 4
- Spleen yang deficiency
  GV 20, BL 20, BL 43, CV 4
- Spleen failing to control the blood
  GV 20, BL 17, BL 20, CV 4, SP 10
- Dampness damaging Spleen yang
  SP 9, CV 12, BL 20, BL 21
Appendix F. Acupuncture and Touch Protocols for RCT

- Spleen deficiency with dampness accumulation
  SP 9, SP 9, CV 12, BL 20, BL 21
- Sunken Spleen qi
  GV 20, BL 20, CV 4
- Spleen—Stomach weakness
  BL 20, ST 36

**Heart Disharmonies**

- Heart qi deficiency
  PC 6, HT 5, BL 15, CV 17, Yin Tang
- Restless Heart qi
  PC 6, Yin Tang, GB 13, DU 24
- Heart yin deficiency
  HT 7, PC 6, HT 6, KID 7, KI 6, CV 14, Yin Tang
- Heart yang deficiency
  PC 6, HT 5, BL 15, CV 17
- Heart blood deficiency
  HT 7, PC 6, CV 14, CV 15, BL 17, BL 20
- Phlegm—fire harassing the Heart
  PC 7, CV 17, BL 15, CV 12, ST 40, LR 2, LR 3

**Liver Disharmonies**

- Constrained Liver qi
  LR 3, LR 14, LR 13, PC 6
- Liver blood deficiency
  BL 17, BL 18, BL 20, LR 8, ST 36
- Ascendant hyperactivity of Liver yang
  LR 2, LR 3
Appendix F. Acupuncture and Touch Protocols for RCT

**General Disharmonies**

- Qi deficiency
  GV 20, ST 36, CV 12, CV 4
- Qi deficiency failing to control Blood
  GV 20, ST 36, BL 17, CV 4
- Qi deficiency with Blood stasis
  GV 20, ST 36, SP 10, BL 17, KI 9, CV 4
- Blood stasis
  SP 10, BL 17, KI 9
- Blood heat
  SP 10, BL 17, LI 11, LR 2, LR 3, SP 1, KI 2, PC 3
- Trauma
  GV 20, CV 12, PC 6

**Exterior Disharmonies**

- Exterior cold
  LU 7, TE 5, GB 20
- Exterior heat
  LI 11, TE 5, GV 14, GB 20

**Touch Intervention**

The active control group will receive touch care in the form of light pressure applied to non-acupuncture points to provide non-specific therapeutic effects.

This touch treatment will consist of light pressure to each of the five points outlined below for four minutes for each point. Treatment consists of two treatments in the first week of entering the trial followed by a weekly visit until participants reach 12 completed weeks of gestation.

Touch is included to account for the non-specific therapeutic treatment effects that can be seen to be present in the acupuncture treatment group, such as attention, care, respite from daily stress, being placed in a relaxing environment, receiving treatment, and spending time with, and being touched by, a treatment provider.
A written sheet detailing dietary and lifestyle risk factors will also be given to women receiving supportive care treatment.

**Touch Protocol**

Each of the following five points will be lightly held for four minutes, giving an overall treatment time of 20 minutes, with the points to be used in the following order.

<table>
<thead>
<tr>
<th>Point</th>
<th>Patient position</th>
<th>Anatomical landmark</th>
<th>Point location</th>
<th>Relationship to channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot</td>
<td>Supine</td>
<td>Metatarsal bones</td>
<td>Dorsum of the foot. In the hollow distal to the junction of the 3rd and 4th metatarsal bones</td>
<td>Midway between the GB and ST channel, approximately at the level of LR 3</td>
</tr>
<tr>
<td>Lower leg</td>
<td>Supine, knee partly flexed</td>
<td>Anterior crest of tibia</td>
<td>On the anterior crest of the tibia, 7 cun below the base of the patella</td>
<td>1 cun distal and 1.5 cun medial to ST 37</td>
</tr>
<tr>
<td>Forearm</td>
<td>Supine</td>
<td>Lateral epicondyle of the humerus</td>
<td>On the extensor surface of the forearm</td>
<td>Midway between LI and TH channels one cun distal and one cun lateral to LI 11</td>
</tr>
<tr>
<td>Hand</td>
<td>Supine</td>
<td>Metacarpal bones</td>
<td>Dorsum of hand in the hollow distal to the base of the 2nd and 3rd metacarpal bones</td>
<td>Midway between the SJ channel and the extra point Luozen (M-UE-24), approximately at the level of SI 3</td>
</tr>
<tr>
<td>Chest</td>
<td>Supine</td>
<td>Clavicle</td>
<td>Antero lateral aspect of the chest. Inferior border of the clavicle, 5 cun lateral to the midline</td>
<td>Midway between the ST and LU channels—at the level of ST 13 and LU 2</td>
</tr>
</tbody>
</table>
Appendix G. TCM Diet and lifestyle information sheets for RCT

**BLOOD DEFICIENCY**

The concept of blood in traditional Chinese medicine shares a close relationship with the Western concept in that it has both a nourishing and moistening function. However, with the concept of Blood deficiency, there is also an emphasis placed on your body’s qi. Blood is seen as a condensed form of qi, with qi playing a vital role in helping the blood to circulate to where it is needed.

Attention is also focused on the strength of your digestive system’s ability to successfully obtain the nutrients from your food necessary for the production of blood.

Food to build blood includes:

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grains</td>
<td>Barley, corn, oats, rice, sweet rice, wheat, bran</td>
</tr>
<tr>
<td>Vegetables</td>
<td>Alfalfa sprout, artichoke, beetroot, button mushroom, cabbage, celery, dandelion leaf, dark leafy greens, kelp, shiitake mushroom, spinach, watercress, wheatgrass</td>
</tr>
<tr>
<td>Fruit</td>
<td>Apple, apricot, avocado, date, fig, grape, mulberry</td>
</tr>
<tr>
<td>Beans</td>
<td>Aduki, black soya, kidney</td>
</tr>
<tr>
<td>Nuts and seeds</td>
<td>Almonds, black sesame</td>
</tr>
<tr>
<td>Fish</td>
<td>Mussel, octopus, oyster, sardine, tuna</td>
</tr>
<tr>
<td>Meat</td>
<td>All red meat</td>
</tr>
<tr>
<td>Dairy</td>
<td>Chicken egg</td>
</tr>
<tr>
<td>Herbs, spices</td>
<td>Nettle, parsley</td>
</tr>
<tr>
<td>Oils, condiments</td>
<td>Amasake, molasses</td>
</tr>
<tr>
<td>Beverages</td>
<td>Soya milk</td>
</tr>
<tr>
<td>Common supplements</td>
<td>Algae</td>
</tr>
</tbody>
</table>

Examples of every day Western foods that can be used to build Blood include:

- Rice porridges with soya milk, apricots and almonds
- Dark leafy green salads with avocado and grated beetroot
- Roast chicken with stir-fried mushrooms and dark green vegetables
- Scrambled eggs with parsley
- Snacks of dried apricots and almonds
- Kidney bean and mushroom lasagne with a spinach salad
- Any red meat dish (note that in TCM, meat is viewed as a strong tonifying food to be eaten in small amounts so that serving sizes are based around two to four ounces per serving, taken several times a week depending on individual energetic patterns).

DAMPNESS

In traditional Chinese medicine dampness represents a condition existing in the body that is a reflection of dampness as it occurs in nature. Dampness results from the body being affected in several ways, such as a problem arising from the inability of the digestive system to transport fluids or from the body being overwhelmed by external damp from the environment (damp weather, damp living conditions, damp-producing foods). It can also arise as a response to an illness or from the overuse of medication that promotes dampness, such as certain antibiotics. Phlegm is seen as a condensed form of dampness. Foods to resolve dampness include:

Grains
- Corn, barley, basmati rice

Vegetables
- Alfalfa sprout, button mushroom, caper, corn, pumpkin, radish, turnip

Fruit
- Papaya, lemon, umeboshi plum

Beans
- Aduki, lentils

Fish
- Eel, tuna

Herbs, spices
- Aniseed, garlic, horseradish, marjoram, nettle, parsley, white pepper

Beverages
- Green tea, jasmine tea

Foods to avoid in cases of dampness

It is essential that those prone to dampness avoid excessive amounts of food that will contribute to promoting dampness in the body these include:

- Dairy products, including milk, cheese, ice cream and all foods that contain high amounts of dairy products such as dairy milk chocolate; sheep and goat products are regarded as less prone to causing dampness
- Pork and rich fatty meats
- Roasted peanuts, including peanut butter
- Concentrated fruit juices, especially orange and tomato juice
- Excess refined-wheat products
- Bananas
- Sugar and sweeteners
- Saturated fats, especially deep-fried foods

In dampness and phlegm, it is important to nourish the spleen, which means that the consumption of raw, cold and processed sugary or fatty foods needs to be limited to aid the spleen’s essential digestive function.
Appendix G. Diet and lifestyle information sheets for RCT

**QI DEFICIENCY**

Qi is the term used in traditional Chinese medicine to describe your body’s energy. Qi flows around your body in a series of meridian pathways, which are separate from your circulatory, lymphatic and nervous systems. They influence the way in which your body functions. The qi that is presently in your body is a combination of your genetic makeup at conception, how you have lived your life since birth and your daily intake of food and air.

Foods that build qi include:

- **Grains**
  - Barley, buckwheat, corn, lentil, oats, rice, sweet rice, wheat bran
- **Vegetables**
  - Asparagus, button mushroom, cabbage, eggplant, peas, potato, pumpkin, shitake mushroom, squash, sweet potato, tomato, yam
- **Fruit**
  - Apple, cherry, date, fig, grape, logan
- **Bean products**
  - Black soya, chickpeas, kidney, tofu
- **Nuts and seeds**
  - Almond, black sesame seeds, coconut (meat), peanut, walnuts
- **Fish**
  - Eel, herring, mackerel, mussel, octopus, oyster, sturgeon, tuna, trout
- **Meat**
  - Beef, chicken, chicken liver, duck, goose, ham, lamb, pheasant, quail, rabbit
- **Dairy**
  - Chicken egg
- **Herbs and spices**
  - Bay leaves, liquorice
- **Condiments**
  - Barley malt, honey, molasses, rice syrup
- **Supplements**
  - Algae

Examples of everyday Western foods that can be used to build qi include:

- Oat porridge with dates and honey
- Roasted sweet potatoes with pumpkin and yams
- Chicken stir fry with shitake mushrooms and rice
- Shepherd’s pie with beef or lamb mince, mushrooms, carrots and mashed potato as a topping
- Tuna fish pie made with hard-boiled eggs and served with mashed potatoes, peas and corn
- Stir-fired tofu, eggplant and mushrooms with black sesame seeds on rice
- Homemade oat/muesli slice with honey and dates

**Foods to avoid**

People with Qi deficiency tend to seek out sweet foods. In traditional Chinese dietary therapy, there are two categories for sweet foods. The first is termed ‘empty sweet’, which in small amounts is considered cooling and eliminating. It contains simple sugars such as fruits, juices, honey and raw sugar. The second category is termed ‘full sweet’ and is considered warming and nourishing. It includes complex carbohydrates, protein and tonifying herbs, as well as food such as rice, potatoes, meat and red dates.

TRUE HEAT

In true heat, the body’s yin energy, which is responsible for moistening and cooling the bodily functions, has been overwhelmed by excessive heat.

Heat may arise in several ways, including exposure to excessive heat in the environment. True heat may also be due to an excess of heat-producing foods and drinks such as alcohol and coffee. This can be further aggravated by tobacco. True heat can also arise in response to an acute feverish illness. Foods that are useful to remove heat include:

- **Grains**: Barley, buckwheat, millet, wheat, wheat bran, wheat germ
- **Vegetables**: Asparagus, aubergine, cabbage, celery, Chinese cabbage, cucumber, dandelion leaf, lettuce, mung bean sprout, potato, seaweed, turnip
- **Fruit**: Apple, banana, blueberry, cranberry, fig, grapefruit, lemon, lime, mango, melon, pear, persimmon, pineapple, plum, rhubarb, watermelon
- **Beans**: Kidney, mung, yellow soy, tofu
- **Bean products**: Kidney, mung, yellow soy, tofu
- **Fish**: Abalone, crab, fresh and salt water clam, octopus
- **Herbs and spices**: Liquorice, tamarind
- **Oils and condiments**: Sesame oil, agar
- **Beverages**: Chrysanthemum tea, dandelion root, elderflower tea, peppermint tea
- **Supplements**: Kelp

Examples of everyday Western foods that can be used to eliminate true internal cold include:

- Water with freshly squeezed lemon juice
- Herbal teas such as peppermint or chrysanthemum
- Fruit salads with any of the above fruits
- Lettuce salads with cucumber, tomato and mung beansprouts
- Soft tofu blended with fruits as a dessert
- Agar fruit jellies with mango
- Mixed-bean salads with kidney beans
- Vegetable juices such as celery
- Fruit juices such as apple, pear and grapefruit juice

**Foods to avoid in cases of heat**

For those with true heat conditions, it is important not to add to this by consuming food and drink that will add further heat and stimulation to their bodies. This includes caffeine, alcohol, sugar and strong heating/pungent spices.
YIN DEFICIENCY

Yin represents the energy that is responsible for moistening and cooling bodily functions. When this energy is depleted, your body begins to show signs of ‘heating up’. This is not a true heat, but rather a lack of the moistening and cooling functions that are necessary to maintain a healthy balance. Foods to tonify yin include:

- **Grains**: Barley, millet
- **Vegetables**: Alfalfa sprout, artichoke, asparagus, kelp, mung bean sprout, pea, potato, seaweed, string bean, sweet potato, tomato, water chestnut, yam, zucchini
- **Fruit**: Apple, apricot, avocado, banana, lemon, lime, mango, mulberry, pear, persimmon, pineapple, pomegranate, watermelon
- **Beans**: Adzuki, black beans, black soya, kidney, lima, mung
- **Bean products**: Tofu
- **Nuts and seeds**: Coconut milk, sesame seed, black sesame seed, walnut
- **Fish**: Fish in general but especially clam, fresh water clam, crab, cuttlefish, oyster, octopus, sardine
- **Meat**: Beef, duck, goose, pork, pork kidney, rabbit
- **Dairy**: Cheese, chicken egg, cows milk, duck egg
- **Herbs and spices**: Marjoram, nettle
- **Oils and condiments**: Honey, malt

Examples of everyday Western foods that can be used to build yin include:

- Fruit smoothies with honey and banana
- Fruit salad made with the fruits listed above
- Fish dishes with coconut milk
- Omelettes with cheese
- Asparagus and egg salads with sesame seeds
- Tacos made with kidney beans and topped with a small amount of cheese
- Baked potato with tofu, soya sauce and sesame seeds
- Pork and apple dishes
- Miso soup with tofu and seaweed

Foods to avoid

It is important to ensure that stimulating foods are not being consumed, as they will only further deplete yin. Caffeine, alcohol, sugar and strong heating/pungent spices all belong in this category. Note: Yin-building foods such as yin-tonifying herbs have a tendency to congest the spleen and promote stagnation if large amounts are consumed. It is therefore important to consume small quantities frequently rather than large quantities irregularly.

YIN DEFICIENCY

Yin represents the energy that is responsible for moistening and cooling bodily functions. When this energy is depleted your body begins to show signs of ‘heating up’. This is not a true heat, but rather a lack of the moistening and cooling functions that are necessary to maintain a healthy balance.

When the body’s yin becomes depleted, it can be more difficult to handle stress and calm your mind, especially in the evening. This can result in problems such as insomnia, which involves finding it difficult to fall off to sleep at night, as well as reoccurring anxiety or a general feeling of ‘stress’.

There are lifestyle activities that can help to preserve and nourish your Yin energy. It is important to find an activity that you find restful and calming. This can be anything that creates a feeling of peacefulness and does not involve talking. While this sounds simple, it can be difficult to put into practice. It is important that this calming activity is practised regularly, ideally on a daily basis.

Ten minutes of simple breathing exercises every day (even if the rest of the day is filled with stresses at home or at work that are beyond your control) will be more beneficial over time than nothing all week followed by an hour of meditation on a Saturday morning. It is the regularity of calming practice that has the more positive effects over time.

Create a quiet space in the evening at least two hours before going to sleep—this may mean shutting down the computer, turning off the television at a set time or ensuring that any work to be done at home is abandoned at a set time.

Create a daily time to help quiet your mind. If you have found meditation techniques useful in the past, you can recommence this practice; however, if you have always found meditation and relaxation exercises difficult, it is important to remember that you do not have to meditate for lengthy periods to achieve beneficial results.

A practical method is to take an almond or raisin and place it in your mouth for 5–10 minutes. For this time, you can concentrate on the taste, bringing your mind back to this sense whenever your mind wants to wander. It can be useful to start with five minutes (set a kitchen timer) and work your way up to 10 minutes over several weeks.

Where possible, avoid activities that you find stimulating or that leave you feeling anxious. While it may be a usual activity for you to read the newspaper or watch the television news or certain dramas, pregnancy can be a time when you are more sensitive to the subject matter covered. It can be beneficial to acknowledge this difference while pregnant and focus on reading positive books, watching happy videos and spending time with friends to reinforce a positive approach.

Appendix G. Diet and lifestyle information sheets for RCT

QI DEFICIENCY

Qi is the term used in traditional Chinese medicine to describe your body’s energy.

Qi flows around your body in a series of meridian pathways that are separate from your circulatory, lymphatic and nervous systems. They influence the way in which your body functions. The qi that is presently in your body is a combination of your genetic makeup at conception, how you have lived your life since birth and your daily intake of food and air.

When your qi becomes deficient, there is often a feeling of being tired and ‘just not right’ rather than a specific symptom that can be diagnosed as a problem with Western medicine. For example, if the qi deficiency involves your lungs, you may continually catch colds. If the qi deficiency involves your digestive system, you may frequently experience loss of appetite or feel bloated after eating. If the qi deficiency involves other systems, there may be symptoms such as a tendency to experience palpitations when tired or a sore, achy lower back that only comes on at the end of a long day or when you are tired. These symptoms can indicate that your body requires more qi for optimal functioning. This can be achieved through a healthy diet and sufficient rest.

It is seen as an important concept in traditional Chinese medicine that you nourish your qi in early pregnancy and pay attention to any areas that require special attention, as this will assist your body as it changes to meet the demands placed upon it by the pregnancy.

There are lifestyle activities that can help to preserve and nourish your qi. As your body’s energy is not at optimal levels, it is important to assist your body by taking into consideration:

- Any physical factors that may be contributing to this deficiency: Although you may not necessarily need bed rest, it will be useful to take periods of physical rest when you feel tired and not to push your body with physical exercise if you do not feel up to it.
- If possible, it can be useful to reduce the number of hours you are working or to arrange some childcare. It can also be useful to arrange some support for any times of the day that you find especially tiring—for example, during lunchtime at work if there is a suitable room where you can rest for 20 minutes or spend 20 minutes lying down when you return home from work.
- Dietary factors: In traditional Chinese medicine, qi can be replenished through food. Freshly prepared food has more vital qi than frozen, stored or packaged food. It is also important to eat breakfast and regular meals in a relaxed environment to obtain good-quality qi from food. Of course, in early pregnancy, there may be overriding considerations for any nausea you may be experiencing; in this case, it can be a matter of eating and drinking whatever and whenever will be helpful to reduce your nausea.

QI STAGNATION

Qi is the term used in traditional Chinese medicine to describe your body’s energy.

Qi flows around your body in a series of meridian pathways, which are separate from your circulatory, lymphatic and nervous systems. They influence the way in which your body functions. The qi that is presently in your body is a combination of your genetic makeup at conception, how you have lived your life since birth and your daily intake of food and air.

When qi does not flow smoothly, it becomes blocked in that area. This is referred to as qi stagnation in traditional Chinese medicine. This can manifest as a dull, achy pain or feelings of bloating or blockage in various areas such as the digestive system, abdomen or breasts.

Qi blockage can also manifest as emotional stagnation. In this case, there is a feeling of ‘stuckness’, depression or irritability that improves with exercise or release through crying or venting any feelings of anger. This can result in problems such as insomnia, which involves waking in the early hours of the morning and finding it difficult to fall back to sleep, as well as reoccurring feelings of anxiety, depression or a general feeling of ‘stress’.

There are lifestyle activities that can help your Qi to remain ‘free-flowing’:

- Exercise: While you may have found vigorous exercise to be useful in the past, there is now a need to adjust these activities to something suitable for early pregnancy—for example, substituting regular walking or swimming for daily runs or gym workouts.
- It can be beneficial to find a suitable creative outlet to help keep your qi in balance. This can involve activities such as writing—for example, keeping a private journal—or something that you used to enjoy in the past, such as knitting, sewing or needlework. It could also be something that you have always wanted to try but never found the time for, such as taking singing classes. Whatever the case, this activity will bring with it feelings of satisfaction and can play an important role in preventing qi stagnation on a regular basis.
- It can also be beneficial to find emotional support by talking through your concerns to your partner, a friend or health professional. For women with qi stagnation it is important not to ‘bottle up’ worries and concerns because this tends to promote further stagnation.

Yang represents the energy that is responsible for warming and activating bodily functions. When this energy is depleted, your body begins to slow down, displaying signs of under-activity and sensations of coldness.

When the body’s yang becomes depleted, it can be more difficult to maintain your usual energy levels. This can result in problems such as tiredness and exhaustion. For some women in early pregnancy, it can also result in an achy, heavy and dragging sensation in their pelvis.

There are lifestyle activities that can help to preserve and nourish your yang energy. As your body’s energy is not at optimal levels, it is important to assist your body by taking into consideration:

- Any physical factors that may be contributing to this deficiency. Although you may not necessarily need bed rest, it will be useful to take periods of physical rest when you feel tired and not to push your body with physical exercise if you do not feel up to it.
- If possible, it can be useful to reduce the number of hours you are working or to arrange some childcare. It can also be useful to arrange some support for any times of the day that you find more tiring—for example, during lunchtime at work if there is a suitable room where you can rest for 20 minutes or spend 20 minutes lying down when you return home from work.
- It is important to keep yourself warm. This can mean ensuring that you have an extra layer of clothing at hand to use if you start to feel chilled and keeping your feet warm. Areas that are seen as especially important in traditional Chinese medicine are the back of the neck and lower back area over the kidneys. It can also be useful to avoid sitting or sleeping close to open windows and drafts, and to use a hairdryer if you have long hair to avoid becoming chilled through wet hair.
- It is beneficial to assist your digestive system by consuming warming foods and drinks such as soup and tea. It can be helpful to identify any cold or raw foods that you feel cold after consuming, such as chilled water or juices, frozen yoghurts, muesli or raw green salads. While these are beneficial for some people, when you have a yang deficiency, consuming an abundance of these foods requires your body to use extra energy for digestion.
YANG DEFICIENCY

Yang represents the energy that is responsible for warming and activating bodily functions. When this energy is depleted, your body begins to slow down, displaying signs of under-activity and sensations of coldness. Foods to tonify yang include:

<table>
<thead>
<tr>
<th>Grains</th>
<th>Quinoa, sweet (glutinous) rice, wheat germ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetables</td>
<td>Leek, mustard greens, onion, radish, scallion, squash, sweet potato, turnip, watercress</td>
</tr>
<tr>
<td>Fruit</td>
<td>Cherry, litchi, lohan, peach, raspberry, strawberry</td>
</tr>
<tr>
<td>Nuts and seeds</td>
<td>Chestnuts, pine nuts, pistachio nuts, walnuts</td>
</tr>
<tr>
<td>Fish</td>
<td>Anchovy, lobster, mussel, prawn, shrimp, trout</td>
</tr>
<tr>
<td>Meat</td>
<td>Chicken, lamb, venison, kidneys (both beef and lamb)</td>
</tr>
<tr>
<td>Herbs and spices</td>
<td>Basil, black pepper, caper, cayenne, chive seed, cinnamon bark, clove, dill seed, fennel seed, fennugreek seed, garlic, ginger, horseradish, nutmeg, peppermint, rosemary, sage, savory, spearmint, star anise, turmeric, thyme, white pepper</td>
</tr>
<tr>
<td>Beverages</td>
<td>Chai tea, jasmine tea</td>
</tr>
<tr>
<td>Common supplements</td>
<td>Algae, brown sugar, malt sugar, vinegar</td>
</tr>
</tbody>
</table>

Examples of everyday Western foods that can be used to build yang include:

- Roast chicken with sage and thyme
- Roasted vegetables with and rosemary
- Rice porridge with cinnamon, nutmeg and a little brown sugar
- Leek and potato soup with black pepper
- Adding any of the spices listed above when cooking.

Foods to avoid

It is important to avoid foods that will further drain the body’s yang energy. Cold food and liquids fall into this category. Here, ‘cold foods’ refers not only to those directly taken from the fridge, but also to raw foods, as these require extra energy for digestion compared to pre-cooked foods. This may mean choosing a pasta salad over a green salad or switching from muesli to oat porridge for breakfast.

Using a warming method of cooking will also enhance the body’s energy by preserving yang: therefore, soups, porridges and slow-roasted foods become the dishes of choice for those with a predominate yang deficiency. The herbs and spices mentioned above are warming and thus, in small amounts, they encourage digestion and circulation throughout the body. While it may seem reasonable to achieve an enhanced warming effect by liberally using the stronger spices such as black pepper, care needs to be taken because they can be used to excess and induce sweating, which actually has a cooling–drying effect on the body.

Appendix K. Diary for RCT

FINAL DIARY FORM

Date: □□□□

day month year

Week ……… of the study

STUDY NUMBER □□□□

This is the final diary form for the study and is slightly different from the previous forms you have been filling out each week. The first section on diet and lifestyle remains the same, with further questions (on the back of this form) that ask for your perception of any changes and any support you received over the time you have spent in this study.

The information you provide will remain confidential—your diary entries will not be read until you have left the study, and only the research team will have access to this information. You will not be identified by your name at any time in this study.

The information in this diary will not be available to anyone while they are treating you and will not in any way affect the treatment you receive. **There are no right or wrong answers.**

1) Diet and Lifestyle Activities.

These questions ask you about your diet and lifestyle. Please tick to answer each question.

For the previous week have you had any:

- □ Coffee? If yes, how many cups per day? — □ Alcohol?
  - If yes, how many days this week?

- □ Cigarettes? If yes, how many per day? — □ Sexual intercourse?

- □ Bed rest? If yes, how many days this week? — □ Medication?
  - If yes please specify ………..
Appendix K. Diary for RCT

For the previous week have you spent time:

☐ Heavy lifting?  If yes, how many times this week?  —
☐ Doing meditation?  If yes, how many times this week?  —
☐ Using relaxation exercises?  If yes, how many times this week?  —
☐ Doing yoga?  If yes, how many times this week?  —
☐ On an internet miscarriage site?  If yes, how many times this week?  —
☐ Exercising longer than 20 minutes?  If yes, how many times this week?  —
☐ Time at work?  If yes, how many hours this week?  —

For the previous week have you used any of the following:

☐ 4 Vitamins  ☐ 5 Homeopathic remedies  ☐ 6 Herbal supplements
☐ 7 Western herbs  ☐ 8 Chinese herbs
☐ 9 Osteopathy  ☐ 10 Reflexology  ☐ 11 Massage
☐ 12 Any other form of alternative treatment (please specify)

……………………………………………………………………..

2) Over the time that you have been involved in this study, was there any one change you made from the diet and lifestyle aspects listed above that you found especially beneficial?

Yes ☐  No ☐

If yes, what was this change?

……………………………………………………………………..

Why did you find this change beneficial?


3) Was there one change you made from the list above that you did not find beneficial?

Yes ☐  No ☐
Appendix K. Diary for RCT

If yes, what was this change?

...........................................................................................................................................

Why did you find this change not beneficial?

...........................................................................................................................................

The following questions relate to your perception of beneficial support.

4) Over the time that you have been involved in this study, did you receive support that you found useful?  Yes [ ]  No [ ]

5) If yes, please select the support that you found the most useful. Was this:
   [ ] Advice  [ ] Emotional support  [ ] Physical help

Please specify..................................................................................................................................................

6) Where did this support come from? Please tick to answer:

   [ ] Friends  [ ] A health professional
   [ ] Family  [ ] The treatment provider for this study
   [ ] Acquaintances  [ ] Other, please specify

...........................................................................

   [ ] An internet support group

Thank you for filling out this diary. We appreciate you taking the time to provide us with this information. Please place in the envelope provided, seal and hand to the research assistant at your next appointment. If you have any questions or concerns, please contact:

Debra Betts   Phone 04 479 4054   Mobile 021 151 0714
E-Mail: 16910687@student.uws.edu.au
DIARY FORM

Date: □□□□

day month year

Week ……… of the study

STUDY NUMBER □□□

We are interested to find out if there are any changes that women with threatened miscarriage make to their diet and lifestyle during their pregnancies. The information you provide will remain confidential – your diary entries will not be read until you have left the study and only the research team will have access to this information. You will not be identified at any time in this study by your name.

The information you provide will remain confidential—your diary entries will not be read until you have left the study, and only the research team will have access to this information. You will not be identified by your name at any time in this study.

The information in this diary will not be available to anyone while they are treating you and will not in any way affect the treatment you receive. There are no right or wrong answers.

Diet and Lifestyle Activities.

These questions ask you about your diet and lifestyle. Please tick to answer each question.

For the previous week have you had any:

☐ Coffee? If yes, how many cups per day? — ☐ Alcohol?

If yes, how many days this week?

☐ Cigarettes? If yes, how many per day? — ☐ Sexual intercourse?

☐ Bed rest? If yes, how many days this week? — ☐ Medication?

If yes please specify …………………
Appendix K. Diary for RCT

For the previous week have you spent time:

☐ Heavy lifting?  If yes, how many times this week?  —
☐ Doing meditation?  If yes, how many times this week?  —
☐ Using relaxation exercises?  If yes, how many times this week?  —
☐ Doing yoga?  If yes, how many times this week?  —
☐ On an internet miscarriage site?  If yes, how many times this week?  —
☐ Exercising longer than 20 minutes?  If yes, how many times this week?  —
☐ Time at work?  If yes, how many hours this week?  —

For the previous week have you used any of the following:

☐ 4 Vitamins  ☐ 5 Homeopathic remedies  ☐ 6 Herbal supplements
☐ 7 Western herbs  ☐ 8 Chinese herbs
☐ 9 Osteopathy  ☐ 10 Reflexology  ☐ 11 Massage
☐ 12 Any other form of alternative treatment (please specify)

Thank you for filling out this diary. We appreciate you taking the time to provide us with this information. Please place in the envelope provided, seal and hand to the research assistant at your next appointment. If you have any questions or concerns, please contact:

Debra Betts  Phone 04 479 4054  Mobile 021 151 0714
E-Mail: 16910687@student.uws.edu.au
Appendix N. Patient information and consent forms for RCT

Locked Bag 1797
Penrith South DC NSW Australia

PATIENT INFORMATION SHEET

The Role of Acupuncture Treatment with the Management of Threatened Miscarriage: An exploratory study

You are invited to take part in a study conducted by Associate Professor Caroline Smith, Centre for Complementary Medicine Research, University of Western Sydney, and Debra Betts, PhD Candidate, University of Western Sydney.

What is the study about?

Threatened miscarriage is a medical term used for vaginal bleeding during pregnancy when a baby is found to have a heartbeat on ultrasound. While it is known that a majority of miscarriages in early pregnancy result from genetic abnormalities, there remains a percentage in which the cause remains unknown.

It may be possible that among this group of women in which genetic abnormalities is not the cause for vaginal bleeding, acupuncture and supportive care can be used as a treatment for threatened miscarriage.

Acupuncture is part of traditional Chinese medicine and involves the insertion of needles into specific acupuncture points.

Supportive care involves receiving dietary and lifestyle advice and having specific body points held while resting for 20 minutes.

The purpose of this study is to investigate whether acupuncture and supportive care can help women with threatened miscarriage and to examine their experiences of receiving treatment.

What does the study involve?

If you are experiencing a threatened miscarriage, you may be eligible for entry into this study. We will be unable to offer you a place in this study if you have a twin or multiple pregnancy, require specialist care for underlying medical health problems or have previously experienced three or more miscarriages.

If you are interested in participating, there will be an appointment with the researcher in which the details of the study will be fully explained to you. You may have the support of friends, family or whānau to help you understand the risks and/or benefits of this study and any other explanations you may require. If you remain interested, after signing a consent form, you will be randomised into one of two groups—one group receiving acupuncture and one group receiving touch—with both groups receiving diet and lifestyle advice.
Appendix N. Patient information and consent forms for RCT

Randomisation is a process in which you are allocated to one of these two groups by computer selection. This means that your group allocation will be by chance—it will not be possible to request that you are placed into a specific group. Treatment will be given at this first appointment and continue until you reach 12 gestational weeks.

As well as receiving weekly treatment, you will be asked to fill out a questionnaire at each appointment and keep a weekly dairy.

There will be a follow-up phone call at 18–20 weeks’ gestation to clarify who your lead maternity caregiver will be for the birth. Your hospital records will be examined to record any hospital admissions related to the pregnancy and the health of yourself and your baby at birth.

On leaving the study at 12 weeks’ gestation, some women may also be asked for an interview regarding their experience of the treatment they received. The interviewer will require your consent to record this interview, and the interview can be discontinued at any time if you do not wish to discuss certain questions or if you wish to end the interview.

There is no payment for the trial.

**How much time will this study take?**

There will be two treatment session during the first week of entering the study and then weekly treatments until your pregnancy reaches 12 gestational weeks. The initial session will be 1½ hours with the follow-up sessions taking 45 minutes. There will be two clinic locations where treatments occur, one in Lower Hutt Hospital and one in Central Wellington at the New Zealand School of Acupuncture. You will have the choice of the location that is most convenient.

Each week during your appointment, you will be asked to fill in a questionnaire that will take approximately 10 minutes of your time. At this time, you will also hand in your weekly diary to the researcher, which we expect to take no more than 10 minutes of your time to complete each week.

For those women participating in the interview, this will take approximately 45 minutes.

**Will the study benefit me?**

This study aims to explore the possible benefits of offering treatment to women and may improve future treatment for women experiencing threatened miscarriage. It may not directly benefit you, although you may benefit from the extra monitoring you receive.

**Will the study have any risks?**

The experience of receiving acupuncture can vary among people, with some people reporting discomfort or a brief, sharp sensation. Some people do not feel any sensations while the needles are in place, while others describe a warm, tingling or numbing sensation around the site of the needle insertion.
Appendix N. Patient information and consent forms for RCT

The risk of minor side effects is small (a rate of 1.3 per 1,000 treatments). These side effects may include nausea, dizziness, fainting, increased pain or bruising. The needles used are sterile, used only once and are disposed of after use in a medical sharps container and then incinerated.

Your participation in this study will be stopped should any harmful effects appear or if your lead maternity caregiver feels it is not in your best interest to continue.

**How is this study being paid for?**

This study is being sponsored by the University of Western Sydney.

**Will anyone else know the results?**

All aspects of this study, including individual results, will be confidential, and only the researchers will have information on your research data, except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and no-research situations. Such requests to access information are rare; however, we have an obligation to inform you of this possibility.

No material that could personally identify you will be used in any reports on this study. Information collected on data forms and in interview transcripts will be kept secure in locked files.

**How will the results be circulated?**

Following completion of the study, we will post a summary of the research findings to all women involved in the study.

**Can I withdraw from the study?**

Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part, you will receive the standard care available from your lead maternity caregiver. If you do agree to take part in the study, you are free to withdraw from the study at any time without giving a reason, and this will in no way affect any future care or treatment.

**Can I tell other people about the study?**

Yes, you can discuss this study with your lead maternity caregiver and if you know of anyone who may be interested, you can give them the lead researcher’s details for them to contact.

**What if I require further information?**

When you have read this information, a researcher will discuss it with you further and answer any further questions you may have. If you would like to know more at any stage, please feel free to contact: Debra Betts at 021 151 0714 / 04 479 4054. Email: 16910687@student.uws.edu.au or Dr Caroline Smith, Associate Professor CompleMED at the University of Western Sydney. Phone: 0061 2 450 920976 or email: cariline.smith@uws.edu.au.
Appendix N. Patient information and consent forms for RCT

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you will be covered by the accident compensation legislation with its limitations. If you have any questions about ACC, please feel free to ask the researcher for more information before you agree to take part in this trial.

What if I have a complaint?

This study has been approved by the Lower South Regional Ethics Committee. The ethics reference is LRS/10/07/030.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate. Free phone: 0800 555 050. Free fax: 0800 2 SUPPORT (0800 2787 7678) or Email: advocacy@hdc.org.nz.
Appendix N. Patient information and consent forms for RCT

Acupuncture Treatment with the Management of Threatened Miscarriage

Consent Form to Participate in Research

I (PLEASE PRINT NAME) ………………………………………………………………….. hereby consent to my involvement in the research project entitled: The Role of Acupuncture Treatment with the Management of Threatened Miscarriage: An exploratory study.

I have read and I understand the information sheet dated 19/8/2010 for volunteers taking part in this study. I have had the opportunity to discuss this study and I am satisfied with the answers I have been given.

I have had time to consider whether to take part in the study and have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my continuing health care.

I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.

I understand that the treatment will be stopped if it should appear harmful to me and I understand the compensation provisions for this study.

I know who to contact if I have any side effects from the study and who to contact if I have any questions about the study in general.

I agree to my Lead Maternity Caregiver being informed of my participation in this study.

I consent to random allocation into an acupuncture group or active control group, providing detailed information about my health, my ultrasound and hospital records being made available to the research worker and attending treatment sessions weekly until 12 completed gestation weeks of my pregnancy.

If invited to participate in an in-depth interview I consent to the interview being recorded.

☐ Yes  ☐ No
I wish to receive a copy of the results. □ Yes □ No

Signature of the participant........................................Date ........../...../........

I, (pleaseprint)...................................................................................................................

Have described to .................................................................the nature of the research project.

In my opinion, they understand the explanation and have freely given their consent.

Signature .................................. .Status in project ............................................
INTERVIEW SCHEDULE FOR RCT PARTICIPANTS

Interview Schedule

This schedule will remain flexible to focus on aspects participants deem to be important.

**Aim:** Women with a diagnosis of threatened miscarriage will be engaged in semi-structured interviews to explore their experiences of receiving acupuncture and supportive care, or touch and supportive care. In particular, women will be invited to share stories that illustrate the impact these therapies have on their lifestyle and their physical and emotional wellbeing.

The following questions will all be covered during the interview, although the interviewer will not necessarily ask each question in any set order, instead following the women’s conversation flow and seeking further clarification as required using open-ended questions such as ‘Can you tell me more about that?’ or ‘How did that make you feel?’

**Introduction**

I have some questions to ask you about the treatment you received as part of the trial you took part in following your diagnosis for threatened miscarriage. Please feel free to bring up any comments as they come into your mind—these questions do not need to be answered in any special order. If you feel uncomfortable with any of the questions, please tell me. I can stop the interview and turn off the recorder at any time.

**Questions**

1) Can you tell me why you entered into this study?

2) It would be helpful if you could tell about the treatment you received.
   A) Were there any specific effects you noticed immediately following the treatment?
   B) Any specific effects in the week following the treatment?
   C) Did you notice any other changes in your general health—physical or emotional?
   D) Do you feel that the treatment you received made you feel any differently about your threatened miscarriage?
   E) Have you received any form of acupuncture or touch therapy before?
   F) Were there any specific effects you were hoping to notice with the treatment?

3) Tell me about the treatment sessions.
   A) Describe what happened in the first session.
Appendix O. Interview Schedule for RCT participants

B) Looking back on the treatments you received, is there anything from the sessions that especially sticks in your mind?

C) Was there anything that occurred during the treatment that you found difficult?

4) If you had a friend experiencing a threatened miscarriage, what advice would you give your friend about possible treatment?

5) Is there anything else that you would like to say about the treatments you received?
INTERVIEW SCHEDULE FOR WESTERN HEALTH PRACTITIONERS

Interview Schedule

This schedule will remain flexible to focus on aspects participants deem to be important.

Aim: To identify what practitioners consider as best practice when delivering care for women experiencing threatened miscarriage. Practitioners will be engaged in semi-structured interviews to explore their experiences of providing care. In particular, practitioners will be invited to share stories that illustrate any diet and lifestyle advice they give and how they view acupuncture treatment as a possible treatment modality.

The following questions will all be covered during the interview, although the interviewer will not necessarily ask each question in any set order, instead following the participants’ conversation flow and seeking further clarification as required using open-ended questions such as ‘Can you tell me more about that?’ or ‘What is your opinion on this?’

Introduction

I have some questions to ask you about your experiences as a health professional in contact with women experiencing threatened miscarriage; in particular, your viewpoint on acupuncture and what you consider best practice for the treatment of threatened miscarriage. Please feel free to bring up any comments as they come into your mind—these questions do not need to be answered in any special order. If you feel uncomfortable with any of the questions, please tell me. I can stop the interview and halt the recording at any time.

Questions

1) It would be helpful if you could tell about your clinical background and experience in dealing with women presenting with threatened miscarriage.
   A) In what context do you deal with women experiencing threatened miscarriage?
   B) How long have you been working in this area of practice?

2) What, in your opinion, are the possible benefits or disadvantages of offering women presenting with threatened miscarriage advice or recommending specific treatments?

3) Is there any advice or support that you think is important to provide to the women you see presenting with a threatened miscarriage?
Appendix P. Interview Schedule for Western health practitioners

4) Is there any particular diet and lifestyle advice you feel women should be aware of?

5) Women often seek diet and lifestyle advice from many sources, including their friends and social media such as the Internet. Are you aware of women receiving advice that you regard as being 1) helpful? 2) unhelpful?

6) What are your views on acupuncture treatment as a possible therapeutic treatment for women experiencing miscarriage?

7) What, in your opinion, are the possible benefits or disadvantages from having acupuncture treatment as this time?

8) What are your views on the use of Chinese herbs for the treatment of threatened miscarriage?

9) Is there anything else that you would like to say about your experiences dealing with women presenting with threatened miscarriage?
WESTERN HEALTH PRACTITIONER INTERVIEWS

Consent Form to Participate in Research

I (PLEASE PRINT NAME) ………………………………………………………………….. hereby consent to my involvement in the research project entitled:

Treatment for threatened miscarriage: exploring treatment perspectives amongst Western health practitioners

1. I acknowledge that the nature and purpose of this research project described on the attached invitation has been explained to me by the researcher worker and my consent is given.

2. I have read the invitation to participate sent to me and have been given the opportunity to discuss the information and my involvement with the researcher.

3. The procedures required for the project and the time involved have been explained to me and any questions I have about the project have been answered to my satisfaction.

4. I consent to attending an interview with the researcher and to this interview being recorded.

5. I understand that my involvement is confidential and that any information gained during the study may be published, but no information about me will be used in any way that reveals my identity.

6. I understand that I can withdraw from the study at any time without affecting my relationship with the researcher now or in the future.

Signature of the participant.................................................................

Date ......./...../...........

I, (please print)

..........................................................................................................................

Have described to ………………………………………………………………………...the nature of the research project.

In my opinion, they understand the explanation and have freely given their consent.

Signature ...........................................................................

Status in project .................................................................
PARTICIPANT INFORMATION SHEET

Acupuncture treatment for threatened miscarriage: exploring treatment perspectives amongst acupuncturists and Western health practitioners

You are invited to take part in a study conducted by Debra Betts, PhD Candidate, Associate Professor Caroline Smith and Associate Professor Hannah Dalen, University of Western Sydney.

What is the study about?

The purpose of this study is to investigate acupuncturists’ and Western health practitioners’ perceptions of best practice when delivering care for women experiencing threatened miscarriage and their expectations of acupuncture as a treatment option for threatened miscarriage.

What does the study involve?

You are invited to participate in an interview to explore your treatment perspectives for women presenting with threatened miscarriage.

How much time will this study take?

It is expected that this interview will take approximately one hour of your time. This will be arranged at a time and place that would be convenient for you.

Will the study benefit me?

The study aims to further knowledge on how women with threatened miscarriage are treated in clinical practice. You will receive a summary of the study findings, which may have the potential to give further insight and understanding; however, this study may not directly benefit you.

Will the study have any risks?

The risk in participating in this research is negligible and related to inconvenience in terms of your time that will be taken in participating in the interview. All responses will be kept confidential. It is anticipated that any inconvenience will be compensated through personal satisfaction at contributing to the body of knowledge for this area of practice.

How is this study being paid for?

This study is being sponsored by the University of Western Sydney.

Will anyone else know the results?

No, the results will be kept confidential and only summarized information will be released.
Appendix Q. Information and consent forms for Western health practitioner interviews

All aspects of this study will be confidential and only the researchers will have information on the research data, except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and no-research situations. Such requests to access information are rare; however, we have an obligation to inform you of this possibility.

No material that could personally identify you will be used in any reports on this study.

Information collected on data forms and in interview transcripts will be kept secure in locked files.

**How will the results be circulated?**

Following completion of the study, we will post you a summary of the research findings.

**Can I withdraw from the study?**

Your participation is entirely voluntary: you are not obliged to participate. If you do participate, you can withdraw at any time without giving a reason. Whatever your decision, it will not affect your relationship with the researcher.

**Can I tell other people about the study?**

Yes, you can tell other people about the study by providing them with the lead researcher’s contact details.

**What if I require further information?**

When you have read this information, the lead researcher Debra Betts will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact: Debra Betts at 021 151 0714 / 04 479 4054. Email: 16910687@student.uws.edu.au or Dr Caroline Smith, Associate Professor CompleMED at the University of Western Sydney. Phone: 0061 2 450 920976 or email: caroline.smith@uws.edu.au.

**What if I have a complaint?**

This is PhD research through the University of Western Sydney and has ethics approval through the Lower South Regional Ethics Committee. The Ethics approval number is LRS/10/07/030.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate. Free phone: 0800 555 050. Free fax: 0800 2 SUPPORT (0800 2787 7678) or email: advocacy@hdc.org.nz

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you will be asked to sign a Participant Consent Form.
Appendix R. Human Ethics approval for Western health practitioner interviews.

Dear Mr Murphy

Re ethics ref: LRS/10/07/030
Study title: The role of acupuncture treatment with the management of threatened miscarriage: an exploratory study

We would like to request a further amendment to the study’s qualitative aspect. This would involve inviting health professionals to participate in an interview on their perspectives on acupuncture and supportive care as a possible treatment option. These practitioners currently have the opportunity to refer women into the study and these interviews would explore their views on the treatment being offered to women in this study. This amendment would require the following changes to the documentation previously supplied to the Lower South Ethics Committee.

A3.1 Describe the study design.

Qualitative Study: Semi-structured interviews will be undertaken to examine health professionals’ perceptions of acupuncture and supportive care as a treatment for threatened miscarriage.

A5.4 If the method of analysis is wholly or partly qualitative, specify the method. Why is this method appropriate? If interviews are to be used, include the general areas around which they will be based and a copy of the interview guide, if one is to be used.

Participants will be invited to participate in semi-structured interviews. These participants would include eight to 14 health professionals that are involved in assessing women presenting with threatened miscarriage. Semi-structured interviews will be used in which the interviewer will be guided by a written topic guide of questions to be asked.

These interviews will be semi-structured so that they remain flexible and focus on aspects that the participants deem to be important. In this way, patient-centred information can be collected that reflects the participant’s experience.

The written topic guide for health professionals will ask participants for their perspectives on acupuncture and supportive care as a treatment for threatened miscarriage and their perspectives on best practice for dietary and lifestyle advice for women presenting with threatened miscarriage. In particular, practitioners will be invited to share stories that illustrate any diet and lifestyle advice they give and how they view acupuncture treatment as a possible treatment modality.

D1. How will potential participants be identified?
Appendix R. Human Ethics approval for Western health practitioner interviews.

Potential participants will be health professionals currently in contact with women presenting with threatened miscarriage. This would include consultants, midwives, fertility practice nurses and health professionals from an early pregnancy unit at Hutt Valley hospital.

D2. How will participants be recruited (for example, advertisements and notices)?

An advertisement will be placed in the New Zealand College of Midwives (NZCOM) Wellington newsletter asking for interested participants to contact the lead researcher Debra Betts (DB).

A personal invite will be sent to consultants involved in early pregnancy care, practice nurses at Fertility Associates in Wellington and health professionals at a maternity assessment unit.

Please find attached:

- An information sheet for health professionals
- A personal invite to participate in a qualitative interview
- The advertisement for the New Zealand College of Midwives (NZCOM) Wellington Newsletter
- A consent form for the qualitative interviews
- The interview schedule for health professionals.

Thanking you for your consideration in this matter.

Debra Betts

NZRN, Dip Ac, BHSc (Acupuncture), PhD candidate University of Western Sydney.