The Evaluation of Acupuncture as an Adjunct Intervention for Antenatal Depression: A Mixed Method Study

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I dedicate this thesis to my passed over parents, and my daughter.
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.

Simone Maree Ormsby

October 2018
Author’s note

As a molecular biologist who was constantly impressed with the mind-blowing complexity of the body, and just how much we still don’t know, I was frequently surprised at the closed-minded attitudes I came across. We have many examples in our academic history of scientists being ridiculed, imprisoned and even executed for their crazy ideas, that later on, became accepted as fact. What occurred was that a technological advance enabled a new ‘vision’ and ‘understanding’. Consequently, I believe, just because we can’t at this moment in time, ‘see’ or ‘touch’ something, it doesn’t necessarily mean, that it doesn’t exist. It may be that the technology is not yet sufficiently advanced to provide detection, or that the method of testing to date has been inappropriate, or even, that the question being asked, is off track. This of course brings me to the scientific exploration of the all-encompassing holistic Traditional East Asian Medicine. Whilst I wholeheartedly agree with Margaret Caudill, that ...

“Although acupuncture itself has gained some acceptance, the Western medical and scientific community has never considered seriously the medical tradition and culture from which this technique sprang. As if a full understanding of acupuncture were encompassed by knowing where to stick the needles! This absurdity is compounded by the fact that the idea of isolating a part from its natural environment for investigation is antithetical to the philosophy and culture of the Chinese medicine tradition.” Margaret A. Caudill, M.D, Ph.D., forward to “Chinese Medicine - The web that has no weaver”, by Ted J. Kaptchuk, 1983.

…. I also appreciate the efforts of acupuncture researchers that have been able to demonstrate benefits, as without these, Traditional East Asian Medicine would be facing even greater difficulty of being accepted. Striking a balance between the two opposing tensions, is nonetheless, a difficult task.
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List of Abbreviations

AACMA Australian Acupuncture and Chinese Medicine Association
ACM Average Closest Match
ACTH Adrenocorticotrophin Hormone
ACTRN Australian and New Zealand Clinical Trials Register
ACU Acupuncture
ADHD Attention Deficit Hyperactivity Disorder
AMA Advanced Maternal Age
AND Antenatal Depression
ANOVA Analysis of Variance
ANS Autonomic Nervous System
ART Assisted Reproductive Technology
ASD Autism Spectrum Disorder

BaM-13 Being a Mother Scale
BDI Beck Depression Index
BMI Body Mass Index

CAR Cortisol Awakening Response
CBT Cognitive Behavioural Therapy
CER Comparative Effectiveness Research
CF Consent Form
CI Confidence Intervals
CL Caseload Midwifery
CM Complementary Medicines
CMBA Chinese Medicine Board of Australia
CNS Central Nervous System
COPD Chronic Obstructive Pulmonary Disease
CP Coupled Point
CRH Corticotrophin Releasing Hormone
CS 1 Camilla Scanlan
CS 2 Caroline Smith
CVD Cardiovascular Disease

DASS-21 Depression Stress and Anxiety Scale - 21
DHEA Dehydroepiandrosterone
DSM - Diagnostic and Statistical Manual of Mental Disorders

ECT Electroconvulsive therapy
ELISA Enzyme-Linked Immunosorbent Assay
EPDS Edinburgh Postnatal Depression Scale

FDA Food and Drug Administration

GD Gestational Diabetes
GPs General Practitioners
GV Governor Vessel

HD Hannah Dahlen
HJJ Huato Jia Ji
HPA Hypothalamic Pituitary Axis
HREC Human Research Ethics Committee
HRSD Hamilton Rating Scale of Depression

ID Identification
IPT Interpersonal Psychotherapy
ITP Interpersonal Psychology
ITT Intention to Treat
IVF In-Vitro Fertilisation

K6 Kessler 6 Instrument

LBW Low Birth Weight
LVCF Last Value Carried Forward
MD Mean Difference
MDD Major Depressive Disorder
MMR Mixed-Methods Research
MP Master Point
MW Midwife

NICM National Institute of Complementary Medicine
NICU Neonatal Intensive Care Unit
NRS Numerical Rating Scale

OB Obstetrician Care
OR Odds Ratio
OT Oxytocin
OT-R Oxytocin Receptor

PIS Patient Information Sheet
PMR Progressive Muscle Relaxation
PND Postnatal Depression
PP Per Protocol
PPD Postpartum Depression
PROM Premature Rupture of Membranes
PSQI Pittsburgh Sleep Quality Index
PTB Preterm Birth
PTSD Post Traumatic Stress Disorder

RCT Randomised Controlled Trial
RR Relative Risk

SD Standard Deviation
SES Socioeconomic Status
SGA Small for Gestational Age
SM Standard Midwifery
SNP Single Nucleotide Polymorphisms
SSRI(s) Selective Serotonin Reuptake Inhibitor(s)
SSNRI Selective Serotonin–Norepinephrine Reuptake Inhibitor
SWSLHD South Western Sydney Local Health District

TAU Treatment as Usual
TCM Traditional Chinese Medicine
TEAM Traditional East Asian Medicine
TENS Transcutaneous Electrical Nerve Stimulation
TSI Torres Strait Islander

UC Usual Care
UK United Kingdom
USA United States of America

VAS Visual Analog Scale

WHO World Health Organization
WHOQoL-26 World Health Organization Quality of Life Scale - 26
WSU Western Sydney University
Abstract

Background

Depression in pregnancy is common; with current prevalence estimates suggesting one in every eight women are affected. Incidence rates amongst vulnerable at-risk groups are however, reportedly much higher. Detrimental consequences are wide-ranging, with associated impacts affecting not only women and immediate family members, but also generations to come. Despite this, research indicates that depressive symptomologies experienced during pregnancy are frequently inadequately managed. A number of factors contribute towards this outcome, including incomplete treatment effectiveness, unacceptable side effects, unsatisfactory relationships with providers, and concerns regarding medication risks to babies. As a consequence, many depressed pregnant women seek out additional therapeutic options.

Preliminary clinical trial evidence suggests that acupuncture may provide a safe and potentially effective adjunct treatment; however further investigation is required. This study therefore aimed to further examine acupuncture as an additional therapeutic possibility for the management of depression experienced during pregnancy that also incorporated explorations of women’s experiences of receiving acupuncture, and midwives’ observations of the intervention.

Methods

This mixed-methods feasibility study comprised of a comparative effectiveness pragmatic randomised controlled trial (RCT), in which fifty-seven women meeting Edinburgh Postnatal Depression Scale (EPDS) scores of ≥ 13 were randomised to either individually tailored, depressed specific acupuncture, progressive muscle relaxation attention comparator, or treatment as usual control groups. The intervention was conducted in the antenatal clinics of two Sydney hospitals. Women in either treatment arm received weekly one-hour sessions, conducted from gestation weeks 24 to 31. Outcome evaluations included: the EPDS; Depression, Stress and Anxiety Scale (DASS-21); and World Health Organisation Quality of Life Scale (WHOQoL-26), assessed at baseline,
weeks four and eight, and six-weeks postnatal; weekly intervention and six-weeks postnatal monitoring of distress using the Kessler 6 (K6); adjustment to mothering using the Being a Mother scale (BaM-13) at six-weeks postnatal; and post-to-pre intervention saliva and blood analysis for oxytocinergic and hypothalamic pituitary axis (HPA) axis system evaluations. In addition, associate researchers independent of the acupuncture intervention conducted eight in-depth interviews with acupuncture recipients, and two focus groups with midwives.

Results

In-depth interviews revealed that acupuncture recipients received multiple benefits from treatment, including feelings of relaxation; an enhanced ability to cope with stress; and an improved psychological state, that overall, contributed to them feeling less overwhelmed, happier, more motivated and positive. Midwives similarly reported in focus groups that they had received positive feedback regarding acupuncture benefits, and in addition, observed improved dispositions in recipients. Furthermore, no adverse events were recorded. Together these findings suggested that acupuncture was safe and well tolerated.

Analysis of data sets from the published questionnaires also provided congruent findings. When compared to the progressive muscle relaxation and treatment as usual control, intention to treat analysis of the end of the intervention EPDS scores demonstrated significant reductions in the acupuncture group (p<0.001). Per-protocol analysis of completers (n=46), also demonstrated significantly lowered stress component of the DASS-21 (p=0.002), and K6 (p<0.001) scores amongst acupuncture recipients. Furthermore, mean cortisol: dehydroepiandrosterone (DHEA) ratios were significantly increased in the acupuncture group (p=0.039), when compared to treatment as usual. No between group differences were observed for other evaluated pregnancy, birthing (n=57) or postnatal outcomes (n=45).
Conclusion

The findings from this feasibility study thus provide supportive evidence that acupuncture is beneficial for the management of antenatal depression, stress and distress, as well as enhancing of an overall improved sense of wellbeing. In addition, the individually tailored acupuncture intervention was both well-tolerated and free from adverse events. Further research is therefore warranted.
Thesis Overview

Background

Depression in pregnancy is common, with current prevalence estimates suggesting one in every eight women are affected (Bennett, Einarson, Taddio, Koren, & Einarson, 2004). Incidence rates amongst vulnerable at-risk groups, such as those of minority or lower socio-economic status are however reported to be much higher (Corbani et al., 2017; Meltzer-Brody et al., 2013). Detrimental consequences are wide-ranging, with associated impacts encompassing poor maternal self-care (Stewart, 2011), obstetric and birthing complications (Chung, Lau, Yip, Chiu, & Lee, 2001; Grote et al., 2010), reduced maternal-infant bonding (Hayes, Goodman, & Carlson, 2013), and postnatal depression (Milgrom, Gemmill, Bilszta, Hayes, Barnett, Brooks, Ericksen, Ellwood, & Buist, 2008). Affected offspring in addition display disrupted physiological, social and emotional development (Deave, Heron, Evans, & Emond, 2008; Diego et al., 2004; Field et al., 2006), as well as a life-long propensity to mental health vulnerability (Epstein et al, 2014; Pawlby, Hay, Sharp, Waters, & O’Keane, 2009). Conventional therapeutic approaches for the management of symptoms include psychotherapies for mild to moderate cases, and psychotherapy combined with psychotropic medication for moderate to severe depression (Austin, Highet, & Group, 2017). Research nonetheless indicates that depressive symptomologies experienced during pregnancy are frequently inadequately managed (Gavin, Meltzer-Brody, Glover, & Gaynes, 2015). A number of factors contribute towards this outcome, including incomplete treatment effectiveness (Epstein et al., 2014), undesirable maternal side effects (Mancini, Hardiman, & Lawson, 2005; Samples & Mojtabai, 2015), concerns regarding medication risks to babies (Epstein et al., 2014; Ride & Lancsar, 2016), unsatisfactory relationships with providers (Byatt, Biebel, Friedman, Debordes-Jackson, Ziedonis, & Pbert, 2013a), and reluctance to seek out help (Bauer, Knapp, & Parsonage, 2016; Henshaw, Sabourin, & Warning, 2013).
As a consequence, pregnant women express interest in additional therapeutic options, such as complementary medicines and therapies, for the management of mental health concerns (Adams et al., 2009; Matthews, Huberty, Leiferman, McClain, & Larkey, 2016; Ride & Lancsar, 2016). As well as potentially gaining relief from symptoms, women reportedly also desire other benefits provided by these therapies, such as safety to babies (Park, Sohn, White, & Lee, 2014; Zhang, Chen, Yip, Ng, & Wong, 2010); warm empathetic interactions with practitioners (Bennett et al., 2009; Henshaw, Flynn, Himle, O’Mahen, Forman, & Feddock, 2011); longer consultation times (Berger, Braehler, & Ernst, 2012) and opportunities to be heard (Henshaw et al., 2011); and psychologically inclusive holistic approaches (Bishop, Yardley, & Lewith, 2007; Rugg, Paterson, Britten, Bridges, & Griffiths, 2011). Increased use of complementary medicines, like acupuncture for pregnancy related complaints and mental health concerns have correspondingly been seen in Australia, (Adams et al., 2009; Adams, Sibbritt, & Lui, 2011).

To date, three clinical studies have been conducted evaluating the effectiveness of acupuncture for antenatal mental health concerns. Findings from the pilot and full powered RCT by Manber and colleagues (Manber, Schnyer, Allen, Rush, & Blasey, 2004; Manber et al., 2010), as well as a quasi-randomised trial by (da Silva, 2007), demonstrated significant post-intervention improvements to both clinician rated, and self-reported mood disorder measures. Overall sample sizes however were small, and consequently, further research is required to verify these findings.

Study aims

This study therefore aimed to further examine acupuncture as an additional therapeutic possibility for the management of depression experienced during pregnancy, by similarly conducting an RCT evaluating acupuncture related impacts to antenatal mood. It was however also considered to be a valuable opportunity to more comprehensively examine the potential benefits of acupuncture, by including post-intervention assessments of changes to biomarkers seen to be disrupted in perinatal mental health disorders; as well as
qualitative interview and focus groups inclusions aimed at ascertaining the perspectives of affected women, as well as midwives in regard to acupuncture for antenatal depression. The overall focus was to evaluate the feasibility of running a larger scaled study by assessing the chosen methodologies, as well as the tolerability and safety of acupuncture for depression experienced during pregnancy.

Methodological approach

This mixed-methods style approach has more recently been suggested to be a more appropriate method for the examination of complex interventions (Campbell et al., 2000) such as acupuncture, as it provides greater opportunity to gather rich detail that would otherwise be lost in the standard RCT format (Evans, 2003; Williams & Garner, 2002). An additional recommendation has been for the increased utilisation of the comparative effectiveness research approach, that enables acupuncture to be evaluated as an adjunct to standard therapy (Witt et al., 2012), so as to bypass the potential underestimation of effects as a consequence of assessments being made against non-inert placebo controls (Birch, 2004; Langevin et al., 2011; Walach, 2009). In this mixed-methods study, a comparative effectiveness pragmatic randomised controlled trial was therefore undertaken, in which fifty-seven women meeting Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987) scores of ≥13 were randomised to either individually tailored depressed specific acupuncture, progressive muscle relaxation attention comparator, or treatment as usual control groups. The intervention was conducted in the antenatal clinics of two Sydney hospitals. Women in either treatment arm received weekly one-hour sessions, conducted from gestation weeks 24 to 31. Primary outcome evaluations included feasibility assessments of methodologies, as well as the safety and acceptability of acupuncture for antenatal depression. Secondary outcomes included: the EPDS; Depression, Stress and Anxiety Scale (DASS-21) (Lovibond & Lovibond, 1995); and World Health Organisation Quality of Life Scale (WHOQoL-26) (WHOQOLGroup, 1998), assessed at baseline, weeks four and eight, and six-weeks postnatal; weekly intervention and six-weeks postnatal monitoring of distress using the Kessler 6 (Kessler et al., 2002); adjustment to
mothering using the Being a Mother scale (BaM-13) (Matthey, 2011) at six-weeks postnatal; and post-to-pre intervention saliva and blood analysis for oxytocinergic and HPA axis system evaluations. Qualitative inclusions comprised of semi-structured forms that prompted study feedback from all participants, in-depth interviews with eight acupuncture recipients in regard to the receipt of acupuncture, and two focus groups with midwives assessing their observations of the study, as well as opinions of acupuncture. Associate researchers that were independent of the acupuncture intervention under investigation, conducted the in-depth interviews and focus groups with midwives so as to encourage honest feedback.

**Significance**

In consideration of current incidence rates, as well as the seriousness of the detrimental impacts that may occur, ranging from maternal self-neglect and suicide, to life-long inter-generational mental health vulnerabilities in offspring, it is no wonder that effective management of antenatal depression is a national health consideration (Austin et al., 2017). Despite considered effects such as these however, it remains a fact that only 10% of affected perinatal women gain effective treatment (Gavin et al., 2015). Reasons for this are both complex and multi-factorial, however certainly contributed to by the lack of universal effectiveness and undesirability of some conventional approaches. The clear voicing of preferences for additional complementary therapeutic approaches by some affected women, should in addition not be ignored. Indeed, a more recent emphasis has been placed upon ‘evidence-based decision-making’ that integrates not only the best approach from a research evidence perspective, but also incorporates clinical expertise and patient values (Haynes, Devereaux, & Guyatt, 2002; Duggal & Menkes, 2011). Correspondingly, there remains a need and valuable opportunity to further investigate any valid therapeutic possibility that may be of benefit (Previti, Pawlby, Chowdhury, Aguglia, & Pariante, 2014; Weisskopf et al., 2015). In regard to acupuncture, these investigations should not only include RCT effectiveness evidence, but also evaluations that provide opportunities for women to voice their experiences of acupuncture and perceived benefits gained.
Structure of this thesis

Below, a brief outline of the structure of this thesis is provided in terms of chapter content. For the remainder of this chapter (chapter 1), background information regarding depression in both the general and perinatal populations is provided, along with conventional medical approaches for the management of symptoms. Issues in relation to these therapies are then discussed, including perspectives provided from those affected, which then leads into discussion around complementary medicines and therapies as adjunct possibilities.

In this chapter two, previous clinical trial evidence evaluating acupuncture for depression in general and perinatal populations is detailed.

In chapter three, evidence of putative mechanistic regulatory effects of acupuncture for mood disturbances is provided, along with a particular focus on HPA axis and oxytocinergic system functioning in perinatal populations.

In chapter four, the methods employed in this mixed-methods study design are detailed. Stage one encompassed the RCT in which mood score, biomarker and semi-structured feedback evaluations were conducted. In stage two, the methodologies employed for in-depth interviews with acupuncture recipients, and focus groups with midwives are provided.

In chapter five, findings from the RCT are provided, which include baseline demographic, end of intervention and six-week postnatal assessments, as well as an analysis of semi-structured sleep quality and intervention feedback forms.

In chapter six, findings from oxytocin, cortisol: DHEA hormone and oxytocin receptor (OT-R) analysis are detailed.

In chapter seven, thematic findings from in-depth interviews and focus groups with midwives is provided.

In chapter eight, an overall interpretation of the findings from the separate components of this mixed-methods design is provided, for which a pragmatic complementary integration approach was taken.
In chapter nine, a final discussion and conclusion chapter is provided, in which the study findings are discussed in reference to related research, limitations and future research directions.
Chapter 1

Introduction and Background
1.1 Depression – Incidence, Significance, Definition, and Risk Factors

Worldwide, depression is reported to be the single largest contributor to global disability, with as many as 322 million people being affected. Rates of incidence also appear to be on the rise, with an 18.4% increase being observed over the decade from 2005 to 2015. Currently in Australia, depressive disorders are estimated to affect 5.9% of the population, with the corresponding calculated impact of the burden of disease being the highest amongst the Western Pacific region (WHO, 2017). Included financial costs are of course, enormous, with 7.5% of the Australian government’s total healthcare expenditure being allocated to this issue during the period from 2007 to 2008 (Doran, 2013). With the World Health Organisation (WHO) predicting depression to become the leading cause of disease burden by 2030 (WHO, 2011), future implications to families, communities and governments will, unfortunately, continue to be significant.

Depression is classified as being of a mild, moderate or severe nature (WHO, 2001), with episodes typically being variable in intensity (RANZCP, 2004). Characteristic features include lowering of mood (which varies little from day to day and is unresponsive to changing circumstances); energy; activity; capacity for enjoyment; and interest in life (WHO, 1992). Many other symptoms can also co-occur such as: marked tiredness after minimal effort; weight (WHO, 1992), appetite, and sleep changes; irritability (Belmaker & Agam, 2008; WHO, 1992); difficult decision making (Murphy et al, 2001); reduced ability to concentrate (WHO, 1992); lack of motivation (Stahl, 2002); self-neglect (Abrams, Lachs, McAvay, Keohane, & Bruce, 2002); lowered self-esteem (WHO, 1992); social withdrawal (Altmann & Gotlib, 1988); feelings of hopelessness (Blatt, D’Afflitti, & Quinlan, 1976); guilt and unworthiness (WHO, 1992); and ideas or acts of self-harm or suicide (WHO, 1992). In order to be classed as a depressive episode, symptoms must be present for a minimum of two weeks (WHO, 1992).

Chronic depression is in addition associated with functional and cognitive decline (Belmaker & Agam, 2008); fatal heart disease (Barth, 2004); diabetes
(Hofmann, Köhler, Leichsenring, & Kruse, 2013); and increased risks of bipolar disorder (Päären et al., 2014), and suicidal ideation (Oquendo, Currier, & Mann, 2006). Reportedly over 80% of those that suicide are depressed prior to their deaths, however this figure may be inflated (Shahtahmasebi, 2013). Currently, worldwide estimates of suicide rates are a staggering 3000 per day (Marcus et al, 2012).

A wide range of socio-demographic and underlying health conditions has been shown to predict depression. The strongest identified prognosticator amongst an Australian community sample over the decade from 1998 to 2008 was health status (Goldney, Eckert, Hawthorn & Taylor, 2010), however chronic pain (Ruoff, 1996); unemployment; social disadvantage and isolation; smoking; being a previously married mid-life female (Wilhelm, Mitchell, Slade, Brownhill, & Andrews, 2003); and having past exposure to trauma, stress (Heim & Binder, 2012), or adverse childhood experiences (Wilkinson & Goodyer, 2011), are in addition, highly correlated. Familial inheritance reportedly also contributes to 38% of cases, especially in instances of early onset, and or severe and recurrent forms (Holma, Melartin, Holma, Paunio, & Isometsä, 2011).

### 1.2 Conventional Therapy for the Management of Depression

Despite efforts to raise awareness about depression (Australian Government, 2000), under treatment may still occur as a consequence of both under-detection (Hawthorne, Cheok, Goldney, & Fisher, 2003), and an unwillingness by affected individuals to seek help (Andrews, Hall, Teesson, & Henderson, 1999; Slade, Johnston, Oakley Browne, Andrews, & Whiteford, 2009). Once diagnosed however, established treatment approaches include psychotherapy and or antidepressants for moderately severe depression, antidepressants prior to psychotherapy for more severe cases, and a tricyclic combined with an anti-psychotic or electro-convulsive therapy (ECT) for depression with psychosis (RANZCP, 2004).

Several limitations nonetheless exist with respect to antidepressant usage, including: acute treatment effectiveness rates above placebo of 18-20%
(moderate to severe forms); little evidence of increased effect with higher initial
doses or drug combinations; continued occurrence of clinically important
symptoms in 55-65% of patients; relapse rates of 30% despite continuation of
medication; and contra-indication in some co-morbidities (Cleare et al., 2015).
Studies have demonstrated that 30% of patients discontinue medication due to
lack of efficacy (Gartlehner et al., 2005), and an additional 20% cease, due to
intolerable side effects (Samples & Mojtabai, 2015). Symptoms that may be
experienced include weight gain, insomnia, emotional (Cleare et al., 2015;
Manber, Allen, & Morris, 2002), and cognitive blunting (Manber et al., 2002),
gastrointestinal and urinogenital disturbances, agitation, anxiety, dry mouth,
blurred vision, dizziness, sweating, sedation, and symptoms of hepatotoxicity
(Cleare et al., 2015).

With respect to psychotherapy, different strategies applied over acute
treatment timeframes appear to be equally effective to antidepressants for mild
to moderate forms (Cleare et al., 2015). However, combined therapies
demonstrate no greater effectiveness than psychotherapy alone (Cleare et al.,
2015; Cox et al., 2014), although probable superiority in moderate to severe
cases (Cleare et al., 2015).

1.3 Antenatal Depression - Significance, Definition, Incidence
and Risk Factors

Traditionally pregnancy had been regarded as a time of emotional wellbeing
and protection against psychiatric disorders (Choate & Gintner, 2011) however,
it is now well established that pregnancy related mental health disorders
including depression are common, with comparable rates of occurrence being
seen in pregnant and non-pregnant female populations (Gavin et al., 2005;
Vesga-Lopez et al., 2008).

Whilst the characteristics of antenatal depression are similar to those
experienced in non-pregnant populations, common emotions such as shame
(Wilson, 2013) and guilt (Condon & Corkindale, 1997; de Tychey et al., 2005)
may be more acutely experienced. Reasons cited for this include worry
surrounding potential deleterious foetal and relationship impacts to family members (Bennett, Boon, Romans, & Grootendorst, 2007); as well as the lingering societal belief that pregnancy is a time of “undiluted joy” (Hübner-Liebermann, Hausner, & Wittmann, 2012).

Risk factors reported for the development of antenatal depression (AND) are provided in Table 1.1, along with associated odds ratios for occurrence. In this table, it can be seen that prior depressive history is the greatest risk factor for the development of AND, followed by exposure to domestic violence and psychosocial stress.

Additional predisposing influences include family history of psychiatric illness (Bunevicius et al., 2009); childhood maltreatment (Plant, Barker, Waters, Pawlby, & Pariante, 2013); psychosocial stress (Bunevicius et al., 2009); social adversity or deficient life support (Lancaster et al., 2010); low education (Bunevicius et al., 2009); young age; past or coincidental negative life events; poor quality intimate relationships; physical, sexual, and emotional abuse (Biaggi, Conroy, Pawlby, & Pariante, 2016); sexual coercion and intimate partner violence (Martin et al., 2006); unwanted or unplanned pregnancies (Räisänen et al., 2014); and previous pregnancy complications, negative birth experiences and caesarean deliveries (Biaggi, Conroy, Pawlby, & Pariante, 2016).

As depression is nearly two times more likely to occur in women than men (WHO, 2014), and observed sex differences are greatest during reproductive years, it has been postulated that women’s more complex reproductive physiology and hormonal flux, may contribute to a greater vulnerability to disruption, particularly during pregnancy (Brummelte & Galea, 2016). Another possible explanation however, is the increased exposure of women to lower incomes and SES (Garfield, Mathews, & Janusek, 2016), as well as domestic violence, sexual abuse, minimal support, and adolescent, unwanted, unsupported pregnancies (Heise, Ellsberg, & Gottmoeller, 2002).
Table 1.1 Risk Factors for the Development of Antenatal Depression

<table>
<thead>
<tr>
<th>Risk factor &amp; reference</th>
<th>Odds ratio (OR)</th>
<th>Confidence Intervals (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of psychiatric illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to pregnancy (Räisänen et al., 2014)</td>
<td>22.36</td>
<td>95% CI 20.86 - 23.98</td>
</tr>
<tr>
<td>Life events / relationships</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure to domestic violence (Melville, Gavin, Guo, Fan, &amp; Katon, 2010)</td>
<td>3.45</td>
<td>95% CI 1.46 - 8.12</td>
</tr>
<tr>
<td>Being single (Räisänen et al., 2014)</td>
<td>1.63</td>
<td>95% CI 1.48 - 1.79</td>
</tr>
<tr>
<td>Heath status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic medical conditions (Melville et al., 2010)</td>
<td>3.05</td>
<td>95% CI 1.63 - 5.69</td>
</tr>
<tr>
<td>Obstetric related</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fear of childbirth (Räisänen et al., 2014)</td>
<td>2.63</td>
<td>95% CI 2.39 - 2.89</td>
</tr>
<tr>
<td>Previous terminations (Räisänen et al., 2014)</td>
<td>1.14</td>
<td>95% CI 1.04 - 1.24</td>
</tr>
<tr>
<td>Gestational diabetes (Räisänen et al., 2014)</td>
<td>1.29</td>
<td>95% CI 1.11 - 1.50</td>
</tr>
<tr>
<td>Multi-parity (Redshaw &amp; Henderson, 2013)</td>
<td>1.40</td>
<td>95% CI 1.11 - 1.77</td>
</tr>
<tr>
<td>Socio-economic status (SES)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower white-collar (Räisänen et al., 2014)</td>
<td>1.42</td>
<td>95% CI 1.20 - 1.69</td>
</tr>
<tr>
<td>Blue-collar (Räisänen et al., 2014)</td>
<td>1.53</td>
<td>95% CI 1.27 - 1.84</td>
</tr>
<tr>
<td>Other (Räisänen et al., 2014)</td>
<td>1.67</td>
<td>95% CI 1.40 - 1.98</td>
</tr>
<tr>
<td>Index of multiple deprivation (most deprived) (Redshaw &amp; Henderson, 2013)</td>
<td>1.51</td>
<td>95% CI 1.05 - 2.15</td>
</tr>
<tr>
<td>Low income (Katz, Crean, Cerulli, &amp; Poleshuck, 2018)</td>
<td>0.79</td>
<td>95% CI 0.64 - 0.96</td>
</tr>
<tr>
<td>Black, minority, ethnic (Redshaw &amp; Henderson, 2013)</td>
<td>2.19</td>
<td>95% CI 1.65 - 2.90</td>
</tr>
</tbody>
</table>

1 ORs of major depression adjusted by history of depression prior to pregnancy, maternal age, parity, smoking status, marital status, socio-economic status (SES), prior miscarriages, prior terminations, in-vitro fertilisation (IVF), anaemia, gestational diabetes, pre-existing diabetes, fear of childbirth and foetal sex

2 Entrepreneurs, students, retired & unemployed women, housewives & all unclassifiable cases

3 Controlled for age, race/ethnicity, relationship status, and number of children in the home

4 United Kingdom based study
A meta-analysis of 21 studies reported that antenatal depression incidence rates ranged from 7.4% in the first trimester, to 12.8% in the second (Bennett, Einarson, Taddio, Koren, & Einarson, 2004). Much higher occurrences are however also reported in vulnerable at-risk groups (Corbani et al., 2017; Edwards, Galletly, Semmler-Booth, & Dekker, 2008; Meltzer-Brody et al., 2013). Despite this prevalence, and the numerous associated adverse consequences for women and newborns (Glover, 2014; Marcus & Heringhausen, 2009), rates of engagement in depression treatment are low (Battle, Salisbury, Schofield, Ortiz-Hernandez, 2013), with approximately only 10% of women gaining effective treatment (Gavin et al., 2015). As was the case for depression in the general population, under-detection is a contributor, with reports of no more than 20% of affected peripartum women being identified (Hübner-Liebermann et al., 2012). Indeed, a recent Australian study revealed that of the 4,366 pregnant women surveyed, 45.9% were asked about depression, 49.6% about anxiety or worry; 29.6% about relationship issues, 16.6% about financial problems and 14.1% about family violence. Midwives were identified as being more likely to ask about health, family violence, and other social hardships than doctors (Yelland & Brown, 2014), which may be reflective of routine antenatal screening programmes, whereas obstetricians and paediatricians reportedly receive minimal training in the recognition and treatment of depression (Wisner, Logsdon, & Shanahan, 2008).

### 1.3.1 Screening for Antenatal Depression

Attempts to correct for under detection have however been put in place. In Australia and the United States of America (USA), the ten question self-reporting questionnaire, the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987) is routinely used. In Germany, a version of this tool is administered. In the United Kingdom (UK), general recommendations include the use of two “Whooley” questions at the first prenatal consultation. If a woman answers positively to reports of ‘feeling down, depressed, or hopeless’ or having ‘little interest or pleasure in doing things’, a clinical investigation of the formal diagnostic criteria is required (Hübner-Liebermann et al., 2012). Rallis and co-workers (2014) nonetheless suggest additional screening for
stress as a separate affective state may be necessary, as it is frequently co-morbid with depression and anxiety (Rallis, Skouteris, McCabe, & Milgrom, 2014) and also detrimental to the foetus (Goldstein, Handa, & Tobet, 2014). Support for such an approach comes from the recent findings of Reid and co-workers (2009), that demonstrated that not only were women suffering from depression (17%), they were also co-morbid for anxiety (25%) and stress (25%).

1.4 Antenatal Depression, Stress and Anxiety – Short and Longer-Term Consequences

Left untreated, antenatal depression is associated with a plethora of negative maternal and foetal outcomes. Affected women may neglect their nutrition, personal and medical care (Epstein, Moore, & Bobo, 2014; Weisskopf et al., 2015), and in addition, are at increased risk of binge drinking (Leis, Heron, Stuart, & Mendelson, 2012), self-medicated drug use (Holden, McKenzie, Pruitt, Aaron, & Hall, 2012; Pajulo, Savonlahti, Sourander, Helenius, & Piha, 2001; Zuckerman, Amaro, Bauchner, & Cabral, 1989), and self-harm (Yonkers et al., 2009). As a consequence, foetal growth and development may be detrimentally impacted (Hanley & Oberlander, 2014; Stein et al., 2014). Decreased maternal responsiveness and increased maltreatment of children may in addition occur though mechanisms that are independent of postnatal depression (Hayes, Goodman, & Carlson, 2013).

Pregnancy and birthing outcomes that are also thought to arise as a consequence of antenatal depression are provided in Table 1.2, along with risk and odds ratios for occurrence. These include pre-eclampsia (Kim et al., 2013; Kurki, Hiilesmaa, Raitasalo, Mattila, & Ylikorkala, 2000; Qiu, Williams, Calderon-Margalit, Cripe, & Sorensen, 2009); intrauterine growth restriction (Grote et al., 2010; Hoffman, 2000); pre-term birth (PTB) (Grigoriadis et al., 2013; Grote et al., 2010; Jarde, Morais, Kingston, Giallo, MacQueen, Giglia, Beyene, Wang, McDonald, 2016; Yedid Sion, Harlev, Weintraub, Sergienko, & Sheiner, 2016); and low birth weight (LBW) (Diego et al., 2004; Grote et al., 2010; Yedid Sion et al., 2016). Increased epidural analgesia use (Chung, Lau, Yip, Chiu, & Lee, 2001),
caesarean sections, instrumental deliveries (Chung et al., 2001; Kim et al., 2013; Yedid Sion et al., 2016); and neonatal intensive care unit admission (Chung et al., 2001; Gentile, 2015) have in addition also been reported. There are however many other associated outcomes including increased nausea (Alder, Fink, Bitzer, Höсли, & Holzgreve, 2007; Swallow, Lindow, Masson, & Hay, 2004), and vomiting (Swallow et al., 2004); gestational diabetes (Kozhimannil, Pereira, & Harlow, 2009); placental abnormalities (Jablensky, Morgan, Zubrick, Bower, & Yellachich, 2005); spontaneous miscarriage (Nakano et al., 2004; Sugiura-Ogasawara et al., 2002); prolonged labour (Hanlon et al., 2009); and reduced AGPAR scores (Yedid Sion et al., 2016), and breastfeeding initiation (Grigoriadis et al., 2013; Hanlon et al., 2009).

<table>
<thead>
<tr>
<th>Condition &amp; reference</th>
<th>Risk ratio (RR)</th>
<th>Odds ratio (OR)</th>
<th>Confidence Intervals (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-eclampsia (Kurki et al., 2000)</td>
<td></td>
<td>2.5, 95% CI 1.1-5.4</td>
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<tr>
<td>Intrauterine growth restriction (Grote et al., 2010)</td>
<td>1.45, 95% CI 1.05-2.02 (categorical measures); 1.02 95% CI 1.00-1.04 (continuous measures)</td>
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<tr>
<td>Pre-term birth (Jarde et al., 2016)</td>
<td></td>
<td>1.56, 95% CI 1.25-1.94</td>
<td></td>
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<tr>
<td>Low birth weight (Jarde et al., 2016)</td>
<td></td>
<td>1.96, 95% CI 1.24-3.10</td>
<td></td>
</tr>
<tr>
<td>Increased epidural analgesia (Chung et al., 2001)</td>
<td>2.56, 95% CI 1.24–5.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased caesarean delivery (Chung et al., 2001)</td>
<td>2.28, 95% CI 1.15–4.53</td>
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</tr>
<tr>
<td>Neonatal intensive care unit admission (Chung et al., 2001)</td>
<td>2.18, 95% CI 1.02–4.66.</td>
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</table>
Postnatally, consequences are also reportedly extensive, with detrimental impacts being seen across multiple developmental domains. Children for example display physiological alterations including heightened hypothalamic-pituitary axis (HPA) activity (Diego et al., 2004; Glover, O’Connor, & O’Donnell, 2010), and stress reactivity (Brummelte & Galea, 2016); along with various neurotransmitter and hormonal imbalances (Diego et al., 2004). Psychological disturbances also range from observations of excitability to withdrawal (Previti et al., 2014), as well as increased mental health vulnerability (Pawlby et al, 2009; Stein et al., 2014). Behavioural consequences also described encompass externalising behaviours, such as attention deficit hyperactivity disorder (ADHD) (Field, 2011), to anti-social (Field, 2011; Stein et al., 2014 ), and criminal activities (Mäki et al., 2003). With respect to developmental milestones, language, cognition (Epstein et al., 2014), motor (Field, Diego, & Hernandez-Reif, 2006; Goodman, Rouse, Long, Ji, & Brand, 2011; Hanley & Oberlander, 2014), emotional and social functioning (Field et al., 2006; Stein et al., 2014) are reportedly all disrupted, with overall developmental delays (Deave, Heron, Evans, & Emond, 2008; Field, 2011) in the order of 9% (Deave et al., 2008) being seen.

1.5 Co-Morbid Antenatal Depression, Stress and Anxiety

Co-morbid prenatal stress, anxiety and depression, in various combinations, have further been associated with negative infant outcomes. Consequences in addition to those previously discussed include increased risk of congenital malformations (Glover & Barlow, 2014; Hansen, Lou, & Olsen, 2000), cardiovascular related diseases (CVD) (Dawe et al., 2012; van Dijk, van Eijsden, Stronks, Gemke, & Vrijkotte, 2012) and asthma (Khashan et al., 2012). Shortened life spans via reduced telomere lengths (Entringer et al., 2011; Entringer et al., 2013); and regional reductions in brain grey-matter density (Buss, Davis, Muftuler, Head, & Sandman, 2010) can reportedly also occur, with physical alterations to the brain being postulated as explanations for cognitive and intellectual impairment, as well as neurodevelopmental and psychiatric disorders (Glover, 2014; Glover & Barlow, 2014).
With maladaptive stress responses being known to play a key role in the development of depression and other mental health disorders (Lloyd & Nemeroff, 2011; Nemeroff & Vale, 2005), the mechanisms via which stress impacts foetuses has also been explored and proposed to in part arise as a consequence of overexposure of maternal cortisol due to increased transplacental transfer (O'Donnell, O’connor, & Glover, 2009), as well as down-regulation of the placental enzyme responsible for the inactivation of cortisol (O’Donnell et al., 2012). Recently a study did demonstrate that excess in utero glucocorticoids were associated with disrupted foetal HPA axis circuitry; altered mood and stress regulation; disrupted autonomic nervous system (ANS) functioning; and a propensity in later life to develop CVD (Goldstein et al., 2014).

1.6 Conventional Therapy for the Management of Antenatal Depression

1.6.1 Pharmacological Approaches for the Treatment of Antenatal Depression

Treatment options for depressed pregnant woman are the same as those available to depressed populations at large, however additional considerations are made in regard to the safety of psychotropic drugs. Recent updated clinical guidelines provided to Australian physicians (Austin, Highet, & Expert Working Group, 2017) recommend serotonin reuptake inhibitors (SSRIs) as the first-line treatment for moderate to severe depression. However, an additional specification is to also assess women’s past response to SSRIs, as well as her risks for miscarriage, preterm birth, and postpartum haemorrhage, and any other factors that may increase adverse effects, such as the half-life of drugs.

Guidelines such as these are based upon data that has accumulated from observational studies (Epstein et al., 2014), case series and patient registries (Bourke, Stowe, & Owens, 2014), as ethical restrictions generally prevent controlled pharmacological studies being conducted during pregnancy (Bourke et al., 2014; Epstein et al., 2014; Yonkers, Blackwell, & Forray, 2014). Consequently, determination of safety profiles, and best times for
administration is difficult to ascertain (Epstein et al., 2014), especially when safety reports are frequently conflicting (Raudzus & Misri, 2009), and controversial (Campagne, 2007; Epstein et al., 2014; Hanley & Oberlander, 2014; Robinson, 2015; Simonelli, Martin, & Bérard, 2010). Debate has also centred around the interpretation of findings, with some authors arguing that studies reporting detrimental medication impacts have inadequately separated out the effects of underlying depression (Suri, Lin, Cohen, & Altshuler, 2014), however when correctly adjusted for, effects are diminished or indistinguishable (Susser, Sansone, & Hermann, 2016; Weisskopf et al., 2015). Others contrastly suggest that prospective studies not detecting increased teratogenic risk may lack statistical power, as when larger studies are examined, statistically significant risks do emerge (Gentile, 2015). Practitioner prescribing reflect these difficulties (Raudzus & Misri, 2009), with pregnant women reportedly receiving a range of recommendations, including: discouragement of commencement or cessation of medication (Becker, Weinberger, Chandy, & Schmukler, 2016; Bourke et al., 2014; Einarson, Selby, & Koren, 2001; Hermansen & Melinder, 2014); reduced and possibly sub-therapeutic dosing (Becker et al., 2016; Sockol, Epperson, & Barber, 2011); maintained current doses; and increased dosing that is considerate of pregnancy related pharmacokinetic changes (Hostetter, Stowe, Strader Jr, McLaughlin, & Llewellyn, 2000; Sit, Perel, Helsel, & Wisner, 2008).

A well accepted impact of psychotropic medication exposure however is neonatal drug ‘withdrawal’ (Bellantuono, Vargas, Mandarelli, Nardi, & Martini, 2015; Hanley & Oberlander, 2014) or toxicity (Gentile, 2015) syndrome, which is typified by a wide range of predominantly short-lived symptoms that may require intensive care admission (Gentile, 2015; Moses-Kolko et al., 2005). According to Previti et al. (2014) the syndrome occurs as a consequence of SSRI withdrawal and toxicity, as well as serotonergic excess, and adverse central nervous system (CNS) effects, with approximately 25–30 % of exposed newborns being affected.

With respect to other iatrogenic impacts, a recent Finnish study examining the consequences of first trimester SSRI use in 1,580,629 offspring over the period
from 1996 to 2013 supported the argument that once confounders were adequately adjusted for, detrimental impacts were minimal. In this study, previously reported associations such as PTB, small for gestational age (SGA), autism spectrum disorder (ASD) and ADHD were all identified, however once pregnancy, maternal and paternal traits had been adjusted for, exposure was only associated with a small increased risk of PTB (Sujan et al., 2017). Other studies have nonetheless also reported a modest increased risk of spontaneous abortion (Yonkers et al., 2014), and persistent pulmonary hypertension (Grigoriadis et al., 2014; Huybrechts et al., 2015), for which risk or odds ratios are provided in Table 1.3, along with those for neonatal ‘withdrawal’ syndrome and PTB.

<table>
<thead>
<tr>
<th>Condition &amp; reference</th>
<th>Risk ratio (RR)</th>
<th>Odds ratio (OR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal drug ‘withdrawal’ (Previti et al., 2014)</td>
<td>3.0, 95% CI 2.0–4.4</td>
<td></td>
</tr>
<tr>
<td>Pre-term birth (Sujan et al., 2017)</td>
<td>1.34, 95% CI, 1.18–1.52</td>
<td></td>
</tr>
<tr>
<td>Spontaneous abortion (Yonkers et al., 2014)</td>
<td>1.45, 95% CI 1.22–1.72</td>
<td>1.87, 95% CI 1.50–2.33</td>
</tr>
<tr>
<td>Persistent pulmonary hypertension (Grigoriadis et al., 2014)</td>
<td>2.50, 95% CI 1.32–4.73</td>
<td></td>
</tr>
</tbody>
</table>

Further associations of major, minor and cardiac malformations have in addition been reported (Nikfar, Rahimi, Hendoiee, & Abdollahi, 2012), however they are also disputed (Austin et al., 2017; Huybrechts et al., 2014); alongside disrupted maternal infant attachment (Brummelte & Galea, 2016); and psychomotor (Casper et al., 2011; Hanley, Brain, & Oberlander, 2013; Previti et al., 2014), neurodevelopmental (Olivier, Åkerud, & Sundström Poromaa, 2015; Previti et al., 2014), socio-emotional (Hanley et al., 2013; Previti et al., 2014) and behavioural effects (Casper et al., 2011; Hanley et al., 2013; Hanley & Oberlander, 2014; Previti et al., 2014). Postulated theories as to how SSRIs may impact include alterations to key early developmental serotonin pathways
(Hanley & Oberlander, 2014), as well as epigenetic modifications (Olivier et al., 2015). Other psychotropic drug types have similarly been associated with various issues (Coughlin et al., 2015; Ennis & Damkier, 2015; Gentile, 2014, 2015), and consequently, numerous authors suggest further research is required to ascertain longer term developmental effects (Lewis, Galbally, Opie, & Buist, 2010; Parry, 2013; Pearlstein, 2008).

With few studies being available to evaluate SSRI effectiveness during pregnancy, the advice provided in the recent Australian guidelines suggests that effectiveness is “not expected to be any different to that in the general population” (Austin et al., 2017, p51). Others have however reported that pregnancy related pharmacokinetic changes may impact dosing (Hostetter et al., 2000; Sit et al., 2008). Of those studies that have been conducted, Wisner and colleagues (2009) demonstrated that untreated depressed pregnant women had significantly greater mean depression scores than the medicated group. Cohen and co-workers (2006) also reported major depression relapse rates of 68% in the group that discontinued, compared to 26 % in those that continued with medication. A study conducted by Yonkers and colleagues (2011) however reported no statistical difference between the unmedicated and medicated group with respect to risk of developing a major depressive episode or relapsing during pregnancy. Based upon these findings, Epstein concluded that “some pregnant women with antenatal depression will benefit from antidepressant treatment, but a substantial proportion of patients will not” (Epstein et al., 2014, p111).

Pregnant women may therefore face a difficult decision regarding whether or not to medicate their depression. With no guaranteed effect (Cleare et al., 2015; Cohen et al., 2006; Epstein et al., 2014), the possibility of exposing offspring to potential harm (Bennett et al., 2007; Ride & Lancsar, 2016), and themselves to undesirable side effects (Manber et al., 2002; Mancini, Hardiman, & Lawson, 2005), it is no wonder that up to 50% of women indicate high levels of decisional conflict (Vigod et al., 2016) when evaluating the risks of medicating against non-treatment (Epstein et al., 2014). Many also report a reluctance to take antidepressants (Battle et al., 2013; Battle, Uebelacker, & Magee, 2012;
Marcus, 2009; O’Mahen & Flynn, 2008), the perception of an over promotion of medication (MacPherson et al., 2013), and narrowed treatment options (Byatt et al., 2013b). Indeed, approximately only one third of women indicate consideration of antidepressants if recommended (Goodman, 2009), instead preferring psychotherapy (Kim et al., 2011; O’Mahen & Flynn, 2008), non-pharmacological options (Battle et al., 2013; Ride & Lancsar, 2016) including complementary medicines (CM) (Freemen, 2009; Matthews, Huberty, Leiferman, McClain, & Larkey, 2016; Ride & Lancsar, 2016), or no treatment, if medication is the only option (Ride & Lancsar, 2016).

1.6.2 Psychological Approaches to the Treatment of Antenatal Depression

The updated Australian practice guidelines strongly recommended that women experiencing mild to moderate antenatal depression be provided with psychoeducation as well as individual structured psychological interventions such as cognitive behavioural therapy (CBT) and interpersonal psychotherapy (ITP). Psychological therapies were also recommended for incorporation in cases of moderate to severe depression, once prescribed medications had become effective. It was in addition suggested that some women may benefit from social support groups and facilitated self-help, however effectiveness evidence in this regard was less robust (Austin et al., 2017).

Nonetheless, like any therapy, limitations have also been reported. These include non-universal effectiveness (Cleare et al., 2015; Epstein et al., 2014), with the findings for more severe forms of depression remaining unclear; relapse despite continuation (Anderson et al., 2008); non-desirability (Manber et al., 2002), especially amongst those not wishing to disclose or revisit past traumas (Farber, Khurgin-Bott, & Feldman, 2009); an unwillingness to try new therapies (Battle et al., 2012), particularly due to perceptions around credibility (Schroer, Kanaan, MacPherson, & Adamson, 2012); and difficult access in remote areas.


1.7 Postnatal Depression – Significance, Definition, Incidence and Risk Factors

Having antenatal depression additionally places the mother at high risk of developing postnatal depression (PND) (Beck, 2001; Milgrom et al., 2008; Robertson, Grace, Wallington, & Stewart, 2004). A recent Australian longitudinal study demonstrated that the two strongest independent predictors of a postnatal EPDS score > 12 were previous depression or antenatal depression, and a low level of partner support (Milgrom et al., 2008). Other risks include previous miscarriage, pregnancy termination (Leigh & Milgrom, 2008), stillbirth or infant death (Oates, 2008); as well as obstetric and neonatal complications (Carson, Redshaw, Gray, & Quigley, 2015; Robertson et al., 2004); being left alone during labour; poor post-partum health (Redshaw & Henderson, 2013); having infants with difficult temperaments (Stein et al., 2014); and parental stress (Robertson et al., 2004), particularly when women are displaying dysfunctional personalities, inadequate coping styles and suboptimal parenting behaviours (Austin, Priest, & Sullivan, 2008).

Typically defined as the occurrence of depression in the year following birth (Austin et al., 2017), postnatal depression is reportedly the most common complication of childbearing (O'Hara & Swain, 1996), with mothers not only having to adjust to and care for their newborns, but also manage their own symptoms. As a consequence, the ability of the mother to connect with and care for her child may be compromised, and in addition, she may overly focus her concerns and difficulties on the infant (Robertson & Fernandes, 2010). The combined demands of motherhood and mental health issues reportedly contributes toward some mothers feeling like failures, as well as others perceiving their newborns to be ‘difficult and demanding’ (Hubner-Liebermann et al., 2012). Resultant feelings of guilt and shame can in turn make women reluctant to seek help, due to a fear of being judged (Hubner-Liebermann et al., 2012; Werner et al., 2015). Unfortunately, perinatal distress can contribute to ‘difficult and demanding’ behaviour in babies and conversely, disturbed irritated babies can trigger postnatal depressive symptoms in mothers (Stein et
al., 2014). Care of other children, and relationships with partners, can in
addition become compromised (Stewart, 2011).

Specific research conducted in this area has revealed that depressed mothers
can exhibit compromised caregiving (Becker et al., 2016), responsiveness
(Milgrom, Westley, & Gemmill, 2004) and bonding (Dubber, Reck, Muller, &
Gawlik, 2015) with their babies, whereby touch (Field, 2010), verbal, and visual
communications (Hübner-Liebermann et al., 2012) are all reduced. In addition,
affected women are more at risk of harsh (Field, 2010), insensitive and sub-
optimal (Garfield et al., 2016; Stein et al., 2014) parenting styles, such as
disengagement and rejection (Barker et al., 2011). Impacts to children with
respect to physiological, social, emotional and behavioural dysregulation are
similar to those seen for antenatal depression (Brummelte & Galea, 2016; Stein
et al., 2014), with postnatal consequences such as negative breast feeding
outcomes (Brummelte & Galea, 2016) sleep and feeding disturbances (Field,
2010); insecure attachment (Stein et al., 2014); poor health (Ban, Gibson, West,
& Tata, 2010; Stein et al., 2014), and failure to thrive (Field, 2010), all being
reported.

Early detection is important, however difficult with respect to distinguishing
PND from symptoms of adjusting to early parenting. These may include sleep
depprivation; tiredness; weight changes; social isolation; stress (Robertson &
Fernandes, 2010); and the ‘baby blues’, which typically encompasses transient
symptoms (Seyfried & Marcus, 2003), that are thought to be a product of
hormonal adjustment (Pitt, 1973; Seyfried & Marcus, 2003). It is also necessary
to differentiate PND from postpartum psychosis, which although rare and
affecting only 0.1% to 0.2%, requires immediate hospitalisation (Hübner-
Liebermann et al., 2012; Seyfried & Marcus, 2003).

With respect to PND, a range of severity may also be experienced. Moderate to
severe forms reportedly occur in 3-5% of cases, and may require specialist
psychiatric services (O’Hara & Swain, 1996). Tragically, severe cases can result
in harm to or death of the infant (Burke, 2003), as well as maternal suicide
(Thornton, Schmied, Dennis, Barnett, & Dahlen, 2013; Wisner et al., 2013),
which alongside accidental injury, is the leading cause of maternal death within the first year postpartum (Thornton et al., 2013).

Meta-analyses report the prevalence of depressive disorders within the first 12 weeks postpartum as ranging from 13% (O’Hara & Swain, 1996) to 19.2% (Gaynes et al., 2005), with the differences in rates being due to varying vulnerabilities in different populations (Werner et al., 2015), as well as different data collection methods (Robertson & Fernandes, 2010). Major depression was identified as occurring in 7.1% of mothers (Gaynes et al., 2005), with 8% also being found to experience symptoms beyond the one year time frame (Dennis, Heaman, & Vigod, 2012). Depression may also go beyond this timeframe, and extend into subsequent pregnancies (Austin et al., 2008; Robertson & Fernandes, 2010), with the greatest risk factor for this occurrence being the severity of the previous episodes (Elliott et al., 2000; Robertson et al., 2010).

As is the case for antenatal depression, under-detection is an issue, with reportedly only 26% of depressed postnatal women being correctly identified in one study (Johanson, Chapman, Murray, Johnson, & Cox, 2000). Attempts to improve detection have included the routine use of the screening EPDS (Milgrom, Ericksen, Negri, & Gemmill, 2005); as well as the publication of lists of potential signs, such as women attempting to hide their condition for fear of losing custody of their child; self-medicating to disguise / control symptoms; and appearing anxious, distressed and agitated, rather than in a flat mood (Robertson & Fernandes, 2010).

1.8 Therapeutic Approaches for Postnatal Depression

The recent Australian clinical practice guidelines suggest that women with mild to moderate PND, that are experiencing difficult relationships with their babies, be referred to appropriate intervention services. For women with moderate to severe PND, SSRIs are recommended as the first-line treatment, however prior to being administered, intentions regarding breastfeeding, as well as the infant’s health and gestational age at birth should be taken into consideration; as effects
of exposure may be increased in preterm and unwell babies (Austin et al., 2017). Additional strategies that have been suggested may also be helpful include the encouragement of breastfeeding, as it may be protective of maternal mental health (Kendall-Tackett, 2007); and antenatal or early post-birth administered psychosocial and psychological strategies designed to prevent PND (Dennis, 2013b).

1.9 Perinatal Mental Health Disturbances and Cycle Perpetuation

More recently, research has provided new understanding regarding how the negative effects of perinatal mental health disturbances may be further perpetuated. These include observations that: 1) the risk of parental conflict, domestic violence and relationship demise is increased, and thus offspring may be exposed to additional stress (Stein et al., 2014); 2) the quality of maternal care provided to infants is a significant predictor of the quality of parenting they then provide (Garfield et al., 2016); and 3) female children exposed to suboptimal parenting trauma exhibit greater perinatal depression severity (Grote et al., 2012; Plant et al., 2013), which in turn increases the likelihood of early life adversity in their own children (Plant et al., 2013).

The mechanisms postulated for these individual and inter-generational effects (Serati, Redaelli, Buoli, & Altamura, 2016) include: gene inheritance (Hanley & Oberlander, 2014; Stein et al., 2014); environmental factors (Stein et al., 2014) that alter neurotransmitter (Brummelte & Galea, 2016), hormone, and inflammatory cytokine (Brummelte & Galea, 2016; Garfield et al., 2016) balances; placental maternal to foetal transfer of microRNA that is thought to be involved in maternal / foetal communication and environmentally-sensitive alterations to foetal development (Lee & Goto, 2013); and heritable genomic epigenetic methylation alterations (Bell, Erickson, & Carter, 2014; Champagne, 2008; Lee & Goto, 2013; Stein et al., 2014). Antenatal depression (Oberlander et al., 2008), stress (Hoffmann & Spengler, 2012), anxiety (Oberlander et al., 2008), and intimate partner violence (Radtke et al., 2011), have all been associated
with epigenetic changes in foetal HPA axis receptor genes, which are correspondingly associated with adult mental health disturbances (Lee & Goto, 2013). Interestingly, hypomethylation at growth regulation sites has also been shown to occur (Liu et al., 2012), which may account for the association between antenatal depression and LBW (Garfield et al., 2016). Low SES, traumatic events, post-traumatic stress disorder (PTSD), early life adversity, poor maternal care (Garfield et al., 2016), and altered postpartum behaviour (Champagne, 2008) have in addition been shown to result in other epigenetic changes. Such alterations are theorised to be part of a prenatal adaptation process aimed to prepare the child for the environment into which it will be born (Lee & Goto, 2013). Consequences are long lasting (Carter, Boone, Pournajafi-Nazarloo, & Bales, 2009; Garfield et al., 2016), and of greatest impact to children (Bauer et al., 2016).

1.10 Limitations with Conventional Approaches for the Management of Perinatal Depression

Currently, limitations with conventional approaches for the management of perinatal mental health disorders account in part for why only 50% of affected women seek help (Bauer et al., 2016; Henshaw et al., 2013); 40% are clinically recognised (Gavin et al., 2015); 30% attend mental health visits (Byatt et al., 2013a); 24% receive any treatment (Gavin et al., 2015); 10% gain effective treatment (Gavin et al., 2015); 6% complete conventional treatment courses (Byatt et al., 2013a); and 3-6% achieve remission (Gavin et al., 2015).

Provider relationship dissatisfaction is one contributing factor for low health service engagement, with findings in qualitative studies revealing that women are more likely to engage in treatment, if they feel 'heard' (Byatt et al., 2013a; Henshaw et al., 2011) and perceive their clinician to be warm, genuine (Henshaw et al., 2011), non-judgemental (Bennett et al., 2007; Byatt et al., 2013a; Henshaw et al., 2011; Ride & Lancsar, 2016), empathetic (Bennett et al., 2007; Byatt et al., 2013a; Ride & Lancsar, 2016), and able to understand the complexity of their difficulties (Bennett et al., 2007). Obstetricians' however have reportedly been perceived as impersonal, unhelpful (Henshaw et al.,
2011), unsupportive (Byatt et al., 2013a), too busy to ‘talk’ to, focused only on the pregnancy (Bennett et al., 2007), inadequately trained in psychiatric issues (Bennett et al., 2007; Bennett et al., 2009; Byatt et al., 2013a), and unable to provide sufficient advice about the benefits versus risks of antenatal psychotropic medication use (Byatt et al., 2013a).

Some women additionally reported midwives were unsupportive and unavailable (Byatt et al., 2013a). Factors potentially contributing to this conception may be due to midwives feeling inadequately trained in the provision of conventional mental health support (Hauck et al., 2015; Jones, Creedy, & Gamble, 2012); as well as constrained by workload time pressures and hindering organisational priorities (Jones et al., 2012). An additional issue faced by midwives is the increasing demand by women for less invasive (Adams, 2006) natural approaches (Hall, Griffiths, & McKenna, 2011), as well as the increased utilisation of CM (Adams, Sibbritt, & Lui, 2011; Frawley et al., 2013; Hall, McKenna, & Griffiths, 2013); which then places them under pressure to “develop the relevant knowledge and systems to respond appropriately” (Hall et al., 2013, p e90), when CM use in hospitals is still opposed (Adams, 2006) and often marginalised (Hall et al., 2013).

1.11 Complementary Medicine and Therapies for the Management of Depression

Accumulating evidence now suggests depressed people are also utilising complementary medicines and therapies for the management of their symptoms. In a recent review, CM use amongst depressed and anxious populations was reportedly 11%, which is also comparable to rates of antidepressant usage (Dennis & Dowswell, 2013b). In another study published in the USA, 34% of psychiatric outpatients with major depressive disorder (MDD), and 20% of non-hospitalized depressed patients were found to be using CM and therapies including acupuncture to manage their depression (Wu, Yeung, Schnyer, Wang, & Mischoulon, 2012). In fact, it has also been stated that depressed Americans were more likely to use CM and therapies than
antidepressants or psychotherapy for the management of their symptoms (Kessler et al., 2001). Similarly, in the UK, mental health issues were the second most common reason for seeking out acupuncture (MacPherson, Sinclair-Lian, & Thomas, 2006). As a therapy, acupuncture was perceived to be both more credible than counselling and more beneficial for depression than either counselling or usual GP care (Schroer et al., 2012). The findings of another survey in the UK similarly demonstrated that 9% of patients attending acupuncture clinics went for assistance with emotional and mental problems, and of these, 67% reported definite positive change (Gould & MacPherson, 2001). Within Australia, depressed populations are also demonstrating a preference for, as well as significant use of CM (Highet, Hickie, & Davenport, 2002; Jorm et al., 2000).

This trend has also been observed in perinatal populations. A recent Australian survey found that 33 % of the 217 surveyed women indicated they would choose ‘natural, herbal or traditional Chinese medicine’, if they became aware of experiencing depression and anxiety (Ride & Lancsar, 2016). A much higher percentage (84%) of 1032 depressed pregnant women in the USA also recently indicated they “would consider using a complementary health approach for weight and or stress management during pregnancy” (Matthews, Huberty, Leiferman, McClain, & Larkey, 2016, p 81). The higher proportion in the latter case may possibly be reflective of actual dissatisfaction with conventional options, rather than hypothetical choices (Battle et al., 2013).

1.12 Summary

In light of current prevalence estimates, as well as the extensive detrimental consequences of perinatal mental health disturbances, it is no wonder the Australian government has made the focus on mental health a national health priority (Australian Government National Health and Medical Research Council, 2016). Despite comprehensive attempts to identify and adequately treat women suffering from perinatal depressive disorders however, it remains the case that not all women's needs are adequately met. As a consequence, it is of great
importance to continue to explore and evaluate “the types of interventions that can reduce long-term negative effects for both mothers and offspring” (Bauer et al., 2016, p 83).

In the chapter to follow, the existing evidence base regarding the effectiveness of acupuncture in the general, as well as perinatal population is explored.
Chapter 2
An Overview of Acupuncture as a Therapy for Depression and Antenatal Depression
2.1 Acupuncture as a Complementary Health Approach for the Treatment of Depression During the Perinatal Period

The origins of acupuncture as part of Traditional East Asian Medicine (TEAM) began thousands of years ago in China (MacPherson, Hammerschlag, Lewith, & Schnyer, 2008). More recently, components of this knowledge travelled to the West where, under the influences of Western culture, a variety of styles, practitioners and settings in which acupuncture is conducted, emerged (MacPherson et al., 2008).

2.1.1 TEAM – Theoretical Concepts Underpinning Treatment Strategies

One of the fundamental ideologies that underpins TEAM, is that an individual is believed to be intrinsically connected to and inseparable from their environment (Maciocia, 1989). The individual is therefore seen to be a complex interplay of both internal and external aspects, and it is through this broader holistic view, that disharmony is diagnosed. Treatment is correspondingly tailored to the summation of all components manifesting in that person, at that particular moment in time.

This theory of inter-connectedness and inseparability of ‘all things’, stems from the ancient teachings of the ‘Dao’, which, in short, describes a never-ending continuum of all living and non-living things (Veith, 1949). As the limitless nature of the ‘Dao’ was so vast, the ancient Chinese scholars separated it into two major divisions, namely yin and yang (Veith, 1949). ‘All things’ were classified as either one or the other, however, within this categorisation, relativities were also permitted with respect to the extent to which something was either yin or yang. Yin was encompassed by aspects such as female, cool, rest, night, structure, fluid, blood and form. Yang was defined as opposites such as male, warmth, activities, daytime, ‘qi’ or ‘life energy’ and bodily processes (Maciocia, 1989).
Applying this categorisation to ‘dis-ease’ enabled in the first instance, the identification of a simple dualistic disharmony, that is, either yin or yang predominance. These concepts, along with their relativities, were then extended to organs and bodily processes, in which more complex interplays of yin and yang were seen. Further intricacy was nonetheless also required to encompass the sophistications of the body. One such incorporation based upon the observations of the seasons (Veith, 1949) was the theory of the five elements, in which the elements were seen to be in a continuous cycle of transformation, and inter-influencing motion (Hicks, Hicks, & Mole, 2010; Maciocia, 1989). An additional inclusion was the concept of ‘externally and internally derived pathogenic factors’, with external causes being thought to occur as a consequence of exposure to pathogens, poisons, inclement weather, and poor diet and lifestyle choices; whereas internal were considered to be a product of emotional and spiritual influences. Whilst experiencing a range of emotions is both normal and appropriate, emotions felt too intensely or for prolonged periods, were thought to create disharmony (Maciocia, 1989). The ability of the individual to move through and process various emotional states, was also considered to be a contributing factor (Maciocia, 1989). These ideas are not dissimilar to Western thinking regarding stress, allostatic overload, and adaptation (McEwen, 1998), and vulnerability and resilience (Garmezy, 1993).

Symptomology is reasoned to arise as a consequence of deficiencies, excesses and disrupted normal flow, in which components of the body such as blood, fluids, qi, cold and heat, all have the potential to stagnate (Maciocia, 1989). Even intense emotional upset, if insufficiently ‘processed’, can lead to stagnation. Once prolonged, stasis can transform into fire, which may correspond to inflammation in the West, and arise as a consequence of thwarted kinetic energy (Maciocia, 1989).

### 2.1.2 Depression from the Perspective of TEAM

Depression from the perspective of TEAM is identifiable in numerous Chinese medicine patterns of disharmony, however an additional critical component, is
disturbance of the ‘shen’ (Schnyer & Allen, 2001). ‘Shen’ is often translated as ‘spirit’ (Kaptchuk, 1983) or ‘mind’ (Maciocia, 1989), and described as encompassing aspects of the psyche such as consciousness; emotions (Maciocia, 1989); personality; one’s ability to think, discriminate and choose appropriately (Kaptchuk, 1983); and also, form meaningful relationships (Maciocia, 1989). When ‘shen’ is disharmonious, disruptions to these functions result in various symptomologies, that are congruent to those seen in Western mental health disturbances (Kaptchuk, 1983; Maciocia, 1989). Treatment strategies therefore aim not only to rectify the precise imbalance of yin, yang, and stagnation manifesting within the individual, but also their disturbance of ‘shen’.

Numerous diagnostic methods are provided to enable this precise determination, along with multiple treatment strategies to rectify these disharmonies. This individualised treatment approach is however difficult to replicate in the format of tightly controlled clinical research studies, hence the challenges faced researching Chinese medicine within the Western medical framework are now discussed.

### 2.1.3 Contrasting Western and Eastern Medical Paradigms and Considerations for Research

The Western medical ‘gold standard’ evaluation of a health care intervention is the double blind randomised controlled trial (RCT) (MacPherson et al., 2008), in which the “standardised, replicable and statistically represented ‘average person’” is examined (Kaptchuk, in MacPherson et al., 2008, p xiii), for the predominant purpose of a “one-size-fits-all therapeutic prescription” (Fønnebø et al., 2007, p3). The approach to treatment in TEAM is however diametrically opposed, in that it is individually focused and responsive to the ever changing circumstances within any individual, at any moment in time (Kaptchuk in MacPherson et al., 2008, forward).

Another difference between the two approaches, is that in the Western research, greater emphasis is placed upon the importance of objective measurement over subjective reporting, whereas in TEAM, subjective reporting
and sensory impressions are prioritised over objective evaluations (Kaptchuk in MacPherson et al., 2008, p xiii). It is also considered likely that the effects of the holistic approach taken in TEAM, are greater than the “sum of the parts” (MacPherson et al., 2008, p 6). Taking these differences into consideration, along with the diversity of TEAM styles being practiced, it is not surprising that research efforts to demonstrate the efficacy of acupuncture, would encounter difficulty.

Consequently much debate centred on the appropriateness of utilising Western research methods to evaluate the merits of TEAM (Hammerschlag, 1998), nonetheless, a reality emerged that if acupuncture is to be accepted as a validated healthcare therapy, it must be via this system of evaluation (Park et al., 2008; MacPherson et al., 2008). Trial design was consequently adapted to address these concerns, and also attempt to “conduct research into acupuncture in a way that is fair to the medicine” (MacPherson et al., 2008, p6).

### 2.1.3.1 Efficacy and effectiveness studies

Recommendations for the modified RCT approach suggested that acupuncture studies follow designs along the efficacy – effectiveness research continuum (Witt, 2011). Efficacy studies more closely adhere to the aims of the standardised placebo RCT design, whereby the most likely active treatment components (Fønnebø et al., 2007), are tested under ideal conditions (McDonald & Janz, 2017; Witt, 2011), to determine whether acupuncture is superior to placebo (MacPherson et al., 2008). The rationale behind this approach, is ease of replication, interpretation, and reliability of results, with studies of this type being referred to as having high internal validity (Witt, 2011). A major issue nonetheless, is defining precisely what these ‘active ingredients’ are, and whether or not they are inter-dependent (MacPherson et al, 2008).

Effectiveness studies instead attempt to assess improvements resulting from a course of flexibly delivered treatments, in a format that more closely reflects ‘usual settings’ (MacPherson et al., 2008). Studies such as these are described as
having higher external validity (Witt, 2011), with control groups often being ‘standard conventional care’. In this approach, greater sample population heterogeneity is generally tolerated (MacPherson et al., 2008), however larger samples may be required to demonstrate significance of effect (Witt, 2011). One issue that has nonetheless arisen, is that the diverse range of acupuncture styles and treatment options permitted, has resulted in a heterogeneity of study designs. Consequently, difficulties have emerged with respect to the overall interpretation and analysis of findings (MacPherson et al., 2001).

As a result, an emphasis was placed upon the need to develop a manualised approach that still allowed for individualised treatment tailoring, however was also structured within a replicable treatment framework (Schnyer & Allen, 2002). The rationale behind this approach was that it would provide “a precise way to train and supervise practitioners, enable evaluation of conformity and competence, facilitate the training process, and increase the ability to identify the active therapeutic ingredients in clinical trials of acupuncture” (Schnyer & Allen, 2002, p 623). Such a design aimed to still be reflective of everyday clinical practice (Witt et al., 2012), yet also facilitate the generalisability and interpretation of findings (Schnyer & Allen, 2002).

Another view to emerge, was that complex interventions like acupuncture should be evaluated using comparative effectiveness research (CER) (Witt, 2011), in which treatment effects are demonstrated prior to component efficacy, by first evaluating the intervention in treatment as usual and clinical practice settings. The overall suggestion was that “acupuncture treatments should be studied 1) “top down” as a multi-component “whole-system” interventions and 2) “bottom up” as mechanistic studies that focus on understanding how individual treatment components interact and translate into clinical and physiological outcomes” (Langevin et al., 2010, p 1).

Widespread implementation of these recommendations has resulted in more appropriately designed efficacy and effectiveness trials that have provided a consensus about which medical conditions acupuncture can assist (Birch, Keppel, Jonkman, Hekker, & Bos, 2004; McDonald & Janz, 2017; Witt, 2011). In
addition, a body of evidence has accumulated that supports that when acupuncture is applied as an adjunct therapy, it is “more effective than routine care alone”, and is of acceptable cost-effectiveness (Witt, 2011).

2.2 Clinical Evaluation of Acupuncture as a Treatment for Depression

Many clinical studies evaluating acupuncture as a treatment for depression have been conducted in the general population, of which several have been compiled into systematic reviews and meta-analyses. The most recently published by Smith and colleagues (Smith, Armour, Lee, Wang, & Hay, 2018) incorporating 64 studies and 7104 participants reported that acupuncture appeared to be beneficial in reducing the severity of depression, however due to study heterogeneity and poor quality evidence, further RCTs of high quality are required. In the section that follows, the details of two of these studies (a pilot and full-powered RCT) conducted by Allen and colleagues is provided, as for this purpose, this research team specifically developed a generalised protocol manual that was later published (Schnyer & Allen, 2001), and used for subsequent examinations of acupuncture for depression in antenatal populations. It was this study and protocol design that served the predominant basis for the development of the acupuncture protocol utilised in this thesis.

The pilot conducted in by Allen and colleagues in 1998, was the first RCT endeavouring to provide robust evidence regarding the efficacy of acupuncture for major depression in women (Allen, Schnyer, & Hitt, 1998). In this study, the authors attempted to maintain ecological validity, by comparing individually tailored depression specific acupuncture (n = 12) to an individually tailored acupuncture treatment that addressed other Chinese medicine disharmonies (such as back pain, n = 11), and a wait-list control (n = 11). Whilst this type of control was not an ‘inert’ placebo, the authors reasoned if depression specific treatment could outperform non-specific treatments, they would also likely outperform “a truly inert placebo” (Allen et al., 1998, p 398). Blinding was also incorporated, with patients and assessors being unaware of group allocations,
and treating acupuncturists having no knowledge of the methods by which the treatments were devised, or which treatments they were performing. As detailed later in the published manual, treatment designs followed complex theories of TEAM, such as: the dynamics of Qi flow along the channels; tongue observations; palpatory findings from the abdomen, points and meridians; the energetic actions of points; point combinations that may be useful for complex patterns; and the areas of the body influenced by the points. In addition, five element constitutional dispositions were evaluated at intake, however ‘root’ style treatments considered imperative in some styles of acupuncture (MacPherson et al., 2008, p 161), were omitted. Other clinical trial restrictions that may have also reduced the external validity of this design included: shorter treatment durations (20 minutes); the series of treatments being designed from a fixed set of points by senior acupuncturists; and treatments being delivered by acupuncturists not making the assessments. An additional study limitation was that some acupuncturists may have discerned the difference between the treatments and thus, become unblinded. Symptom changes were assessed by clinicians’ using the Hamilton Rating Scale for Depression (HRSD). After delivering 12 treatments over a period of eight weeks, findings demonstrated that symptom relief was significantly different between groups (p<0.01), with the greatest reduction in scores being seen in the depression specific acupuncture group. A non-significant trend towards greater symptom reduction was also seen in the depression specific treatment when compared to wait-list (p<0.12). Similar findings were achieved with the self-report measure, the Beck Depression Inventory (BDI). An analysis conducted after the women from the other two groups had also received the depression specific acupuncture treatment demonstrated that remission rates were 64%. A six-month follow-up study conducted by the same research team in addition reported that only four of the 17 women who had achieved full remission at the end of treatment (24%), relapsed within this timeframe (Gallagher, Allen, Hitt, Schnyer, & Manber, 2001). Overall, effectiveness (Allen et al., 1998) and relapse rates (Gallagher et al., 2001) were reportedly similar to those obtained using pharmaceutical and psychotherapy treatments.
As findings were promising, yet needed to be tested in larger populations, this research group later conducted the larger scale trial (Allen et al., 2006), in which 151 participants (104 women, 47 men) were enrolled. Results obtained were however unable to demonstrate differential efficacy between the depression specific, non-specific acupuncture and wait-list groups, as significant reductions in HRSD scores were seen in all (p<0.001). The specific and non-specific acupuncture groups did nonetheless demonstrate greater decreases in severity when compared to the wait-list control (p<0.001), although no significant differences when compared to each other. The authors suggested findings highlighted the difficulties faced researching complex interventions in these formats, as well as the need for further modification and research, with potential reasons for these outcomes being: 1) the acupuncture protocol was sub-optimal, especially as the delivering acupuncturist was not able to modify treatment according to observations, as is standard practice; 2) the non-specific acupuncture needling effects were greater than anticipated; 3) a combination of both of these factors may have applied; especially when the mechanism(s) by which acupuncture needling may produce an effect is yet to be fully understood; 4) the delivery of the intervention may have deviated from the protocol, as compliance wasn’t monitored in every case; 5) the different skill sets and experience levels of the treating acupuncturists may not have been as interchangeable as reasoned; 6) outcomes measures may not have been sufficiently sensitive to detect the specificity of acupuncture points chosen for depression; and 7) limiting an acupuncturists’ normal repertoire of tools may have reduced treatment effects. Practitioner blinding in addition, appeared to be unsuccessful, however was considered unlikely to have impacted upon outcomes (Allen et al., 2006).

2.3 Clinical Evaluation of Acupuncture for the Management of Antenatal Depression

The examinations of whether acupuncture was also beneficial for women experiencing depression during pregnancy were conducted in the same way, after modifications for pregnancy were incorporated (Schnyer & Allen, 2001).
In the pilot RCT (Manber, Schnyer, Allen, Rush, & Blasey, 2004), 61 women with major depressive disorder (MDD, HRSD 17 scores ≥14) were randomised to depression specific acupuncture (n=20), non-specific acupuncture (n=21), and a massage control (n=20). Patients that responded to the acute treatment phase (HRSD17 score<14 and ≥50% reduction from baseline), also continued treatment until 10 weeks postpartum. Results showed a statistically significantly higher response rate (69%) for depression specific acupuncture compared to massage control (32%), and an intermediate (47%) response rate compared to non-specific acupuncture. The BDI scores in the depression orientated acupuncture group also demonstrated a significantly higher average rate of reduction in BDI scores from baseline to the end of the first month of treatment, compared to the massage control. At 10 weeks postpartum, responders to the acute phase of all treatments combined had significantly lower depression scores when compared to non-responders (Manber et al., 2004). Study limitations were similar to those previously reported and included sample size, the homogeneity of the population, and limited treatment tailoring.

As replication was also required in a larger sample, the scaled-up version was conducted in 2010, with 150 women being randomised. Findings demonstrated that women in the depression specific acupuncture group (n=52) experienced a greater rate of reduction in symptom severity, compared to combined controls (n=49 in each group, p< 0.05), and non-specific acupuncture alone (p< 0.05). A significantly greater response rate (63.0 %) was also observed when depression specific acupuncture was compared to the combined controls (44.3 %; p< 0.05), and non-specific acupuncture alone (37.5 %; p <0.05). Symptom reduction and response rates did not differ significantly between control acupuncture (37.5 %) and massage (50.0 %) (Manber et al., 2010). As for the pilot, treatment tailoring was restricted.

Two additional groups published findings in regard to acupuncture for emotional complaints. In the first of these studies, Knight and co-workers (2001) conducted a sham controlled RCT on 55 acupuncture naïve women experiencing nausea during the first trimester of pregnancy, in which anxiety
and depression levels were also monitored. The sham procedure consisted of taping cocktail sticks to the region near each acupuncture point (n=27). Verum acupuncture needles were inserted for 15 minutes, and also taped in place (n=28). The acupuncturist became aware just prior to the session whether verum or sham was to be performed. The authors were expectant that the ‘sham’ procedure would generate physiological effects. Three to four sessions were conducted over three weeks. Details of treatment were concealed from both the participants and assessor. Findings demonstrated both anxiety (p=0.062) and depression (p=0.002) scores decreased over the duration of the trial, however there were no observed between groups differences (p=0.4 for anxiety; p= 0.9 for depression). The authors discussed possible limitations with study design, such as: the sub-optimal protocol due to individual tailoring not being permitted at subsequent sessions; non-ideal treatment delivery time spacing, short treatment durations, the possibility the sham procedure was not totally inert, and potential loss of patient blinding.

In the second, da Silva (2007) examined the “effects of acupuncture under real life conditions in the treatment of emotional complaints during pregnancy” (p65). In this quasi-randomised RCT, fifty-one women were allocated by chance to receive either acupuncture (n=28) or no treatment (n=23). Both groups presented with emotional complaints such as anxiety, depression and irritability. Women in the control group were counselled in both individual and group sessions, and if deemed necessary, were able to access one herbal agent for anxiety or depression. Acupuncture recipients received between 8-12 sessions over a period of eight-weeks. Points were standardised for each session; however, four additional points were permitted for individualisation. Needles were retained for twenty-five minutes. The women in this group also had access to counselling, and herbal agents, at the discretion of the obstetrician. Women self-rated their symptom severity using the Numerical Rating Scale (NRS), as well as in terms of how much these symptoms disturbed five aspects of their lives (mood, sleep, relationships, social activities, sexual life and joy of living). Findings showed that NRS scores of emotional distress decreased by at least half in 15/25 (60%) acupuncture recipients, and in 5/19
(26%) controls (p=0.013). In addition, the impact of distress on three out of five life aspects was significantly less in the treatment group, compared to the control (p<0.05). The author reported “acupuncture seems to be an efficacious means of reducing symptoms and improving the quality of life of women with emotional complaints during pregnancy” (da Silva, 2007, p 70). Study limitations in this case included sample size, quasi-randomisation, and the inability to fully tailor treatment. The lack of ‘sham’ and ‘placebo’ controls was however an intentional modification, due to previously experienced limitations regarding the ‘non-inertness’ of this procedure, as well as difficulty maintaining blinding (da Silva, 2007).

A search of the literature up until mid-2018 revealed that no additional studies evaluating acupuncture for antenatal depression had been conducted. A summary table of the main features of these four studies is provided in Table 2.1 below.

Dennis and Dowswell (2013a) updated their previous systematic review assessing pharmacological, psychosocial and psychological interventions for the treatment of antenatal depression. Included within this review were the pilot and full powered RCTs of Manber and co-workers (Manber et al., 2004; 2010).
### Table 2.1 Summary of the Main Features of the Four Clinical Studies Evaluating Acupuncture for the Treatment of Emotional Disorders During Pregnancy

<table>
<thead>
<tr>
<th>Publication</th>
<th>Main study design</th>
<th>Study end Points</th>
<th>Methodology</th>
<th>Results</th>
<th>Commentary / limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Knight et al., 2001)</td>
<td>RCT Nausea specific acupuncture (n=28) vs sham (cocktail stick, n=27).</td>
<td>Nausea, anxiety &amp; depression scores using the self-report visual analogue scale (VAS)</td>
<td>Acupuncture naïve women in the first trimester pregnant women with nausea ±vomiting received 3-4 sessions per week, for 3-4 weeks. Needles retained for 15 mins. Deqi obtained in verum acupuncture. Blinded assessor &amp; participants</td>
<td>Anxiety (p=0.062) &amp; depression (p=0.002) scores decreased. There was evidence of time effects in scores for anxiety and depression but no group differences (p=0.4 for anxiety; p=0.9 for depression).</td>
<td>Acupuncture treatment was tailored but not adjusted at follow-ups. Treatment spacing was not ideal. Patients may have become unblinded. Sham may not be ‘inert’ (da Silva, 2007).</td>
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<tr>
<td>(da Silva, 2007)</td>
<td>Quasi-randomised. Emotional complaints orientated acupuncture + standard care (n=28) versus standard care (n=23).</td>
<td>Anxiety, depression &amp; irritability, as well as disturbances to mood, sleep, relationships, social activities, sexual life &amp; joy of living using self-reported Numerical Rating Scale (NRS)</td>
<td>All participants had access to counselling and or 1 herbal agent if required. Acupuncture recipients in addition received 8-12 sessions over 8 weeks. Pre-programmed points were used with the addition of 4 possible others for individualisation. Needle retention was 25 mins.</td>
<td>Emotional distress scores decreased by at least half in 15/25 (60%) of acupuncture patients &amp; 5/19 (26%) controls (p=0.013). Distress impact was significantly less in 3/5 life aspects in acupuncture compared to control (p&lt;0.05).</td>
<td>Acupuncture appeared promising for emotional disturbances. The treatment protocol may have been suboptimal due to limited tailoring options.</td>
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<tr>
<td>(Manber et al., 2004).</td>
<td>Double blinded RCT pilot depression specific acupuncture (n=20) for MDD versus non-specific acupuncture (n=</td>
<td>Depression scores &amp; response rates. Self-reported BDI &amp; clinician rated HRSD17.</td>
<td>Senior practitioners tailored treatment for blinded junior acupuncturists to deliver. Non-specific treatment was tailored to presenting disharmony other than mental health. 12 sessions were delivered over 8 weeks. Needles were retained for 20 minutes. Needle insertion &amp; deqi</td>
<td>Statistically significantly higher response rates for depression specific acupuncture (69%) vs massage (32%), &amp; intermediate vs non-specific acupuncture (47%). Significantly higher average rates of reduction in BDI scores for depression specific acupuncture at the end of the first month vs</td>
<td>Findings were promising that acupuncture may assist with antenatal MDD. Generalizability was limited by sample homogeneity. Sample size was small.</td>
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<tr>
<td>Study</td>
<td>Intervention</td>
<td>Outcome Measures</td>
<td>Results</td>
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<tr>
<td>(Manber et al., 2010)</td>
<td>Double blinded RCT pilot depression specific acupuncture (n=52) for MDD versus non-specific acupuncture (n=49) &amp; massage controls (n=49).</td>
<td>Depression scores &amp; response rates. Self-reported BDI &amp; clinician rated HRSD17.</td>
<td>Depression specific acupuncture demonstrated a greater rate of decrease in symptom severity (p&lt;.05) vs the combined controls or control acupuncture alone (p&lt;.05). A significantly greater response rate (63.0%) was also seen than the combined controls (p&lt;.05) &amp; control acupuncture alone (p&lt;.05). Symptom reduction &amp; response rates did not differ significantly between controls (control acupuncture, 37.5%; massage, 50.0%).</td>
<td>Depression specific acupuncture appeared promising as symptom reduction &amp; a comparable response rate comparable to standard depression treatments was demonstrated. Treatment sets were updated monthly, hence were not individually tailored every session.</td>
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Stimulation was standardised. Forbidden pregnancy points were avoided. Minimal verbal communication provided. Responders continued treatment until 10 weeks postpartum. Responders to the acute phase of all treatments had significantly lower depression scores at 10 weeks postpartum than non-responders. 

Treatment sets were updated monthly, hence were not individually tailored every session.
The study conducted by da Silva (2007) was not included, due to the quasi-randomisation process employed, as well as the assessment of emotional complaints, rather than just depression alone. The reviewer’s findings with respect to the pilot and full-powered RCT from Manber and co-workers were as follows: when depression specific acupuncture was compared to the non-specific acupuncture control, there was not a significant decrease in the number of women experiencing clinical depression (pilot, n=35; RR 0.47, 95% CI 0.11 to 2.1), or depressive symptomology (pilot, n=35; MD -3.00, 95% CI -8.10 to 2.10). There was also no beneficial effect found when depressive symptomology was measured using the BDI (pilot, n=35; MD -3.00, 95% CI -6.85 to 0.85). With respect to the powered RCT, the authors found that “women who received depression-specific acupuncture were more likely to have a treatment response rate (a 50% reduction in HRSD scores from baseline), than those receiving non-specific acupuncture” (full powered, n=86; RR 1.68, 95% CI 1.06 to 2.66) (Dennis & Dowswell, 2013a, p 12). There was however, no significant difference between the two groups in regard to remission rates (classified as HRSD < 8; full powered, n=86; RR 1.26, 95% CI 0.67 to 2.40). Due to the high proportion of highly educated, Caucasian women of above average SES being enrolled, and those with comorbid mental health and medical disorders being excluded, the authors stated that the “results are not generalisable to specific minority groups or pregnant women with other mental health concerns” (Dennis & Dowswell, 2013a, p 14). Despite these limitations, the authors also concluded that whilst the evidence for acupuncture for the treatment of antenatal depression was not strong, the findings were consistent with recent reviews evaluating acupuncture for the treatment of depression (Dennis & Dowswell, 2013a). As previously discussed, false negatives may have also been generated as a consequence of findings being compared to a physiologically non-inert ‘non-specific’ acupuncture controls, as well as the limited TEAM protocols.

2.4 Clinical Evaluation of the Postnatal Impact of Antenatally Administered Acupuncture

After reporting in the pilot study that acupuncture may be useful for the prevention of PND (Manber et al., 2004), a similar postpartum follow-up analysis was performed by
Kent (Kent, 2011), after the larger scale trial (Manber et al., 2010). In this analysis, 121 women who had received either depression specific acupuncture, non-specific acupuncture or massage during pregnancy, were reassessed at ten weeks, and six- and nine-months post birth. As had been the case in the pilot study, those that had responded to any of the antenatal treatments had significantly lower post-partum depression scores (BDI) compared to non-responders. In addition, a significant treatment assignment by time interaction on postpartum HRSD 17 scores was also seen, whereby women who had received depression specific acupuncture demonstrated maintained improvements, whilst women in both the non-specific acupuncture and massage controls groups experienced worsening of symptoms. The findings were therefore suggestive that “successful treatment of depression during pregnancy may lower the risk of developing PPD”\(^1\), and in addition, that depression specific acupuncture may have been more postnatally protective (Kent, 2011, p viii).

### 2.5 Summary

To date the clinical evaluation of acupuncture as an adjunct therapy to reduce antenatal depression severity is limited. Whilst overall preliminary findings suggest that acupuncture may be beneficial in reducing antenatal symptoms, as well as protect against postnatal depression, further evaluation is required due to existing limitations with study sample sizes, and research designs. This study therefore aimed to add to this existing evidence base, whilst at the same time addressing where possible some of the discussed methodological challenges, including the need for individualised treatment tailoring, computer generated randomisation schedules, and more physiologically inert controls.

In addition, none of the studies evaluating acupuncture for antenatal mood disorders have explored participant and midwives’ perspectives of antenatal depression, or women's experience of receiving acupuncture. Furthermore, biomarker examinations that may potentially correlate with post-intervention changes in antenatal depression severity have not been conducted, and consequently, the benefits of inclusion of both qualitative examinations, and biomarker analysis are highlighted.

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\(^1\) Postpartum depression
These existing research gaps therefore suggest the need for an early phase effectiveness study approach, in consideration of the complexity of antenatal depression, as well as the need to achieve a greater generalisability of findings to routine clinical settings.

In the next chapter the rationale for the choice of examined biomarkers is provided.
Chapter 3
Depression, Biomarkers and Acupuncture
Research findings have demonstrated that the functioning of the neuroendocrine system is frequently disrupted in mental health disturbances, particularly amongst those populations exposed to more extreme or prolonged life stressors. Two of the systems in which impacts have been documented include the oxytocinergic and HPA axis. As both of these complex systems are involved in widespread physiological, emotional and social functioning, it is not surprising that when disrupted, a plethora of negative outcomes, as well as alterations to key biomarkers are reported. As the overall population of women in this study belongs to this demographic, it was of particular interest to explore the possible influences of acupuncture to the functioning of both of these systems. Consequently, in this chapter, the normal functioning of these systems is reviewed, along with dysfunctions reported in depressed perinatal populations. Following on from this, a summary of the explorations of the possible influences of acupuncture to these systems in depressed and perinatal populations is provided.

3.1 The HPA Axis and Oxytocinergic Systems

3.1.1 Cortisol and DHEA

Cortisol, the main glucocorticoid hormone released from the adrenal gland is involved in broad ranging physiological processes, including systemic responses to stressors of both physical and psychological origin (Quax et al., 2013), as well as physiological awakening, in which the diurnal pattern of release is referred to as the cortisol awakening response (CAR) (Wilkinson & Goodyer, 2011).

As part of the ‘fight or flight response’ to stressors (Sapolsky, Romero, & Munck, 2000), the regulation of cortisol release occurs via the HPA axis, whereby corticotrophin releasing hormone (CRH) secreted in the hypothalamus stimulates the release of adrenocorticotrophin hormone (ACTH) in the pituitary gland, which upon entering systemic circulation, stimulates the secretion of cortisol from the adrenal cortex (Duthie & Reynolds, 2013). After the acute stress event, termination of secretion is then facilitated by the binding of
cortisol to glucocorticoid and mineralocorticoid receptors in the hypothalamus and pituitary gland; in what is referred to as a negative feedback loop (Duthie & Reynolds, 2013; Wester, Lamberts, & van Rossum, 2014). Further cellular and tissue level regulations incorporated into this system include: the priming of the system prior to stressors; stimulatory and suppressive actions aimed at ensuring neither ‘under or overshooting’; preparative actions that condition the reaction to subsequent stressors (Sapolsky et al., 2000); alterations to glucocorticoid receptor and signalling pathways (Quax et al., 2013); and the enzymatic inactivation of cortisol via the conversion to cortisone (Quinkler & Stewart, 2003). Disruptions nonetheless may occur within any of these processes, whereby inadequate or inappropriate responses to threats may be seen, such as the inability of the system to return to baseline functioning after removal of the threat, or non-habituation to stressors of similar magnitude (Wilkinson & Goodyer, 2011).

Dehydroepiandrosterone (DHEA) and the sulphated ester DHEAS, are additional hormones secreted from the adrenal glands (Maninger, Wolkowitz, Reus, Epel, & Mellon, 2009), that like cortisol, are subject to the same diurnal release (Wood, 2009). Unlike the catabolic actions of cortisol however, DHEA is an anabolic steroid that is antagonistic in action to cortisol, and hence it provides anti-glucocorticoid regulatory effects (Guerry & Hastings, 2011), in addition to antioxidant and anti-inflammatory properties (Maninger et al., 2009).

3.1.2 Oxytocin

Oxytocin (OT), a neuropeptide also manufactured in the pituitary gland, was originally identified for its role in parturition, and breast feeding (Gimpl & Fahrenholz, 2001). However, later research also revealed that OT was involved in additional reproductive related activities, including sexual (Argiolas & Gessa, 1991), affiliative, grooming (Witt, Winslow & Insel, 1992), parental (Pedersen, 1997) and bonding behaviours (Carter, Boone, Pournajafi-Nazarloo, & Bales, 2009); as well as non-reproductive roles ranging from HPA and autonomic nervous system regulation (Norman et al., 2012), to social stimuli processing (Lim & Young, 2006) and prosocial behaviours (Carter, 2014; Insel, 2010).
As was also the case with glucocorticoids, regulation of OT effects occurs via controlled release, as well as changes to receptor (OT-R) functionality (Gimpl & Fahrenholz, 2001; Inoue et al., 1994). Further influences to emotional and social functioning however, are also provided by genetic and epigenetic alterations to OT and OT-R genes (Bell, Erickson, & Carter, 2014; Insel, 2010; Jack, Connelly, & Morris, 2012; Kumsta, Hummel, Chen, & Heinrichs, 2013), which for example may impact upon ones capacity to buffer stress (Chen et al., 2011; Poulin & Holman, 2013) and early-life adversity (McQuaid, McInnis, Stead, Matheson, & Anisman, 2013), as well as experience parental sensitivity (Insel, 2010), and psychological resilience.

3.2 Disrupted HPA Axis and Oxytocinergic Systems and Perinatal Mental Health Disturbances

3.2.1 Disrupted HPA Axis and Perinatal Mental Health Disturbances

Evidence indicates that women exposed to frequent or extreme stressors either before (Bublitz & Stroud, 2012) or during the perinatal period, exhibit disrupted HPA axis functionality, as well as increased risk of adverse maternal and foetal outcomes (Douglas, 2012). Enhanced CARs for example have been demonstrated in pregnant women exposed to major sexual abuse as a child (Bublitz & Stroud, 2012). Elevations to evening cortisol, as well as blunted HPA axis responses have similarly been reported in women suffering from pregnancy related worries, and or previous significant stressors (Obel et al., 2005). Prenatally detected placental and HPA axis dysfunctions have interestingly also been shown to be predictive of preterm delivery (Glynn, Davis, & Sandman, 2013), a frequently reported observation amongst depressed pregnant populations (Jarde et al., 2016). Perinatal women displaying higher cortisol (Duthie & Reynolds, 2013; Glynn et al., 2013; Nierop, Bratsikas, Zimmermann, & Ehlert, 2006), lowered DHEA (Galen Buckwalter et al., 1999), and altered ACTH and CRH responses (Duthie & Reynolds, 2013), not surprisingly also exhibit increased postpartum depressive ratings and behaviours. Elevated maternal cortisol levels have been shown to result in enhanced HPA axis activity in babies, as well as fearful and reactive behaviours.
Additional studies provide further evidence that the disrupted maternal hormonal environments associated with various postnatal mood disorders, are reflected in altered HPA axis functionality in babies and children (Glover & O’Connor, 2010), as well as their increased risk of developing later life depression (Wilkinson & Goodyer, 2011).

### 3.2.2 Disrupted Oxytocinergic Systems and Perinatal Mental Health Disturbances

Examination of disruptions to the oxytocinergic system during perinatal mental health disturbances provide similar findings, with both dysregulated secretions and tissue responsiveness being reported under a variety of conditions. An interesting finding by Levine, Zagoory-Sharon, Feldman, & Weller (2007) however, was that even amongst women considered to be in good health, wide intra-individual prenatal and early post-partum OT levels are observed, with stable, increasing, decreasing, and both increasing and decreasing concentrations being seen. Despite this however, an overall association between individuals displaying elevations of OT and higher prenatal bonding scores was noted. Skrundz and colleagues (2011) similarly reported that lower mid-pregnancy OT levels were significantly predictive of post-partum depressive behaviours. Other studies likewise reinforce these findings, suggesting that lower prenatal OT levels are associated with increased negative maternal affect (Garfield, 2012; Light et al., 2004), lower infant birth weights (Garfield, 2012), and postnatal depressive symptomology (Light et al., 2004).

Additional post-partum investigations similarly demonstrated that first-time mothers with reduced OT levels displayed insecure maternal attachments, as well as reduced activity in the reward and OT hypothalamic regions of their brains (Strathearn, Fonagy, Amico, & Montague, 2009). Eapen and colleagues (2014) likewise observed that lowered post-partum OT levels were associated with prenatal depression, separation anxiety, negative maternal interpersonal relationships, and anxious attachment styles. Lowered postpartum OT levels and dysregulated 24 hour cortisol releases have in addition been associated with posttraumatic stress symptoms and anxiety (Garfield, 2012b). Two
broader investigations further demonstrated that depression in mothers was associated with a lowering of OT in the entire family (Apter-Levy, Feldman, Vakart, Ebstein, & Feldman, 2013), as well as higher parental OT levels being associated with positive parental-child social engagement, affect synchrony and communication (Feldman, Gordon, & Zagoory-Sharon, 2011).

Altered behaviours and mood disturbances during the perinatal period have similarly been attributed to alterations to OT and OT-R genes (Bell et al., 2014; Mileva-Seitz et al., 2013). Light and colleagues (2010) for example found that new mothers with higher subclinical depression scores had marginally decreased leukocyte gene expression of OT-R, whilst OT prepropeptide levels remained unchanged. Single nucleotide polymorphisms (SNPs) in the OT and OT-R genes have in addition been linked to prenatal depression, individual variations in maternal behaviour, and the development of postpartum depression (Mileva-Seitz et al., 2013). An OT-R haplotype found to be overrepresented in depressed mothers was interestingly also found to be correlated with lower OT levels in families, that were at increased risks of developing psychopathology (Apter-Levy, Feldman, Vakart, Ebstein, & Feldman, 2013). Further reinforcement has been provided from other studies demonstrating that SNPs in the OT-R gene are associated with recurrent maternal MDD, that is also predictive of their own daughters’ symptoms of depression and anxiety (Thompson et al., 2011); as well parental sensitivity, that is negatively affected if depressive symptoms are present (Riem, Pieper, Out, Bakermans-Kranenburg, & van Ijzendoorn, 2011).

3.3 The Evaluation of the Influences of Acupuncture on the HPA Axis and Oxytocinergic Systems in Depressed or Perinatal Populations

As disrupted HPA axis and oxytocinergic system functioning not only impacts affected individuals, but also future generations (Bell et al., 2014; Champagne, 2008; Lee & Goto, 2013; Meaney, 2001; Stein et al., 2014) via environmental (Davis, Glynn, Waffarn, & Sandman, 2011; Fries, Ziegler, Kurian, Jacoris, & Pollak, 2005), epigenetic (Carter et al., 2009; Kumsta, Hummel, Chen, &
Heinrichs, 2013; Champagne, 2008; Kumsta et al., 2013), and gene effects (Insel, 1997; Lim & Young, 2006; Meaney, 2001), it follows that therapies of potential benefit, should be thoroughly investigated. In the next section, the ability of acupuncture to exert influences to both of these systems is therefore explored.

3.3.1 The Evaluation of the Influences of Acupuncture on the HPA Axis in Depressed or Perinatal Populations

Whilst some studies have reported the positive effects of acupuncture on the HPA axis system in both animals and humans studies (Johansson et al., 2013; Magarelli, Cridennda, & Cohen, 2009; Lin et al., 2017; Rizzo et al., 2017; Wei et al., 2017), an extensive search of the literature found only four studies that specifically evaluated depressed or perinatal populations. In the first study, the benefits of electroacupuncture for depression was compared to a sham acupuncture control (Vazquez, Gonzalez-Macias, Berlanga, & Aedo, 2011). In this study, a defined set of points (n=23) was compared to non-standard locations (n=19), at each 30-minute biweekly session. Findings demonstrated that when verum treatment was compared to sham, significant reductions in depressive symptomology (p=0.03), as well as cortisol levels (p=0.02) were seen. In the second study, patients with persistent depressive disorder (n=44) received bilateral auricular acupuncture or sham needling 2 mm from verum points for four weeks. It was unclear how many sessions were performed during that time, however findings demonstrated that auricular acupuncture resulted in a significant reduction in depressive symptoms (p<0.01), and cortisol levels (p<0.05) (Pirnia et al., 2018). In the third, auricular acupressure was evaluated in regard to anxiety, fatigue and cortisol, in women recovering from caesarean section (Kuo, Tsai, Chen, & Tzeng, 2016). In this study, auricular seed acupressure was applied to Shenmen, twice a day, for four consecutive days (n=40), and compared to standard care (n=40). Results showed that at five days postpartum, acupressure significantly reduced cortisol levels (p<0.05), heart rate (p<0.001), anxiety symptoms (p<0.01), and fatigue (p<0.01).

In the fourth study, a contrasting finding was reported by Haddad-Rodrigues, Spanó Nakano, Stefanello, & Campos Pereira Silveira (2013), in which verum
auricular treatment was compared to a sham control for the management of anxiety symptoms in lactating mothers who birthed preterm infants with very low birth weights (n= 29). Fourteen women received unilateral verum treatment at five auricular points. It was unclear how many sessions were performed, however the intradermal needles utilised were retained until the follow-up assessment. The sham group received toothpick pressure at each point, followed by the taping of metal non-insertion modified needles. Treatment was performed by a nurse with acupuncture training. No statistical differences in STAI-State anxiety scores or cortisol levels were observed between groups. Possible design flaws incorporated may however have compromised findings, due to: 1) the lack of inertness of the sham procedure as the tooth pick application would have provided an acupressure effect, and in addition, the metal retained modified non-insertion needle would have also provided both an acupressure, as well as a possible electrovalent effect, as ear seeds or metal spheres of different types of metal are frequently placed on auricular points during verum treatments (Birch & Ida, 1998; Manaka, Itaya, & Birch, 1995); 2) the omission of body points, as auricular therapy in some types of acupuncture is performed only as part of a supplementary technique; 3) the possibility that only one treatment was applied, which generally would be considered insufficient (Birch, 2004); and 4) the non-individualisation of the treatment protocol, and thus the lack of external validity.

3.3.2 The Evaluation of the Influences of Acupuncture on the Oxytocinergic Systems

Searching the literature for mechanistic studies examining the potential effects of acupuncture to the oxytocinergic system yielded no studies specific to depressed general or perinatal populations. Thirteen clinical studies in pregnant women were however identified whereby the effects of TEAM were assessed for possible influences on this system. A brief summary of the studies is provided in Table 3.1, in which it can be seen that in nine out of the 13 studies, TEAM appeared to reduce the requirement for synthetic OT, possibly indicating up-regulated endogenous functioning. Of the studies in which non-significant
differences were reported, findings may have been compromised by minimalistic protocols, as well as the inclusion of the point, GV20, whose specified main function is to pull energy up from the base, and therefore opposite to that required during labour (Deadman, Al-Khafaji, & Baker, 1998).

Table 3.1 Possible Influences of Acupuncture to the Oxytocinergic System

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population &amp; method</th>
<th>Main finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Fatemeh &amp; Zahra, 2010)</td>
<td>Transcutaneous electrical nerve stimulation (TENS) for labour enhancement at acupuncture points vs sham location</td>
<td>Fewer OT units used (not significant).</td>
</tr>
<tr>
<td>(Aghamohammadi, Behmanesh, Zafari, &amp; Tofighi, 2011)</td>
<td>TENS for labour enhancement at acupuncture points vs same location &amp; lower voltage</td>
<td>Significant shortening of 1st stage labour (p=0.0001) &amp; number of women requiring OT (p=0.019).</td>
</tr>
<tr>
<td>(Liu et al., 2008)</td>
<td>Electro-acupuncture at LI 4 + intravenous OT vs intravenous OT</td>
<td>Labour enhancement was superior (p&lt;0.01).</td>
</tr>
<tr>
<td>(Gaudernack, Forbord, &amp; Hole, 2006)</td>
<td>Acupuncture treatment (x 1) applied within 24 hours of premature rupture of membranes (PROM) vs no treatment</td>
<td>A significant reduction in labour duration (p=0.027) &amp; the number of women requiring OT infusion (p=0.018)</td>
</tr>
<tr>
<td>(Hantoushzadeh, Alhusseini, &amp; Lebaschi, 2007)</td>
<td>Acupuncture vs sham for back &amp; contraction pain, cervical rigidity, anxiety or nervousness, &amp; generalised labour specific analgesia</td>
<td>Significantly less OT units were used (p&lt;0.001)</td>
</tr>
<tr>
<td>(Ziaei &amp; Hajipour, 2006)</td>
<td>Acupuncture vs non-treatment to enhance early stages of labour with 3-6 cm cervical dilatation</td>
<td>Significantly less women needed OT for labour augmentation (p=0.03).</td>
</tr>
<tr>
<td>(Skilnand, Fossen, &amp; Heiberg, 2002)</td>
<td>Acupuncture for labour pain compared to sham.</td>
<td>Significantly reduced pain scores, labour duration &amp; analgesic &amp; OT use (p&lt;0.001).</td>
</tr>
<tr>
<td>(Zeisler, Tempfer, Mayerhofer, Barrada, &amp; Husslein, 1998)</td>
<td>Acupuncture vs non-acupuncture control for preparation for labour</td>
<td>Significantly less women required OT augmentation for 1st stage(p=0.01); &amp; 2nd stage (p=0.03)</td>
</tr>
<tr>
<td>(Aghdam &amp; Daryabakhsh, 2012)</td>
<td>Acupressure vs non-acupoint pressure for labour enhancement.</td>
<td>Significant reductions in delivery duration, pain intensity, caesarean rate &amp; OT requirement (p&lt;0.001)</td>
</tr>
</tbody>
</table>
(Kashanian & Shahali, 2010) | Acupressure at SP 6 vs simple touch for labour enhancement. | Significantly reduced OT unit use ($p=0.003$) |
---|---|---|
(Ramnerö, Hanson, & Kihlgren, 2002) | Acupuncture performed as an adjunct to conventional analgesia and to analgesia alone. | Significant differences in analgesia use & relaxation scores. Non-significance with respect to OT requirement - 0.25 (-1.75 to 1.26). Non-indicated labour point (GV 20) may have compromised findings. |
(Rabl, Ahner, Bitschnau, Zeisler, & Husslein, 2001) | Acupuncture vs non-acupuncture control for induction of labour. | Significant reduction to cervix length ($p=0.04$) & time to delivery ($p=0.03$); non-significant difference in OT requirement. |
(Kvorning, Nilsson, Löfberg, Algotsson, & Akeson, 1998) | Acupuncture vs non-treatment for pain relief during labour. | No difference in OT requirement, although GV 20 administration may have compromised findings. |
(Lyrenäs, Lutsch, Hetta, & Lindberg, 1987) | Acupuncture vs non-treatment for preparation for labour. | Acupuncture increased gestation time, labour duration, Ventouse delivery & OT requirement. GV 20 may have compromised findings. |
(Gregson, Tiran, Absalom, & Older, 2015) | Acupressure (20 min) at LI 4 & SP 6 vs sham acupressure for labour induction in post-date pregnancies, followed by home therapy x 4 per day. | Verum acupressure provided no significant improvement with respect to time-to-commencement of labour, OT requirements or mode of delivery. |

3.4 Summary

In this chapter, the normal and disrupted functioning of the oxytocinergic and HPA axis systems with respect to mood and social interactions; responses to stressors; and birthing, breastfeeding and maternal infant bonding was reviewed. The ability of acupuncture to influence, as well as provide restorative influences to these systems was in addition explored, via biomarker evaluations in clinical studies. Whilst study designs were heterogeneous, of variable rigour, and often small in size, overall findings were suggestive that acupuncture may exert positive and homeostatic influences to these systems. As a consequence, it was considered valid to include biomarker assessments in this evaluation, as
stress, anxiety, depression and maternal bonding were all of particular interest. The biomarkers deemed suitable for inclusion were salivary oxytocin, cortisol: DHEA ratios, and OT-R expression analysis.

In the next chapter, the mixed-methodologies utilised in this study are provided.
Chapter 4
Methodological Overview and Research Design for a Mixed Methods Feasibility Study Evaluating Acupuncture as an Adjunct Therapy for Antenatal Depression
4.1 Introduction

In this chapter, the research methodology employed in the mixed-methods study evaluating acupuncture for depression during pregnancy is detailed, along with rationale for the utilisation of this approach.

4.2 Epistemology as a basis of research

Epistemology is a branch of philosophy interested in the nature and origin of knowledge, with a particularly emphasis on questioning not only the sources of knowledge, but also the assumptions upon which these are based, and therefore what we "do know" and "can know" (Allison & Pomeroy, 2000, p92). The Oxford English Dictionary defines epistemology as “the theory of knowledge and understanding, especially with regard to its methods, validity, and scope, and the distinction between justified belief and opinion”. Epistemology therefore it would seem, is the foundation of scientific inquiry, that invariably embraces the broadest of search techniques and the greatest flexibility in study design, so as to generate the greatest capacity to capture the most diverse collection of potentially significant findings (Hirschheim, 1985).

4.3 Clinical Research – Aims and Study Designs

The general approach to scientific inquiry comprises a structured three stage process that begins with observation, the generation of plausible theory based upon observation and then the testing of generated theories (Cook, Bordage, & Schmidt, 2008). The overarching aim is to make sense of observation. Descriptive studies, generally utilised in the first stage, focus upon the process of describing the observation. Clarification studies test the various models or theories generated, and justification studies test what works (Cook et al., 2008). Clinical investigations of health care interventions are typically justification studies, (Cook et al., 2008), with the RCT being considered to be the gold standard with respect to methodological rigour (Petrisor, Keating, & Schemitsch, 2006; Schulz, Altman & Moher, 2010).
The belief that “RCTs are always superior to all other types of evidence” (Grossman & Mackenzie, 2005, p516) has however, also elicited some concerns. Opponents of this perspective argue that: 1) RCTs “address only one, limited, question, namely whether an intervention has—statistically—an effect” (Verhoef, Casebeer, & Hilsden, 2002, p275); 2) RCTs are not always possible nor the best study design for every situation, as “some types of evidence commonly supposed to be inferior to all RCTs are actually superior to many” (Grossman & Mackenzie, 2005, p516); 3) overemphasis on RCT evidence “diminishes consideration of other types of evidence”, and only provides “information about groups, not individuals”, thus “the entire complexity of the setting in which the subjects/patients find themselves is missing” (Williams & Garner, 2002, p9); and 4) the sole reliance upon RCT evidence invariably results in “patients’ preferences, clinical circumstances, and ... expertise” being “under-valued in the decision-making process” (Bhandari & Giannoudis, 2006, p303). Consequently, in addition to high quality RCT evidence being considered necessary to the assessment of non-pharmaceutical interventions (Petrisor, Keating, & Schemitsch, 2006; Schulz, 2010), it has also been recommended that the scope of examinations be widened (Evans, 2003; Williams & Garner, 2002) to include process evaluations within trials, typically qualitative in nature, to also provide valuable information regarding the implementation, receipt, and setting of an intervention (Oakley et al., 2006), as well as feasibility from the perspective of recruiters, (Brown, Long, & Milliken, 2002), clinicians (Fletcher, Gheorghe, Moore, Wilson, & Damery, 2012) and participants (Evans, 2003; Grant, Mackinnon, Christensen, & Walker, 2009; Madsen et al., 2002). Such a holistic approach to trial evaluation has been argued to be applicable to any large-scale research study (Green, 2012), but particularly so for complex interventions (Campbell et al., 2000), as they are generally not as well suited to the standardised RCT format. Study designs that embrace this approach and incorporate substantial contributions of both quantitative and qualitative methods have been termed ‘mixed-methods’ research, and more recently represent, a newer, and emerging third research paradigm (Creswell, 2003).
4.4 Rationale for Mixed-Methods Research

Up until relatively recently however, research design has typically been polarised between objective quantitative methods and subjective qualitative techniques (Creswell, 2003). Quantitative researchers have strongly advocated that data collection should be emotionally detached, objective and unininvolved (Johnson & Onwuegbuzie, 2004), so as to generate ‘hard’, ‘generalizable’ (Sieber, 1973), reliable measurements, that are free from the influences of context (Johnson & Onwuegbuzie, 2004). Qualitative researchers on the other hand have argued that all observation is subjective, as each observer observes through their own unique lens of reality (Johnson & Onwuegbuzie, 2004), and consequently, that research is capable of unearthing both ‘deep’ and ‘rich’ understanding (Sieber, 1973). Yet despite these diametrically opposed perspectives, the blending of the two paradigms began in 1959, when Campbell and Fiske examined psychological traits using a combined data collection approach (Creswell, 2003). Since that time, others have advocated that mixed-methods research is the “natural complement of traditional qualitative and quantitative research” (Johnson & Onwuegbuzie, 2004, p14). Suggested virtues include the possibility of: neutralising or cancelling out the limitations and maximising the strengths of each method; informing the direction taken in one method from the insights provided by the other; drawing together data provided by both methods, thereby allowing triangulation and or convergence; and providing additional analytical comprehensions from methods that are ‘nested’ within each other (Creswell, 2003). MMR therefore, has the potential to produce superior quality research, as a consequence of its inclusive and complementary methodological pluralism (Johnson & Onwuegbuzie, 2004).

4.5 Typologies and Designs of MMR

MMR may thus be defined as being flexibly located somewhere on the continuum between quantitative and qualitative research (Creswell, 2003), with open-ended possibilities in relation to the extent of use of either paradigm (Bryman, 2006). According to Johnson and Onwuegbuzie (2004), the overarching goal of this approach is to enable research methods to “follow
research questions in a way that offers the best chance to obtain useful answers”, with design details being flexibly chosen and able to be modified along the way, “depending on the conditions and information … obtained” (p20).

4.6 Pragmatism as a Theoretical Framework for MMR

With quantitative and qualitative researchers approaching research from diametrically opposed theoretical perspectives however, a new approach that bridged the two different styles was needed for MMR. With quantitative researchers utilising positivism (Johnson & Onwuegbuzie, 2004) or postpositivism to verify theory from empirical observation and measurements (Creswell, 2003), and qualitative researchers using constructivism to generate theory from open-ended techniques that examined interactions amongst individuals in relation to historical, social and cultural contexts (Creswell, 2003), one could however see the difficulty in combining the two. Creswell (2003) and Johnson and Onwuegbuzie (2004) suggested that pragmatism could be a suitable ‘philosophical partner’ for MMR (Johnson & Onwuegbuzie, 2004), as with pragmatism, theory is derived from actions, situations and consequences, with an overall emphasis on problem solving and ‘what works’ (Creswell, 2003), rather than a dualistic split between mind and reality. Although pragmatism is not the only possibility, it does allow the drawing upon of different qualitative and quantitative assumptions, world views, methods, data collection and analysis techniques, on a ‘best fit’ basis (Creswell, 2003), and as such, lends itself perfectly to MMR. Utilising this approach therefore, not only has the potential to broaden opportunities to answer research questions, but also to enhance communication and collaboration amongst researchers (Johnson & Onwuegbuzie, 2004).

4.7 Strategies of Inquiry and Justification in MMR

After deciding upon the appropriate theoretical platform, the strategies of inquiry utilised in the MMR design additionally needed to be considered. Greene, Caracelli, & Graham (1989) identified five such possibilities including triangulation, complementarity, development, initiation and expansion.
Triangulation is indicated when researchers wish to converge or corroborate data collected from the different quantitative and qualitative methods (Bryman, 2006; Johnson & Onwuegbuzie, 2004), whilst investigating the same phenomenon (Johnson & Onwuegbuzie, 2004). Complementarity can be employed when researchers wish to elaborate, enhance, illustrate or clarify the results obtained from one method with those obtained from another (Bryman, 2006; Johnson & Onwuegbuzie, 2004). Development is selected if the results of one method are to be used to help develop or inform the methods of the other (Bryman, 2006; Johnson & Onwuegbuzie, 2004). Initiation may be chosen when investigation of paradox, contradiction and or new perspectives are sought, whereby the questions or results from one method are recast in reference to the questions or results of the other (Bryman, 2006; Johnson & Onwuegbuzie, 2004). Finally, expansion is chosen when the breadth and range of examination is extended through the incorporation of different methods of inquiry (Bryman, 2006; Johnson & Onwuegbuzie, 2004).

### 4.8 Data Collection and Analysis in MMR

Data analysis techniques appropriate to this combined approach, also needed to be developed. Onwuegbuzie and Teddlie (2003) suggested a seven-stage data analysis process for MMR that comprised of: data reduction, or the reducing down of the data set utilising techniques from either method, for example, thematic analysis for qualitative data and descriptive statistics for quantitative data; data display, or the pictorial representation of data collected from either method as charts, graphs and so on; data transformation, an optional stage whereby quantitative data may be converted into narrative data for qualitative analysis or qualitative data transformed into numerical codes for statistical evaluation; data correlation, or the combining of the two distinct data types to create either new or consolidated data sets or variables; data comparison, where the different data sets are compared; data integration, whereby the data from both types are integrated into either a coherent whole or two separated sets of coherent wholes; and lastly, legitimization, the final crucial step used to
assess both the trustworthiness of the data collected, as well the interpretation of results (Johnson & Onwuegbuzie, 2004).

4.9 Pilot or Feasibility Studies

Feasibility studies are then utilised to enhance the likelihood of successful larger scale trials by providing preliminary information regarding: study procedures; tools (Arain, Campbell, Cooper, & Lancaster, 2010); protocols (Arain et al., 2010; Thabane et al., 2010); sample size (Thabane et al., 2010); recruitment (Arain et al., 2010; Thabane et al., 2010); retention estimates (Thabane et al., 2010); randomisation; data management (Thabane et al., 2010); treatment effect estimates (Arain et al., 2010; Thabane et al., 2010); safety, staffing, budget and time requirements; potential collaboration and or coordination considerations (Thabane et al., 2010); and the suitability of procedures from the perspective of both clinicians and participants (Campbell et al., 2000; Campbell, Quilty, & Dieppe, 2003).

If procedures are however more clearly established, pilot studies may be more appropriate to examine recruitment, randomisation, treatment and follow up. If successful, these ‘mini’ versions of the main study may then constitute the first phase, whereby the outcome data obtained is able to be incorporated in with that obtained from the later, larger scale study (Arain et al., 2010).

As a number of new methodologies had been introduced, such as the depression specific protocol, and saliva and blood sample collection for biomarker analysis; and in addition, recruitment had not been previously tested in an Australian antenatal population experiencing mental health disorders, it was considered appropriate in this case to conduct this study in the format of a feasibility assessment.
4.10 The Mixed-Methods Research Strategy Employed for the Evaluation of Acupuncture as an Adjunct Therapy for Antenatal Depression

For the purposes of this study, the evaluation of acupuncture as an adjunct therapy for antenatal depression was explored utilising both quantitative and qualitative approaches. The decision to employ MMR was made in order to widen the scope of the findings, by incorporating subjective data provided by qualitative methods, in with that obtained via standardised quantitative measurements. Such an approach appeared apt for the broader examination of a multifaceted intervention such as acupuncture (MacPherson, Hammerschlag, Lewith, & Schnyer, 2008), as well as the complexity of antenatal depression, that is frequently preceded by complicated lives, medical histories, and treatment management. It was reasoned that the addition of qualitative evaluations would provide a valuable opportunity to capture detail of women’s lived experiences of antenatal depression and conventional treatments, as well as trial participation and receipt of acupuncture.

With respect to the most suitable design framework for this research investigation, pragmatism, a perfect ‘philosophical partner’ for MMR (Johnson & Onwuegbuzie, 2004) was chosen as, within this approach, data collection and interpretation methods from both qualitative and quantitative methodology can be utilised on a ‘best fit’ basis (Creswell, 2003). ‘Complementarity’ was additionally selected as the most appropriate strategy of inquiry for data interpretation, as within this method, ‘elaboration, enhancement, illustration or clarification’ of the results obtained from one method is intentionally provided by the investigation of the other (Bryman, 2006; Johnson & Onwuegbuzie, 2004).

The mixed-method study design employed to answer these questions is illustrated in Figure 4.1, and was comprised of the following two main components:
**Stage One**

In stage one, a 3-armed pragmatic feasibility RCT was conducted in which participating women experiencing depression during pregnancy were randomised to one of three groups – individually tailored depression specific acupuncture, equivalent attention progressive muscle relaxation (PMR) comparator, or treatment as usual.

**Stage Two**

Stage two was run concomitantly to the RCT and consisted of two separate qualitative explorations. In the first, in-depth interviews were conducted with a portion of the acupuncture recipients, who had at that stage completed the acupuncture intervention. Focus group were also run with midwives working in the antenatal clinics in which the RCT was conducted, firstly with midwives working in the continuity of care model, then separately, with midwives working within the non-continuity of care model.
Research Design

Stage One

A three-armed pragmatic RCT evaluating acupuncture as a treatment for antenatal depression
Antenatal depression specific acupuncture vs progressive muscle relaxation (PMR)

Stage Two

Midwives Focus Group – Semi-Structured Interviews

Purposively Selected - In - Depth interviews

A) Questionnaires:
   - EPDS
   - DASS-21
   - WHOQoL-26
   - K6
   - BaM-13

B) Semi-Structured Questionnaires: study participation & sleep quality

C) Salivary Biomarkers: OT cortisol & DHEA

Data Collection

Acupuncture

PMR

Treatment as usual

Data Collection

Acupuncture Arm

Quantitative Analysis

Qualitative Thematic Analysis

CLM\textsuperscript{a}

SM\textsuperscript{b}

\textsuperscript{a} Caseload Midwifery

\textsuperscript{b} Standard Midwifery

Figure 4.1 Acupuncture for Antenatal Depression (AcuAnteDep): A Mixed Methods Feasibility Study
4.10.1 Stage One - A Pragmatic Randomised Controlled Trial
Evaluation of an Antenatal Acupuncture Intervention as an Adjunct Therapy for Antenatal Depression

4.10.1.1 The pragmatic three-armed RCT study design

The pragmatic parallel group RCT design was chosen to enable the comparison of individually tailored, semi-standardised depression specific acupuncture as an adjunct to treatment as usual, to an equivalent attention PMR comparator as an adjunct to treatment as usual, to treatment as usual.

Primary research objectives:

1) To examine the feasibility of conducting a RCT of acupuncture for women experiencing antenatal depression. Feasibility will explore an assessment of recruitment procedures; the acceptability of randomisation, sample collection and delivery of the intervention; compliance with the interventions and data collection; and study attrition.

2) To determine whether the overall study design including the therapeutic interventions were acceptable to women experiencing depression during pregnancy, as well as allied health professionals

Secondary research objectives:

1) To examine whether women who received the acupuncture intervention demonstrated a greater reduction in the severity and or duration of antenatal depression when compared to the PMR attention comparator and treatment as usual.

2) To explore whether the women who received the acupuncture intervention demonstrated a greater reduction in stress and anxiety, as well as improvement to quality of life, sleep satisfaction and maternal and neonatal outcomes, when compared to the PMR attention comparator and treatment as usual.

3) To determine whether the women who received the acupuncture intervention displayed alterations to their oxytocinergic and HPA systems when compared to the PMR attention comparator and treatment as usual.
4.10.1.2 Inclusion and exclusion criteria

i. Inclusion Criteria: pregnant women 18 years of age or older, at 24 weeks gestational, currently experiencing a mood disorder with a score of ≥13 or more on the Edinburgh Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987), indicative of a high probability of current depression (Cox et al., 1987; Milgrom, Schembri, Ericksen, Ross, & Gemmill, 2011).

ii. Exclusion Criteria: pregnant women experiencing a medically diagnosed major depressive episode of greater than or equal to two years of continuous duration; psychotic, manic or other features rendering them incapable of consent; PTSD with a phobia to acupuncture needles; a current psychiatric assessment of suicidal risk; a condition that necessitates bed rest; obstetric bleeding disorders; or gestational diabetes with a current requirement for the need of insulin. Participants additionally were excluded from enrolment if they did not agree to refrain from receiving acupuncture during the trial period, other than that provided by the researcher, so as to not potentially confound findings.

In the next section, practical details regarding the implementation of stage one of the trial are provided, along with an RCT flow diagram (Figure 4.2).
Figure 4.2 Stage One: Pragmatic RCT Treatment Flow Chart

Not recruited

EPDS screening of all women ≤ 24 weeks gestation (G)

Informed signed consent, recruitment & baseline data collected

EPDS < 13

EPDS > 13

G24 – pre-intervention time point saliva sample collected

G24 – pre-intervention EPDS, DASS-21, K6 & WHOQoL-BREF questionnaire data collected

Model of care stratification & computer generated randomisation

Treatment as usual antenatal care group

G24-G27 weekly treatment as usual. K6 (G25-27)

Treatment as usual antenatal care & depression specific acupuncture group

G24 - G27 weekly depression specific acupuncture. K6 (G25 - 27)

Treatment as usual antenatal care & progressive muscle

G24 - G27 weekly PMR. K6 (G25 - 27)

G27 - intervention data collected

G27 - saliva sample collected

G27 - mid-intervention EPDS, DASS-21, K6 & WHOQoL-BREF questionnaire & sleep data collected

G28 – G31 weekly treatment as usual. K6 (G28 - 30)

G28 – G31 weekly depression specific acupuncture. K6 (G28 - 30)

G28 – G31 weekly PMR. K6 (G28 - 30)

G31 intervention data collected

G 31 - end of intervention time point saliva sample collection

G31 - end of intervention EPDS, DASS-21, K6 & WHOQoL-BREF questionnaire & sleep data collected

6-week post-partum self-report & EPDS, DASS-21, K6, WHOQoL-BREF, & BaM-13 questionnaire data collected

Key: DASS-21 – 21-item Depression and Anxiety Scale: WHOQoL-BREF – 26 World Health Organization Quality of Life Scale (Brief): K6 - Kessler 6: BaM-13: The 13-item Being a Mother Scale.
4.10.1.3 Sample size calculation

One purpose of conducting a feasibility study is to generate preliminary data that may be helpful for a future larger phase III trial, with respect to sample size and power calculations estimates (Thabane et al., 2010). Whilst sample size calculations may not be required for all pilot or feasibility studies, it has nonetheless be argued to be important to aim towards the retention of a sufficiently large enough sample “to provide useful information about the aspects that are being assessed for feasibility” (Thabane et al., 2010, p5).

In order to assess a suitable sample size, mean antenatal EPDS scores in a recent Australian study (Milgrom et al., 2011), as well as post acupuncture intervention group differences derived from a meta-analysis of two antenatal depression studies (Dennis & Dowswell, 2013a) was examined. It was estimated from these that using a power of 80% and two-sided testing at a 5% significance level, detecting a significant difference in end of intervention mean EPDS scores of 8.9 ± SD of 5 for the acupuncture group plus treatment as usual versus 13 ± SD of 6.5 for treatment as usual, would require a total recruitment number of 75 participants. However, in consideration of the high treatment attrition rates reported for depressed populations (Elkin et al., 1989), along with the possibility that pragmatically designed trials may require larger sample sizes to demonstrate treatment effects, due to the less tightly controlled experimental conditions (Witt, 2011), an additional recruitment target of 30% was considered desirable. Hence, a total recruitment goal of 96, or 32 participants per group was suggested to provide adequate power, hence approximately half of that number would likely provide adequate information regarding feasibility assessments.

4.10.1.4 Ethics approval

Ethical approval for this study was granted in February 2015 from the New South Wales Department of Health, South West Sydney Local Health District Human Research Ethics Committee (SWSLHD-HREC/14/LPOOL/400, (Appendix A and B) and the Western Sydney University Human Research Ethics Committee (WSU-HREC/H10993, Appendix C). The trial was registered with the Australian and New Zealand Clinical Trials Register (ACTRN12615000250538).
The protocol (version 1.0) was designed in accordance with the SPIRIT guidelines for interventional trials (Chan, Tetzlaff, Altman, et al., 2013a; Chan, Tetzlaff, Gøtzsche, et al., 2013b), and was conducted in accordance with the Declaration of Helsinki (1964), and the International Conference on Harmonization Good Clinical Practice (1996).

4.10.1.5 Hospital sites and antenatal in-service RCT information and staff training

The study was conducted at Campbelltown and Camden hospitals in South Western Sydney, Australia. Both sites provide antenatal outpatient services that are under the governance of the same health authority; however birthing services are only available in the larger Campbelltown hospital. The region serviced, particularly by Campbelltown Hospital, includes suburbs considered to be of disadvantaged SES (NSW Government Health & South Western Sydney Local Health District, 2018), high ethnic diversity and greater than state average indigenous population density (NSW Government Health, 2015; NSW Government Health & South Western Sydney Local Health District, 2018).

In-service RCT training was provided to the antenatal clinic service manager, midwives and obstetricians, for the purpose of familiarising colleagues with the rationale and procedures of the RCT, as well as practical implications for shared care. In addition, assistance was requested with recruitment.

4.10.1.6 Participants and recruitment methods

Women making appointments for their first antenatal visit were introduced to the study via a flyer (Appendix D) included in antenatal information packs mailed out by antenatal clinic administration staff. The purpose of informing women about the study at that stage was an attempt to enhance recruitment potential, as there was on average a six-week delay between booking in and the first available appointment, hence it was possible that some women may have been past 24 weeks gestation by the time of the first appointment, and consequently, no longer able to enrol. Interested women were thus able to make direct contact with the principal researcher. Posters for the study (Appendix E)
were also displayed on the antenatal service reception desk and nearby bathrooms, as well as on clipboards containing the EPDS (Appendix F), that women were required to fill out during the first antenatal visit. The principal researcher was additionally provided with a weekly list of women referred by midwives to the perinatal mental health team, due to either currently experiencing or being at high risk of developing an antenatal mental health concern. Based on the information provided, the principal researcher screened women for eligibility and attempted to make contact. Upon indicating interest in the study, potential recruits were provided with the patient information sheet (PIS, Appendix G) and consent form (CF, Appendix H). After this time, the principal researcher followed-up potential recruits until gestational week 24, after which time, all women still intending to join were re-screened for eligibility. Those meeting the eligibility criteria, with EPDS scores of >13 or more were enrolled once signed CFs had freely been obtained.

4.10.1.7 Blinding and randomisation

In this study, blinding of the principal researcher and participants was not considered possible due to: 1) resources not being available to employ junior practitioners to administer treatments; and 2) the individualised treatment tailoring incorporated into the protocol requiring ongoing adjustment at each and every session. Consequently, participants were not blind to group allocation. Health care providers were however blinded to participant group allocation; unless this information was revealed to providers directly by participants. Provisions were made for the blinding of the principal researcher during data entry and analysis, however, due to limited resources, half of the data set was entered by an independent associate researcher from the National Institute of Complementary Medicine (NICM), and the remaining portion, by the study investigator.

The randomisation schedule was prepared by an independent researcher at NICM, and computer generated to contain three groups for the stratification of the three different models of antenatal care (obstetrician, continuity and non-continuity midwifery), as well as random ‘blocks of 3’ within each group, so as
to enable the allocation of women to the three groups (acupuncture, PMR, or treatment as usual, 1:1:1). The randomisation allocation was concealed using opaque envelopes.

4.10.1.8 Treatment schedule

As mental health disturbances are frequently chronic and complicated by co-morbidity, it was considered important to conduct an adequate number of acupuncture treatments to enhance the likelihood of obtaining measurable clinical benefit. Routinely in clinical settings, acupuncturists frequently conduct treatment sessions a week apart, especially for chronic conditions, until symptoms improve, after which timeframes between sessions are generally extended, for the purpose of continued symptom alleviation. In the experience of the principal researcher, noticeable changes in chronic condition symptomatology is generally achievable after four to six treatments, hence this was considered to be a minimum timeframe required. The incorporation of an additional two treatments was however considered important to enhance the likelihood of measurable benefit. This decision was made in consideration of: the complexity of the condition and presenting symptoms; the semi-standardisation of the protocol employed and the subsequent restricted access to treatment strategies routinely utilised in clinical settings, such as unlimited point choices, moxibustion, herbs and diet and lifestyle advice; and the busy and noisy environment of the hospital setting, which was in contrast to a typical acupuncture clinic.

After deciding upon eight treatments, the next consideration was in regard to which stage of pregnancy the intervention should be commenced. Based upon the clinical experience of the principal researcher and supervisory panel, 24 weeks of gestational was considered suitable, as by that stage, the proportion of women experiencing debilitating hyperemesis gravidarum or premature pregnancy loss is generally reduced. In addition, by commencing the intervention at gestational week 24, women would be completing by the end of gestational week 31, which was considered to be a time in which attrition due to premature birth or immobility and pregnancy discomfort was unlikely.
4.10.1.9 Interventions

Women randomised to receive either acupuncture or PMR were scheduled to receive weekly one-hour sessions for a total of 8 weeks commencing from gestational age 24. At the end of every session, five minutes was set aside to gain feedback regarding the treatment, with notes being recorded to provide a link to the next session. All treatments were conducted in the antenatal clinics of either Camden or Campbelltown hospital or at NICM, Western Sydney University (WSU).

4.10.1.9.1 Flexible individually tailored depression specific acupuncture protocol

The trial protocol included individualised treatment flexibility (MacPherson et al., 2008), typical of the ‘whole systems’ approach (Fønnebø et al., 2007; Witt et al., 2012), within the framework of a semi-standardised protocol (Birch, 2004; MacPherson & Schroer, 2007; Schnyer & Allen, 2001; Schnyer, Iuliano, Kay, Shields, & Wayne, 2008), in an attempt to fulfil the dual requirements of maintaining the ecological validity of acupuncture interventions (Witt, 2011), as well as providing generalisability and interpretability (MacPherson & Schroer, 2007; Schnyer & Allen, 2001).

The acupuncture protocol drew upon Traditional Chinese Medicine (TCM) theoretical foundations and treatment strategies, as well as some generalisable TEAM approaches. The intervention followed a three stage semi-standardised individualised process (Figure 4.3) that incorporated both a ‘root’ and ‘branch’ style treatment (Horowitz, 2011; MacPherson, 2006), as well as auricular acupressure. The ‘root’ treatment (Step 1), aimed to provide a fundamental harmonisation via the extraordinary meridian system, while the ‘branch’ (step 2) focused on remaining disruptions in a more symptomatic way (Horowitz, 2011; Maciocia, 1989; O’Brien & Birch, 2011). Utilisation of the extraordinary meridian system as a root style approach has been suggested to facilitate a longer lasting, more penetrating effect (Horowitz, 2011; Maciocia, 1989), by virtue of this systems ability to regulate the ‘qi’ of all of the yin and yang channels (Deadman, Al-Khafaji, & Baker, 1998); access and distribute ‘pre-heaven essence’ throughout the entire body (Maciocia, 1989; Maciocia, 2006); and affect a person at a constitutional level, due to its embryological roots.
Specific functioning of this system relevant to depression include influences to the marrow (Maciocia, 2006), brain, spinal cord, hypothalamic pituitary ovarian axis (Albertson, 2009), circulatory, hepatic, biliary, and endocrine systems (Low, 1983). Pathology within the extraordinary meridian system is thought to manifest in the mind or ‘shen’ (Maciocia, 2006), and as such treatment is recommended for mental health and or emotional problems (Albertson, 2009; Maciocia, 2006); as well as for cases of mixed pattern complexity involving multiple meridians (Maciocia, 2006), such as that seen in co-morbidity. In step 1, diagnosis of the most disharmonious extraordinary meridian pair was made via the presence of relevant mood disturbance symptomology (Maciocia, 1989), (provided by Maciocia in 1989, see Appendix I), in combination with disease indicating palpatory findings along involved channel trajectories (Deadman et al., 1998; Maciocia, 2006; Manaka et al., 1995). If uncertainty remained regarding which point of the extraordinary meridian pair was to be the Master point (MP, see Table 4.1), each was tested with acupressure to determine which of the two provided the greatest meridian improvement. After identification, gender specified unilateral needling of the MP on the right-hand side of the body and the Coupled (CP) point on the left-hand side was performed, in the direction of meridian flow, so that the areas traversed by both vessels were influenced (Maciocia, 2006). This method is recommended by Maciocia (2006) for problems of the head and internal organs, weakened body condition and anxiety. It is also suitable for pregnant women lying on their side. Japanese style practitioners typically apply polarity devices to the Master and Coupled points to remedy detected pathologies in the extraordinary vessel system (Birch & Ida, 1998; Manaka et al., 1995), however for the purposes of generalisability, polarity in this case will be achieved via side of sex directed unilateral needling and reversed order withdrawal (Maciocia, 1989).

Whilst needles were retained for 10-15 minutes, further diagnosis was performed via palpation and questioning. As many of the symptoms of depression correspond to TCM ‘yang deficiency’, such as, lethargy, reduced libido and lack of motivation (Maciocia, 1989), it has been theorised by Wang
and Zhang (2010), that disruption to the major yang channel, the extraordinary meridian Governor Vessel (GV) that traverses the middle of the back and head, is implicated in depression. Wang and Zhang (2010) suggest to needle the most painful or obstructed points along this channel or on the slightly adjacent Huato Jia Ji (HJJ) points, to provide a remedy (Wang & Zhang, 2010), which also serves a dual main channel and extraordinary vessel function (Maciocia, 2006). Upon reverse order removal of the CP and MP, Step 2a commenced with the needling of two points located in this way, followed by either GV 20 [bai hui] + GV 16 [feng fu] (Ellis, Wiseman, & Boss, 1989), the ‘Sea of Marrow’, indicated for mania, suicidal tendencies and calming the spirit; or ‘Shi Shen Cong 4–4 Alert spirits’, indicated for mania, depression, insomnia and calming of the spirit (Deadman et al., 1998). Selection in either case was based upon palpation tenderness and or symptom differentiation.

Whilst these needles were retained, Step 2b involved the insertion of 2-6 additional tender points, as required, according to the numerous theoretical possibilities presented in Table 4.2 and Appendix I, Table T.1, such as the ability to clear reflex areas; for a total combined total of 15-20 minutes. An example of a step 2b treatment choice could be in relation to the association between depression and inflammation (Kendall-Tackett, 2010), viewed as ‘heat’ in TCM. Discernment of the presence of heat is made via positive palpation tenderness at ‘fire’ points on meridian trajectories, to which the applied remedy is to extinguish the ‘fire’ with the needling of ‘water’ and ‘metal’ points’ (Maciocia, 1989) on the same meridian.

Whilst these needles were being retained, step 3 comprised of selecting two auricular points to apply stainless steel spheres (Helio Supply Co.) to, and retain for five days, in order to extend the treatment effect with a mild but continuous stimulation (Birch & Ida, 1998). Selection of appropriateness was made according to the combination of functionality and tenderness elicited using an ear probe, at for example, a ‘depression’ point (see Appendix I Table T.2 for more options, and auricular maps in Appendix I).

For the purposes of simplification and generalisability, lifestyle and dietary advice was avoided. Modifications were also made in consideration of mid to
late stage pregnancy, whereby points considered useful for preparation for labour were avoided (Betts, 2009). Similarly, in consideration of the frequent co-occurring morbidity of anxiety amongst this population, strong needling techniques that elicit painful ‘de qi’ sensations were omitted (Wayne et al., 2008). Needles were instead inserted into the most sensitive area within the specified point location or ‘live’ point (Schnyer, Iuliano, Kay, Shields, & Wayne, 2008), to a depth that enabled retention (2-6mm); either perpendicularly (even technique) or obliquely with the meridian flow (tonification), before being taped in place; so as to allow for adjustment of position during the session. Acuglide (Helio Supply Co.) single use stainless steel needles of 0.16 mm gauge and 30 mm length were predominantly used, with 0.14 mm or 0.12 mm selected for more tender locations.

For the development of this protocol, recent reviews of acupuncture for the treatment of depression (Nahas & Sheikh, 2011; Smith et al., 2018; Stub, Alræk, & Liu, 2011; Wu, Yeung, Schnyer, Wang, & Mischoulon, 2012; Zhang, Chen, Yip, Ng, & Wong, 2010) were examined. Three main approaches to treatment were identified: fixed points for mood disturbance alleviation; fixed points of this function in combination with additional points selected according to TCM pattern differentiation; and flexible point selection, based entirely upon TCM pattern discrimination. Variations amongst these included the diagnosis of disrupted extraordinary meridians Chong and Ren in one study (Wenbin, 2002), an abdominal points focus in another (Cheng & Tang, 2007), and scalp acupuncture in a third (Huang & Xia, 2004). Many of the studies included auricular acupuncture as well as the use of multiple points along the extraordinary GV meridian. Two research groups developed flexible manualised protocols based on TCM pattern differentiation (MacPherson & Schroer, 2007), one of which provided modifications for pregnancy (Schnyer & Allen, 2001). Both were drawn upon for the therapeutic possibilities presented in Table 4.2, and Appendix I, Tables T.1-2, with further incorporations being sourced from the protocol manuals of Matsumoto and Euler (2002, 2008), as detailed in section 4.10.1.9.1.1 below.
It has been theorised that the inclusion of extraordinary meridian treatment in combination with mental disturbance orientated pattern differentiation / symptom alleviation, may provide additional therapeutic outcomes. Finston (2009) utilised a similar strategy in patients with severe mental disorders and reported significant reduction in or alleviation of psychotic symptoms.
Figure 4.3 Acupuncture Treatment Flow Chart

'Root' – Needle MP RHS\(^a\), CP LHS\(^b\) of disharmonious Extraordinary Meridians (Table 4.1) - 10-15 min.

\[\downarrow\]

Palpate Du Line & HJJ Identify 2 most painful

**Step 2a**

Remove in the reverse order. Needle 2 most painful Du line or HJJ points – retain for 15 min.

\[\downarrow\]

Whilst retained add

GV 16 & GV 20 or Shi Shen Cong 4 + **Step 2 b**

Add up to 2-4 points–based on presenting symptoms–see Table 5.2 and Appendix I for options

\[\downarrow\]

After a total of 15-20min remove needles

**Step 3**

Add 2 press balls to auricular points for retention–see Appendix I for options

\(^a\)Right hand side
\(^b\)Left hand side
Table 4.1 Master and Coupled Point Pairings of the Eight Extra Vessels

<table>
<thead>
<tr>
<th>Extraordinary Meridian</th>
<th>Master Point (Right)</th>
<th>Couple Point (Left)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ren Mai – Directing Vessel</td>
<td>Lung (LU) 7</td>
<td>Kidney (KD) 6</td>
</tr>
<tr>
<td>Yin Qiao Mai – Yin Heel Vessel</td>
<td>Kidney (KD) 6</td>
<td>Lung (LU) 7</td>
</tr>
<tr>
<td>Chong Mai – Penetrating Vessel</td>
<td>Spleen (SP) 4</td>
<td>Pericardium (PC) 6</td>
</tr>
<tr>
<td>Yin Wei Mai – Yin Linking Vessel</td>
<td>Pericardium (PC) 6</td>
<td>Spleen (SP) 4</td>
</tr>
<tr>
<td>Dai Mai – Girdle Vessel</td>
<td>Gall Bladder (GB) 41</td>
<td>Triple Burner (TB) 5</td>
</tr>
<tr>
<td>Yang Wei Mai – Yang Linking Vessel</td>
<td>Triple Burner (TB) 5</td>
<td>Gall Bladder (GB) 41</td>
</tr>
<tr>
<td>Du Mai – Governing Vessel</td>
<td>Small Intestine (SI) 3</td>
<td>Bladder (BL) 62</td>
</tr>
<tr>
<td>Yang Qiao Mai – Yang heel Vessel</td>
<td>Bladder (BL) 62</td>
<td>Small Intestine (SI) 3</td>
</tr>
</tbody>
</table>

### Table 4.2 – Step 3 - Additional Relevant Point Possibilities

<table>
<thead>
<tr>
<th>Symptom &amp; Theoretical Foundation</th>
<th>Points*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Yang Deficiency a</td>
<td>GV4 &amp; GV 14 or GV 4 &amp; TE 4</td>
</tr>
<tr>
<td>Anxiety + Pressure pain at PC 8 or SP 2 – Pericardium or Spleen Metal &amp; Water Points b,c</td>
<td>PC 3 &amp; 5 or SP 5 &amp; 9</td>
</tr>
<tr>
<td>Anxiety + Pressure pain at CV 12 – Points of the Heart Shu area c</td>
<td>T5 / HJJ / T5 / BL 15 / BL 44 / BL 49</td>
</tr>
<tr>
<td>Anxiety + Pressure pain at CV 17 c</td>
<td>GB 13</td>
</tr>
<tr>
<td>Depression / mental disturbance - 'blood stagnation in the head' 1b</td>
<td>1st – SP 6 &amp; 9 2nd – PC 8 / PC 6 / PC 3+5</td>
</tr>
<tr>
<td>Depression from adrenal exhaustion 2bc</td>
<td>KD 6 &amp; LU 5 or KD 6 &amp; KD 27</td>
</tr>
<tr>
<td>Depression &amp; sphenoid bone disturbance - Pressure pain at GB 4/5/6 c</td>
<td>Needle most tender</td>
</tr>
<tr>
<td>Depression &amp; pituitary disturbance 3b</td>
<td>SI 3, SI 13, BL 2 &amp; 1 cun above BL 10</td>
</tr>
<tr>
<td>Melancholic depression c – If positive for pressure pain / pulsation at CV 9 c</td>
<td>ST 24 R, LU 9</td>
</tr>
<tr>
<td>Depression – Liver 2 Pressure Pain – Water and Metal Points b</td>
<td>LR 4 &amp; 8</td>
</tr>
<tr>
<td>Depression – Pressure pain LR organ region &amp; LR 14 b</td>
<td>LHS – lateral to LU 5, LR 4 &amp; LR 14 R</td>
</tr>
<tr>
<td>Chronic depression &amp; weakened immune system – Pressure pain R ST 26 / 27 &amp; TE 16 b</td>
<td>Tender point around LI 10 / 11</td>
</tr>
<tr>
<td>Sub-clinical underactive thyroid gland 4b</td>
<td>Eustachian, TE 4, K9 / 10, BL 43, HJJ C6 / 7</td>
</tr>
<tr>
<td>Inflammation – TCM meridian heat signs - Metal &amp; Water Points to extinguish d</td>
<td>Meridian dependent</td>
</tr>
</tbody>
</table>

Mental Health Relevant Points - selected by point function & palpation tenderness 4

See Appendix I Table T1 for options

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* Points were selected based on tenderness and ability to reduce pain at diagnostic areas. Points in each category were added until tenderness clears, hence not all of the points in each list were necessarily required. Some may be needled unilaterally or bilaterally depending on availability & dosage considerations. a (Maciocia, 1989); b (Matsumoto, & Euler, 2002), c (Matsumoto, & Euler, 2008) – If PC 8 was not tender, it could be needled. If PC 8 is uncomfortable then PC 6 could be needled as an alternative. If PC 8 is tender, PC 3 & 5 are needled; 1st diagnosed as tenderness in a diamond or square pattern 1 cun from GV 20; 2nd diagnosed as palpation tenderness at CV 6 and 0.5 cun below and diagonally lateral from navel centre or with pulses that are a) rapid, tight & thin in all 3 positions; b) sinking & slow; c) very weak in both guan positions; 3rd – diagnosed as tenderness with light pressure at BL 2 to yu yao & 1 cun above BL 10; 4th – diagnosed along with symptoms as tenderness of HJJ cervical C6-C7 & ST 9, tightness of the clavicle insertion of the sternoleidomastoid (SCM) muscle + GV 14 area accumulation or dowagers hump; eustachian tube point is located by pulling the ear forward, under the attachment of the ligament at the back of the ear near the lobe and the skull; d (Kendall-Tackett, 2010); other options are presented in the texts (b) (c), however are restricted for the purposes of the protocol; 4th – Macpherson and co-workers (2013) identified 2 dominant TCM depressive patterns, Liver Qi stasis (66%) and Spleen deficiency (34%), hence LR 3 – indicated for stagnant Liver Qi & calming of the mind, and/or ST 40 – to clear damp and phlegm & calms the spirit may be appropriate (see appendix I, Table T1). T 5 = 5th thoracic vertebrae.
Adaptations from published manuals for the treatment of mood disturbances

The protocol manuals specifically designed for the treatment of depression with acupuncture by MacPherson and Schroer (2007) and Schnyer and Allen (2001) had been experimentally validated, first as pilots (Allen, Schnyer, & Hitt, 1998; Manber, Schnyer, Allen, Rush, & Blasey, 2004), and then as larger RCTs (Allen et al., 2006; Manber et al., 2010).

The aim of both was to strike a balance between the opposing forces in trial design, of tightly controlled standardised experimental design being required for high internal validity and generalisability, whilst also still maintaining the external validity of acupuncture (Witt, 2011).

Theoretical frameworks considered important for diagnosis and treatment included Chinese medicine concepts such as: the eight principles; qi, blood and body fluids; the five elements or phases, including causative / constitutional factors (MacPherson & Schroer, 2007; Schnyer & Allen, 2001); pathogenic factors; sheng and ko cycle relationships; zang fu syndromes; and the eight extraordinary vessels (MacPherson & Schroer, 2007), particularly du and chong mai, due to implications in depression (Schnyer & Allen, 2001).

The guidelines provided from both were incorporated into this protocol as detailed below.

Firstly, in the manual developed by MacPherson and Schroer (2007) components considered necessary for inclusion were:

1) Maintaining aspects characteristic of, and specific to, acupuncture, with the exception of the elimination of dietary and lifestyle advice.

2) Conducting traditional acupuncture diagnostic assessments via: asking questions, palpating, observing, smelling and hearing at each session, excluding palpation of the lower abdomen, as a modification for pregnancy.

3) Identify patterns of disharmony from your normal repertoire of traditional acupuncture frameworks, for the purpose of guiding treatment at each session.
4) Flexibly applying each treatment on an individual patient basis; selecting appropriate length and gauge needles; inserting to appropriate depths; retaining for adequate timeframes and interpreting treatment reactions for the ongoing treatment process.

Secondly, additional incorporations from the protocol manual of Schnyer and Allen (2001) included:

1) Utilisation of auricular points as a supportive therapy (see Table 4.4).
2) Adapting acupuncture points as necessary, with pregnancy contraindicated points were avoided (Betts, 2009).
3) Balancing upper and lower, local and distal and left and right aspects of the body.
4) Choosing points to address more than one treatment principle at the same time, so as to keep needle numbers down.

Lastly, treatment strategies for rectification of mood disturbance were incorporated from the manuals of Kiiko Matsumoto and David Euler (2002, 2008) based upon the relevant theoretical explanations. In volume two, treatments were derived from the chapter dedicated to psychological disorders.

Three prominent experts in the field of acupuncture practice and research (Professor Caroline Smith, Dr Debra Betts and Mr Paul Movsessian) were additionally consulted during the protocol development, to ensure both the appropriateness of the method, as well as sufficient generalisability to the acupuncture community at large. Suggestions kindly provided were incorporated.

As the principal investigator held a bachelor degree in acupuncture, with 13 years of full-time and four years of part-time clinical experience, as well as registration with both the Chinese Medicine Board of Australia (CMBA), and the Australian Acupuncture and Chinese Medicine Association (AACMA), she was adequately qualified to perform the acupuncture treatments. Due to cost limitations, the principal investigator also conducted all of the PMR sessions.
4.10.1.9.2 Progressive Muscle Relaxation (PMR) equivalent attention control

PMR was originally developed by Jacobson (1938) to achieve an overall body relaxation. Since this time, PMR has been extensively utilised in studies as a control for non-specific placebo like treatment effects (Stevens, Hynan, Allen, Braun, & McCart, 2007), as evaluations of effectiveness have demonstrated mixed findings, as well as an absence of treatment effects (McCallie, Blum, & Hood, 2006).

In the context of this study, the therapy was utilised for the purpose of controlling for the effects of being involved in the intervention. This was considered to be particularly important for this cohort, as depression is associated with a desire for social withdrawal, and consequently it is conceivable that weekly travel to the treatment site, along with the receipt of care and attention from the practitioner, as well as resting for 45 minutes whilst receiving the intervention, could conceivably impact upon depression symptomology. This control thus served as an equivalent attention comparator for the estimation of the non-specific placebo like effects of intervention involvement.

The PMR intervention consisted of weekly one-on-one one-hour sessions, for a total of eight weeks. As was the case in the acupuncture intervention, the first session was commenced after the collection of the full case history, unless participants had insufficient time, in which case, the session was rescheduled for another time. In the first session, the participant was instructed to lie in a comfortable position, prior to being introduced to the technique, and then guided through an overall body relaxation. Sessions two to seven commenced with a brief assessment of how the woman was feeling on that day, as well as how she has felt since the previous session. After that, the guided meditation was performed to achieve an overall body relaxation, as well as focus on a different area of the body each time: lower legs and knees (week 2); upper legs and buttocks (week 3); lower back and pelvic floor (week 4); upper back and chest (week 5); arms and shoulders (week 6); and head, face and neck (week 7). In the final session, the aim was to integrate the weekly session focus, as well as achieve on overall body relaxation. At the end of every session, five minutes was
spent collecting feedback regarding how the women felt. If at any time a participant was unable to attend, or indicated finding the commitment difficult, she was offered to have sessions conducted over the telephone, or to be sent recordings of sessions for home administration.

4.10.1.9.2.1 PMR Intervention Protocol

The protocol for the conducted sessions is provided in Appendix J. Session one, the introduction to the technique and session eight, the integrating concluding session are provided in full. Session two, the first session in which a particular area of the body was focused upon, is also provided in full. Sessions three to seven however, were identical in format apart from the area on the body being focused upon, hence only the substituted sections have been provided.

4.10.1.9.3 Treatment as usual

All of participants in the study received identical standard antenatal depression hospital care, which consisted of regular antenatal appointments with midwives or obstetricians, for the purpose of monitoring: foetal development; potential obstetric issues such as gestational diabetes and hypertension; and in the case of this cohort, mental health concerns identified at booking in. If any woman was discerned by any of the providers to be experiencing a worsening of their mental health, they were either referred to the mental health team, if not already engaged with this service, or urgently attended to by social workers on site. Depending on the severity of the mental health issues, and the choices of the enrolled women, women were either not treated for their mental health concerns, or were accessing standard therapies including antidepressants and or psychotherapy.

The consequences of experiencing depression during pregnancy was considered to be sufficiently serious to require that conventional treatment strategies being utilised be maintained or introduced as needed, and thus, that the interventions be evaluated as adjunctive therapies (Zaslawski, 2003). Consequently, the treatment as usual control served three main purposes:

1) Ensuring the safety of participants, from a mental health perspective.
2) Enabling the examination of whether additional benefits could be discerned from either of the interventions, on top of those provided by conventional mental health approaches.

3) Providing a reference for compliance to standard therapy, and natural progression or remission of depression severity and regression towards the mean (Birch, 2004). As depression is typically episodic in nature, changes in the intensity of depression symptomology is commonly experienced over time (Royal Australian and New Zealand College of Psychiatrists, 2004).

As an additional ethical consideration, the treatment as usual group were offered a course of four acupuncture sessions after collection of the final data point at six weeks postnatal, as form of compensation for not receiving the possible benefits of either intervention during pregnancy.

4.10.1.10 Safety monitoring

The safety of all participants was monitored by the conduction of a weekly psychologically assessment via the Kessler 6 (K6) instrument (Appendix K) (Furukawa, Kessler, Slade, & Andrews, 2003), either during the consultations conducted for the interventions, or by telephone for those in the treatment as usual allocation. This process was considered to be particularly important for the non-treatment group, as without this monitoring, two three-week periods during the intervention would have passed without any direct contact with the principal researcher. If a notable worsening or ‘cut-off’ score of 25 was reached, immediate referral was made to antenatal mental health services. Immediate referral was also made to the antenatal service manager or social work, if any woman indicated during any times the EPDS was administered, that they had experienced thoughts of self-harm within the past seven days.

Provisions were also made for the documentation and reporting of any adverse events arising from the intervention, including prevalence rates, to associated governing ethics committees. If such an event did occur, participants would be reminded of their right to withdraw from the study. The principal researcher in
addition monitored whether common post needling consequences such as bleeding at points or bruising occurred, for the purposes of documentation and reporting.

4.10.1.11 Primary and secondary outcome measures

In stage one, primary outcome feasibility considerations and secondary outcome assessments were incorporated throughout the three substages, and consisted of published mood and quality of life questionnaires (part A); purposively designed, semi-structured feedback forms (part B); and assessment of biomarker hormone concentrations (part C).

Outcome measures were collected at various timepoints including baseline, mid-intervention (session four), end of intervention (session eight), birthing and hospital discharge (medical records), and at six weeks postnatal.

All questionnaires were self-administered within the presence of the principle investigator, apart from the six-week postnatal follow-up returned by post; so as to provide women with the opportunity to clarify uncertainties regarding filling out forms, as well as to enable the principal researcher an opportunity to scan for missing data. In order to facilitate honest answering, the participants were informed that data would be entered into databases by independent researchers.

Every effort was made to minimise missing data and study attrition arising from drop outs. If women did decide to withdraw, the principal researcher asked all participants if they would consider providing data at the next major collection point, either by telephone, or returning posted forms. If the women declined, no further information was requested after this time. Similarly, if the six-week postnatal follow-up forms were not returned or returned with missing data, the principal researcher re-contacted participants for the purpose of collecting the additional information.

The questionnaires utilised to quantitatively assess the clinical outcomes in part A included the Edinburgh Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987); the Depression Stress and Anxiety Scale (DASS-21) (Lovibond &
Lovibond, 1995); the K6; and the World Health Organization Quality of Life Scale (WHOQoL-26) (The WHOQOL Group, 1998). Adjustment to mothering was also evaluated via the Being a Mother scale (BAM-13) (Matthey, 2011). To facilitate compliance, forms were chosen that were quick to administer, as this has been shown to be problematic in depressed populations (Demyttenaere, 2003), especially in cases of more severe depression (Buist et al., 2006); as well as to not overly burden participants (Kimberlin & Winterstein, 2008), (see section 4.10.1.11.1).

Semi-structured feedback forms were administered in part B at the mid-intervention point (corresponding to the end of session four), as well as at the end of the intervention (after session eight), for the purpose of obtaining feedback from participants regarding sleep quality and experiences of the intervention (see section 4.10.1.11.3). Data in both cases was collected for a summative qualitative content analysis, whereby, in addition to counting the frequency of words or content, this method also incorporated the interpretation of content for the purpose of discovering underlying meaning (Hsieh & Shannon, 2005).

Additional quantitative assessments were performed in part C, whereby saliva was collected from all participants prior to randomisation, for the purpose of determining pre- and post-intervention oxytocin and cortisol: DHEA hormone concentrations, (see section 4.10.11.6).

4.10.1.11.1 Stage one (A) - published questionnaires
4.10.1.11.1.1 Edinburgh postnatal depression scale

The EPDS was first developed by Cox (1987) as a 10 item self-reporting questionnaire designed to assess a woman’s postnatal mood over the preceding seven-day period (Appendix F). A score of 10-12 out of a possible 30 was taken to indicate a likelihood that a woman may be suffering from a mild form of depression, whereas a score of 13 or more was considered to be indicative of a possible moderate to more severe depression. Since its introduction, the EPDS has been extensively utilised and repeatedly found to be sensitive (Eberhard-Gran, Eskild, Tambs, Opjordsmoen, & Samuelsen, 2001), specific (Cox et al.,
1987; Matthey, 2011), and clinically valid (Eberhard-Gran, Eskild, Tambs, Opjordsmoen, & Samuelsen, 2001). The tool has also been adapted to antenatal settings (Gibson, McKenzie-McHarg, Shakespeare, Price, & Gray, 2009; Murray & Cox, 1990), and found to be sensitive and accurate (Adouard, Glangeaud-Freudenthal, & Golse, 2005; Chorwe-Sungani & Chipps, 2017; Murray & Cox, 1990), as well as acceptable to both women and administrators (Hewitt et al., 2009; Leigh & Milgrom, 2007), and consequently, is routinely used both as an antenatal (EPDS) and postnatal (EPDS) depression assessment tool.

4.10.1.11.1.2 Depression stress and anxiety scale

The DASS was developed by Lovibond and Lovibond (1995) as a 42-item scale, for the purpose of measuring “the ubiquitous and clinically significant emotional states usually described as depression, anxiety and stress” [page 1], whereby the core symptoms that may present in each scenario are assessed. Since development, the psychometric properties of the DASS have been clinically validated (Brown, Chorpita, Korotitsch, & Barlow, 1997) and in addition, the tool has been shown to be a reliable measure across many different cultural settings (Oei, Sawang, Goh, & Mukhtar, 2013). As the co-morbidities of anxiety and stress are frequently reported to be experienced alongside depressive symptomology (Glover, 2014), the DASS was included in this RCT, to also ascertain the extent to which participants were suffering from these conditions.

To facilitate participant compliance as well as not overly burden women with lengthy questionnaires (Kimberlin & Winterstein, 2008), the shorter 21 item measure (Appendix L) that dedicates seven items to each morbidity was selected. In this scale, scores ranging from 7-10 for depression, 6-7 for anxiety and 10-12 for stress are indicative of symptoms being experienced at a level of moderate severity (Lovibond & Lovibond, 1995).

4.10.1.11.1.3 Kessler 6 scale

Kessler (2002) developed a short screening scale for the assessment of psychological distress that demonstrated both strong psychometric properties, as well as the ability to discriminate cases identified in the fourth version of the American Psychiatric Association’s manual for the diagnosis of mental disorders
(DSM-IV), from non-cases. Subsequent validation studies have demonstrated that the K6 is a suitable screening tool for DSM-IV mood or anxiety disorders, due to both the brevity of administration, as well as consistency across subsamples (Furukawa et al., 2003), (Appendix K).

4.10.11.1.4 World Health Organization Quality of Life Brief scale

The World Health Organization (WHO) (1998) developed a 100-item instrument, the WHOQoL-100, for the purpose of obtaining an overall measure of quality of life experienced by different populations, in which the assessment of both general health as well as 24 specific quality of life factors, such as the presence of: pain, positive feelings, social support and transport, were categorized into four broad domains, namely, physical, psychological, social and environmental. A shorter version of this tool was also developed that contained one general quality of life question, as well as one item from each of the 24 specific facets included in the WHOQoL-100. This shortened version of the tool, the WHOQoL-26 (Appendix M), demonstrated both discriminant and content validity, as well as internal consistency and reliability (The WHOQOLGroup, 1998) and consequently was chosen for inclusion in this RCT, for the reasons stated previously, namely: 1) to not overly burden participants with long questionnaires and also to 2) broaden the scope of assessment of changes that may have resulted from the acupuncture intervention, as the whole person orientated approach may result in generalised improvements that may not be detectable from mood orientated measurement tools alone.

4.10.11.1.5 Being a Mother scale

In 2011, Matthey created the ‘Being a Mother’ scale (BaM-13) (Matthey, 2011), to assess the experiences of mothering from the early postpartum period, up until children were of school age (Appendix N). The BaM-13 was developed to capture more broadly a mother’s experience of her child, herself as mother and the level of closeness she feels towards her child, by extending the period of assessment beyond that provided by other postpartum assessment measures. The scale of 13 questions is reported to be both reliable and valid, as well as having good clinical discrimination between different women’s experiences.
Using the tool, stressed women were three times more likely to score 9 or more, with a sensitivity of 72.5%, a specificity of 74.4%, a positive predictive value of 34.9%, and a negative predictive value of 93.5% (Matthey, 2011).

4.10.1.11.2 Stage one (A) - additional data collection

Additional data collected from participants at specific timepoints throughout the RCT, included:

Baseline demographics; gestational age at recruitment; previous pregnancy and or birth histories; relationship status; levels of education attained; employment status; country of birth and indigenous status. Trial specific clinical data such as: mental health medical diagnoses; obstetric co-morbidities; age of onset of index depressive episode; number, severity and average length of previous depressive episodes; length and severity of current depressive episode; previous history of antenatal and or postnatal depression if applicable; knowledge of family history of depression; and previous and or current utilisation of complementary medicines or therapies, psychotherapy, or pharmaceutical medication for mental health disturbances (Appendix O and P).

A general medical history inclusive of current symptomologies for the purpose of determining a Chinese medicine diagnosis, that included tongue and pulse diagnostic assessments (Appendix Q).

Obstetric, birthing and postnatal secondary outcomes including: occurrences of obstetric co-morbidities and complications; gestational age of delivery; length of labour; mode of delivery; intervention methods required; pain relief utilised; birth weights; Apgar scores; need, reason for and length of stay in neonatal intensive care unit (NICU); breastfeeding utilisation at birth, discharge, and six-weeks postnatal; length of maternity ward stay; and women’s experiences of depression in the postnatal period and current management methods (Appendix R).
4.10.1.11.3 Stage one (B) - semi-standardised questionnaires

4.10.1.11.3.1 End of session 4 and 8 intervention feedback forms
At the mid-intervention point, as well as at the end of the intervention, all participants randomised to either of the treatment groups were provided with a semi-structured questionnaire to obtain feedback regarding their views of their group allocation and overall experiences of the intervention (Appendix S).

4.10.1.11.3.2 End of session 4 and 8 sleep feedback forms
Also, at the same time points, all participants were provided with a semi-structured questionnaire for the purpose of collecting feedback regarding their views of the quality of sleep they were generally experiencing, as well as whether they had noticed changes in this regard, either with increasing gestational age, or as a consequence of the intervention, if applicable (Appendix T).

4.10.1.11.4 Assessment of feasibility
Assessments will be made in regard to the feasibility of conducting a similar larger scale trial, from the perspective of whether one “can be done, should be done, and, if so, how” (Eldridge et al., 2016, p2).
In particular feasibility will be addressed as follows:

1) Recruitment procedures were assessed in terms of whether the methods used were successful for the purpose of recruiting the target population under consideration. Measurements of this outcome were based upon numbers of eligible women screened and total recruitments retained, as well as comparisons to recruitment success / failures in other studies of similar populations.

2) The acceptability of the study to participants as measured by enrolment, participant feedback and study attrition.

3) The success of the randomisation process as measured by the distribution of baseline characteristics between groups.

4) The acceptability of the sample collection procedure to participants as measured by compliance.
5) The suitability of the sample medium and methods chosen for the successful measurement of biomarkers.

6) The acceptability of the delivery of the intervention as measured by adverse event reports, participant feedback and study attrition; as well as analysis of primary and secondary outcome measurements.

7) The effectiveness of the delivery of the intervention and measurement tools chosen, as measured by analysis of primary and secondary outcome assessments.

8) Compliance with the interventions as measured by participant feedback and study attrition.

9) Compliance with data collection as measured by missing data and non-returned postnatal assessment forms.

10) The acceptability of the overall study design as measured by feedback provided by participants, midwives and ward personnel.

4.10.1.11.5 Analysis of study outcomes

Stage one (A and C) - descriptive statistics comparisons of frequencies and means by group were utilised to describe the characteristics of the study population. An intention to treat analysis was conducted for the EPDS, with the rationale for inclusion as well as method chosen to perform this analysis also provided below. Inferential statistics were used to examine differences between groups including Chi square and per-protocol analysis of variance for the primary and secondary endpoints. Effect sizes using relative risks and mean differences were reported with 95% confidence intervals and results considered significant if p values were less than 0.05. Linear mixed model repeated measures analysis of primary and secondary mood and quality of life score questionnaires were also performed, for which the rationale for inclusion is provided below. Post-hoc secondary analysis was undertaken for primary and secondary endpoints. Post-hoc exploratory analyses were additionally performed on resultant biomarker concentrations. All analyses were performed utilising SPSS software (version 24.0). Prior to the data being made available to the investigator for analysis, study identification (ID) and treatment codes were re-allocated to allow the analysis to be undertaken blind to group allocation.
Stage one B - semi-structured questionnaire responses were analysed utilising the qualitative summative content analysis approach.

4.10.1.11.5.1 Repeated measures analysis
The linear mixed model was chosen for repeated measures analysis, as in this method, all data collected from each individual at every time point is incorporated, despite attrition from the study. Utilising this approach, as much detail as possible is thereby provided for the analysis of the entire population. In contrast, the general linear model repeated measures analysis of variance (ANOVA) incorporates only individuals with completed data sets. The elimination of individuals from analysis in small sample sizes could however result in a source of introduced bias, especially if there is a specific reason for which participants are not completing. The additional reason for choosing the linear mixed model over the general linear model repeated measures ANOVA was due to time being able to be incorporated into the model as a categorical variable, rather than equidistantly spaced; as is the assumption in the general linear model repeated measures ANOVA. This was relevant to this study due to 1) participants varying the intervention schedule and consequently, the time frame between intervention collection points, and 2) the variability of birthing resulting in the 6-week postnatal collection point varying amongst individuals from the end of intervention.

4.10.1.11.5.2 Intention to treat multiple imputation calculation of missing EPDS data
Commonly in clinical trials issues arise in relation to missing outcome measures (Gupta, 2011), such as that occurring due to non-returned assessment forms, missed answers on questionnaires and participant withdrawal. An established statistical method for dealing with missing data is that of ‘intention to treat’ (ITT) analysis (Gupta, 2011), whereby data from all randomised participants is imputed for analysis, regardless of what happens after randomisation. Whilst arguments exist regarding the benefits for and disadvantages of performing an ITT analysis (Gupta, 2011), it is a general recommendation to minimise research bias (Sterne et al., 2009; White, Carpenter & Horton, 2012), as well as to standardise the reporting of clinical trials [CONSORT statement] (Moher, Schulz,
More recently however a revision of the CONSORT statement intentionally replaces references to ‘ITT analysis’ with a request that trialists provide specific information about retaining participants in their original randomised grouping, as a consequence of a lack of consensus regarding the definition of ITT (Hollis & Campbell, 1999; Schulz, Altman, & Moher, 2010; White et al., 2012).

A variety of methods can be utilised to impute missing data (Sterne et al., 2009; White et al., 2012), of which one, the ‘last value carried forward’ is both widely used and commonly criticised (Gadbury, Coffey, & Allison, 2003; White et al., 2012). A method argued by Peter Elliott and Graeme Hawthorne in 2005 (Elliott & Hawthorne, 2005) to be superior to the ‘last value carried forward (LVCF)’ is that of the ‘closest match or average closest match (ACM)’. In this method, an individual in the same randomisation allocation with the same score at the same time point is used to predict the possible follow-up score in the individual for which the datum point is missing, by copying across the score the matched individual obtained at that follow-up time, thereby providing the ‘closest match’. An alternative option is the ACM in which Elliott and Hawthorne (2005) suggested averaging the follow-up scores of four individuals with matched scores in the same data point to the individual with the missing datum, to provide an imputed average of the follow-up score.

Based upon the arguments presented by Elliott and Hawthorne (2005), the method chosen for the imputation of missing primary outcome data for the EPDS was the ACM. For the purposes of comparison, the method of LVCF was also utilised as a method for imputation, and findings are reported in Appendix V.

4.10.1.11.6 Stage one (C) - Participants’ biomarker hormone concentration assessment

As recommended by Ahn and co-workers (2005), the advancement of clinical research into acupuncture could be facilitated by designing clinical trials that included both ‘manualized’ protocols, as well as ‘mechanistic studies’ (Ahn &
Kaptchuk, 2005). To that aim, pre- and post-intervention assessment of hormones typically implicated in mental health issues were assessed.

Specifically, participant saliva was collected for the purpose of quantitative evaluation of pre- to post-intervention between group differences in OT, cortisol and DHEA concentrations, as these three biomarkers are frequently reported to be dysregulated in times of stress and depression (Bell, Erickson & Carter, 2014; Duthie & Reynolds, 2013; Maninger, Wolkowitz, Reus, Epel & Mellon, 2009; Seth, Lewis & Galbally, 2016). The purpose of this investigation was two-fold. Firstly, to determine whether participants’ biomarker concentrations did reflect the dysfunctional hormonal milieu frequently reported in similar cohorts, and secondly, to determine whether the acupuncture intervention was able to exert an influence on hormone concentrations, when compared to those in the PMR attention comparator and treatment as usual controls.

Upon enrolling in the study, all gestational week 24 pre-intervention saliva samples were collected from participants, prior to randomisation. All post-intervention samples were collected after completion of the intervention, either during gestational week 31 for the treatment as usual group or after completion of the final session, for those in either treatment arm.

4.10.1.11.6.1 Rationale for utilising saliva as a medium and choice of assay method

Saliva was chosen as the most suitable medium to assay pre- and post-intervention changes to participant’s OT, cortisol and DHEA concentrations, due to the ease of multiple sample collections, non-invasiveness of the procedure and established validity. The optimised assay method provided by Enzo Life Sciences (2013) was selected for the analysis of OT, as it incorporated a concentration step recommended to enhance reliable detection, whereas the protocols from Salimetrics (2016) were decided upon for the determination of cortisol and DHEA (Salimetrics, 2016), as in both cases only very small quantities of saliva were required, which then enabled the majority to the sample to be utilised for the detection of OT.
4.10.1.11.6.2 Sample collection
In order to minimise the impacts on samples of the diurnal rhythm of cortisol (Harville et al., 2007; Lazinski, Shea, & Steiner, 2008) and DHEA (Wood, 2009), as well as pulsatile release of OT (Amico, Ulbrecht, & Robinson, 1987), within individual pre-and post-intervention samples were collected as closely as possible to the same time of day, without causing unnecessary burden to participants. Prior to collection, sample tubes (15ml sterile CELLSTAR polypropylene tubes, catalogue number 188271; Greiner Bio-One, Frickenhausen, Germany) were pre-chilled on ice, after which participants deposited a minimum of 4 ml of saliva, using the passive drool technique. Tubes were rested on ice in between deposits. Once collected, tubes were either temporarily stored at −20 °C for later transport on ice, or directly transported on ice to WSU for freezing and storage at −20 °C.

4.10.1.11.6.3 OT analysis of participants’ saliva
4.10.1.11.6.3.1 Concentration of salivary OT
The OT concentration step was performed as recommended by Enzo Life Sciences (Enzo Life Sciences Inc., 2013), utilising Waters Corporation Sep-Pak C 18 200 mg reversed-phase resin columns (catalogue number WAT 054945; Waters Corporation, Milford, MA, USA). On occasion, minor modifications were required, as detailed below:

a) Neat saliva samples were thawed overnight at 4°C prior to being spun at 3500 rpm in a pre-cooled benchtop centrifuge (Beckman Coulter Allegra X-12R; California, United States) for 30 minutes at 4°C. Volumes of supernatants over 3 ml were then aliquoted into pre-chilled 1.5ml graduated micro centrifuge tubes (catalogue number 61620; Greiner Bio-One, Frickenhausen, Germany) for refreezing at −20 °C, for later cortisol and DHEA analysis.

b) The three ml neat supernatants stored on ice were then used for OT concentration. In two cases, pre-intervention sample volumes remaining after removal of the 200 µl required for cortisol and DHEA analysis, were less than 3 ml, hence to ensure accurate comparison of both pre-and
post-sample OT concentrations, identical post-intervention supernatant volumes were applied to the columns. This modification will have resulted in total OT concentrations being comparatively reduced in these two participants; however, these concentrations were then re-calculated to a three-ml volume for analysis.

c) Column eluates were evaporated to dryness at room temperature under vacuum using a rotational vacuum concentrator (Christ RVC 2-25 CD Plus; Osterode, Germany; Vacuubrand PC 3002 Vario; Wertheim, Germany), before refreezing at −20 °C for later OT analysis.

4.10.11.6.3.2 Salivary OT enzyme-linked immunosorbent assays (ELISA)

The protocol manual provided by Enzo Life Sciences in the ‘Oxytocin ELISA 96 Well Kit’ (catalogue number ADI-900-153A-0001, Farmingdale, NY, USA), was followed precisely as recommended (Enzo Life Sciences Inc., 2013). Plates were read using a plate reader spectrophotometer (POLARstar Omega; BMG LABTECH, Offenburg, Germany) at 405 nm.

4.10.11.6.4 Salivary cortisol and DHEA enzyme-linked immunosorbent assays

Neat saliva supernatants were thawed on ice prior to the procedure. The protocol manuals provided by Salimetrics in the ‘Salivary Cortisol Enzyme Immunoassay Kit’ (catalogue number 1-3002) and ‘Salivary DHEA Enzyme Immunoassay Kit’ (catalogue number 1-1202); Salimetrics, State College, PA, USA) were followed precisely as recommended (Salimetrics, 2016a), with plates being read using a plate reader spectrophotometer (POLARstar Omega; BMG LABTECH, Offenburg, Germany) at 450 nm. After the procedure, any remaining supernatants were refrozen for possible future use.

4.10.11.6.5 Participant pre- and post- enzyme-linked immunosorbent assays hormonal analysis

POLARstar Omega software was used to calculate participant salivary hormone concentrations from standard curves. Samples were plated in duplicate, and consequently mean sample concentrations were utilised for analysis of pre-and post-intervention biomarker ranges, as well as between group post to pre-
intervention oxytocin and cortisol to DHEA ratios differences. Descriptive statistics analysis was additionally performed to assess overall variation in time of sample collections, as well as average collection times, so as to provide additional detail regarding the possible impacts of diurnal rhythms and pulsatile release on resultant hormonal concentrations.

4.10.11.6.5.1 Analysis of between group post to pre-intervention cortisol: DHEA ratio changes

The calculation of a ratio of cortisol to DHEA concentration is proposed to be a superior method by which to assess the functionality of the HPA axis, as when the two hormones are assessed in reference to each other, they reportedly provide a more accurate indication of allostatic load (Maninger et al., 2009), as a consequence of their interactive and antagonistic nature (Guerry & Hastings, 2011).

Whilst every attempt was made to collect pre- and post-intervention samples at the same time of the day, to ensure that hormones concentration obtained would reflect only the flux within the participant, rather than those added in as a consequence of diurnal rhythm variation, it was not always possible. The potential impacts of within individual sample collection time variation could however be cancelled out by calculating the independent ratios of the two hormones at each of the time points. In this way, the ratio derived from the same sample becomes independent of the effects of time. Comparisons could then be made between the ratios with respect to the post- to pre-ratio differences.

The analysis approach that was considered to be the simplest and least likely to incorporate errors was the generalised linear model, in which changes to the post-intervention cortisol: DHEA ratios were predicted by both the pre-intervention cortisol: DHEA ratios, as well as the randomised group allocation. Utilising this method, mean post-intervention cortisol: DHEA ratios was the dependent variable compared to group allocation as a factor [BY] and the pre-intervention cortisol: DHEA ratios as a covariate [WITH]. Into this model, group allocation, pre-intervention cortisol: DHEA ratios and the intercept were also incorporated.
An adjustment for the presence of a male foetus was also included, as the intrauterine presence of this gender had previously been reported to be associated with higher maternal cortisol concentrations (DiPietro, Costigan, Kivlighan, Chen, & Laudenslager, 2011); although this findings was not replicated in another study (Buss et al., 2012).

Similarly, as both cortisol and DHEA concentrations had been reported to vary as a function of gestational age, whereby cortisol levels increase (Allolio et al., 1990; Buss et al., 2012; DiPietro et al., 2011; Goland, Conwell, Warren, & Wardlaw, 1992; Harville et al., 2007), and DHEA levels decline (Bloch, Daly, & Rubinow, 2003; Goland et al., 1992; Monticone, Auchus, & Rainey, 2012; O’Leary, Boyne, Flett, Beilby, & James, 1991) over time, it was also thought necessary to additionally incorporate an adjustment for the number of days the participants were in the intervention, as some women were unable to complete the treatment regimen within the specified timeframe, and consequently, the gestational age of completion varied. The model was adjusted for the presence of a male foetus as a factor (along with randomised group allocation [BY]), as well as the number of days in the intervention as a covariate (with pre-intervention cortisol: DHEA ratio [WITH]). Into the model, group allocation, pre-intervention cortisol: DHEA ratio, presence of a male foetus, the intercept and the number of days in the intervention were included.

4.10.11.6.5.2 Analysis of between group post to pre-intervention OT changes

Whilst OT release is reportedly pulsatile (Carter, 2014) and not subject to diurnal variation (Blagrove et al., 2012; Kuwabara, Takeda, Mizuno, & Sakamoto, 1987), for consistency, an identical analysis was performed to examine between group post-intervention OT concentration differences, as predicted by those obtained at pre-intervention, as some reports suggest that OT concentrations do increase with gestational age (Kumaresan, Anandarangam, Dianzon, & Vasicka, 1974; Kuwabara et al., 1987; Prevost et al., 2014), whereas others report stable (Feldman, Weller, Zagoory-Sharon, & Levine, 2007) and or bi-directional trends (Levine, Zagoory-Sharon, Feldman, & Weller, 2007).
4.10.1.12 RCT protocol publication and protocol deviations

The RCT protocol was published in ‘Trials’ in 2016 (Ormsby, Smith, Dahlen, Hay, & Lind, 2016), and is provided in full in Appendix W. No deviations from the conduction of the published or registered protocol occurred. A component was however removed from discussion in this document, due to difficulties encountered with the analysis of between group oxytocin receptor density differences (see chapter 6), as well as the requirement for space for stage two of the mixed-methods design.

4.10.2 Stage Two – Qualitative Investigations of the Experiences of Acupuncture Recipients and Participating Midwives in the Pragmatic RCT Evaluating Acupuncture for Antenatal Depression

4.10.2.1 Rationale for qualitative inclusions in the overall research design

The qualitative components employed in the overall research design included 1) in-depth interviews with a subgroup of acupuncture recipients, and 2) focus groups with midwives working in both continuity of care and non-continuity of care models. Qualitative methodology was chosen as the most appropriate methodology to enable the detailed exploration (Bryman, 1984; DiCicco-Bloom & Crabtree, 2006) of participants’ experiences of antenatal mental health management, as well as their views regarding the possible role that acupuncture could provide within the ‘context-specific settings’ (Hoepfl, 1997) of the hospital system. The utilisation of both qualitative methods enabled the examination of both personal experiences, as well as shared perspectives (Tong, Sainsbury, & Craig, 2007), and thus provided depth and detail (DiCicco-Bloom & Crabtree, 2006) otherwise unattainable via quantitative measurements, that was possibly pertinent to both a larger scale trial, as well future related research (Tong et al., 2007).
4.10.2.2 Ethics approval

Ethics approvals for both the in-depth interviews with acupuncture recipients and focus groups with midwives was sought as an amendment to the main RCT approval granted from South Western Sydney Local Health District (SWSLHD, HREC/14/LPOOL/400), and was obtained on November 18th, 2015 (Appendix X). As part of this amendment, the existing PIS and CF provided to potentially eligible pregnant women was modified to incorporate the possibility that if they are randomised to the acupuncture group, they may be asked to be interviewed in relation to their experiences, after completion of the acupuncture sessions. In addition, a PIS (Appendix Y) and CF (Appendix Z) were developed to provide midwives with information regarding the focus group sessions.

4.10.2.3 In-depth interviews with acupuncture recipients - rationale and objectives

In-depth interviews are generally conducted in a one-on-one format and utilised for the purposes of collecting data for theory generation, hypothesis testing, or for the enhancement of understanding via the exploration of perceptions and views in relation to research themes (DiCicco-Bloom & Crabtree, 2006). Interviews may be structured, semi-structured or unstructured, with 5 to 10 questions typically being developed to explore study topics (DiCicco-Bloom & Crabtree, 2006), however additional flexible questioning may be incorporated for the purposes of clarification and or in-depth examination (DiCicco-Bloom & Crabtree, 2006; Tong et al., 2007). Once commenced, the interviewer quickly aims to establish rapport by beginning with a general, non-threatening question, after which the interviewer guides the session via the use of non-leading probes (DiCicco-Bloom & Crabtree, 2006). Honest feedback is encouraged and facilitated by the interviewees being assured of anonymity, and also that they will not be identifiable from their responses.

For this study, in-depth interviews were selected as the most appropriate method of data collection, as they provide a means by which “the complexities and subjective elements of delivery of care and patient experiences of treatment
processes” can be assessed (Broom, 2005, p73); as this was the main purpose of the investigation.

Specifically, the aims were to:

1) Explore women’s experiences of mental health issues and conventional treatments
2) Knowledge of and views of acupuncture
3) Reasons for enrolling in the RCT and experiences of the intervention.

The perspective of acupuncture recipients was sort in order to provide greater understanding of the challenges depressed women face with respect to treatment, as well as detail regarding their experiences of receiving acupuncture for antenatal depression, women randomised to this treatment group only were approached to be interviewed. It was not thought necessary to interview the other treatment arms in relation to the women’s experiences with conventional treatment, or their specific reasons for enrolling in the RCT, as it was considered likely that these would be similar across all groups. Furthermore, the semi-structured questionnaires administered to all participants during stage one had already provided participants’ feedback in relation to individual women’s experiences of randomisation and the intervention. In addition, ‘field notes’ collected for each individual over the course of the RCT, provided additional detail regarding information disclosed to the principal researcher, as well as her observations during the course of the RCT, that could also be incorporated into the overall group assessment.

4.10.2.3.1 Participants and recruitment

Upon obtaining ethics approval, women who had completed the eight-session acupuncture intervention were approached to be interviewed. If any of these participants had previously been enrolled using the original PIS, they were provided with the amended version. Upon agreeing to participate and freely signing the updated consent forms, the women were informed that their details would be passed onto the interviewer, an independent associate researcher Camilla Scanlan (CS1), who made direct contact to organise a suitable time.
Initially eleven women provided the principal researcher with verbal consent to be interviewed, however two were later unable to find a suitable time, and one other became uncontactable, and consequently eight interviews were successfully completed. Recruitment was terminated after this time, as preliminary analysis of transcripts had revealed that after the fifth interview, no additional concepts or themes had emerged, hence saturation was evident (Bradley, Curry, & Devers, 2007).

4.10.2.3.2 In-depth interview methodology

The associate researcher, CS1, was selected to perform the interviews due to her expertise, as well as independence from the acupuncture RCT. A one–to–one format was utilised, using the open-ended questioning prompts purposively developed in Figure 4.4. As recommended for this method, ‘leading’ questions were avoided (Gill, Stewart, Treasure, & Chadwick, 2008), however further exploration of areas of evolving interest did occur (Tong et al., 2007). All of the interviews were conducted by telephone, and were under one hour in length. Interviews were converted to transcripts by Pacific Solutions transcription services. Participant names were replaced with pseudonyms and all identifying data was removed prior to transcripts being made available to the principal researcher for analysis. Recordings and transcripts were stored in locked filing cabinets at WSU.
Figure 4.4 In-Depth Interview Questioning Prompts for Women who Participated in the RCT

A. How did you come to be involved in the study? What were your reasons for signing up?

B. Can you describe for me your first awareness of experiencing depression, either in this pregnancy or in the past?

C. What methods are you currently using if any to manage your depression? What have you used in the past and what have been your experiences with these methods?

D. Prior to this study, what had been your previous knowledge of acupuncture? Had you had it before as a treatment? If so, can you explain to me what you went for and what your experiences were when you went? Had you ever thought about using it for mental health concerns? If so, could you please tell me about your considerations?

E. When you were randomised to receive acupuncture in the study, what were your thoughts?

F. What were your experiences of receiving the acupuncture?

G. Did your partner, friends or family notice any differences in the way you were after the sessions? Can you describe what these were?

H. What are your thoughts about whether any improvements you experienced were just because you had someone to talk to and or an hour to lie down?

I. For how long after each session did you feel these perceived benefits lasted?

J. Was this the same each week or did you notice differences over time?

K. Would you consider having it again or recommending it to your friends? If so, could you please explain to me your reasoning?
4.10.2.4 Midwives focus groups – rationale and objectives

Focus groups utilise a semi-structured discussion format that encourages the voicing of both individual responses, as well as dialogue between participants (Tong et al., 2007), with the ideal number of participants being considered to be between four and eight (Kitzinger, 1995). As a result, both individual and shared perspectives can be ascertained (Tong et al., 2007), along with group attitudes and dominant cultural norms (Kitzinger, 1995). A disadvantage of this method however is the possible discouragement of dissent amongst majority views, although, it can also be equally argued that bolder members of the group may ‘break the ice’ in relation to sensitive matters and encourage comments from more reticent attendees. Either way, the main aim is to provide a supportive environment so that views, even if they do deviate from mainstream culture, can be safely expressed (Kitzinger, 1995).

In this study, the individual and shared perspectives of midwives working in the wards in which the RCT was run were sought in order to gain valuable detail regarding the issues they feel women experiencing depression during pregnancy face with conventional treatments, as well as the possible role acupuncture could provide as an additional therapeutic option for antenatal depression. Views were separately sought from midwives working in continuity and non-continuity models of care, in the event that different perspectives were provided.

Specifically, the aims were to ascertain:

1) The views of midwives in regard to acupuncture in general, as well as for the treatment of depression during pregnancy.

2) Midwives overall observations of the RCT, as well as specific reflections of women who had received the acupuncture intervention.

3) Midwives views in regard to the possible incorporation of acupuncture into mainstream maternity care for depression during the perinatal period.
4.10.2.4.1 Participants and recruitment

Separate focus groups with midwives from both the continuity and non-continuity of care models took place during standard meeting times, so as to minimise impacts to staff. The antenatal service manager emailed invitations to all midwives to alert them to the sessions (Appendix AA), with invitation posters also being displayed on staff room notice boards. Prior to the commencement of the scheduled sessions, attending midwives were provided with a participant information sheet to read, in which the procedures were clearly outlined, including that the sessions were to be digitally recorded, transcribed verbatim and de-identified, so that the principal researcher would not be able to trace back individual responses to their origin. Prior to commencement of the sessions, signed consent forms were freely obtained from all present.

4.10.2.4.2 Focus groups - methodology

Focus groups were conducted by associate researcher Hannah Dahlen (HD). As a practising midwife with extensive knowledge of the discipline, HD was perfectly positioned to facilitate focus group discussions with midwives, whilst also remaining independent of the acupuncture intervention under examination. The format employed was that of facilitated semi-structured group discussion, prompted by the flexible open-ended questions provided in Figure 4.5, that additionally allowed for further exploration or clarification of individual and or shared perspectives as required (Tong et al., 2007). Prior to commencement, the midwives were re-assured of anonymity, so as to encourage frank discussion. Digital recordings of the focus group sessions were transcribed verbatim by Pacific Solutions transcription service. Recordings and transcripts were stored in locked filing cabinets at WSU.
Figure 4.5 Midwives Focus Group Questioning Prompts

1. What are your feelings or understandings about the study?

2. What are your feelings regarding acupuncture?

3. How do you think depressed pregnant women view acupuncture?

4. What have been your observations of the women receiving acupuncture in the study? Have you received from them any feedback?

5. What are your views in regard to making acupuncture accessible to depressed pregnant women?

6. What are your thoughts about the feasibility of introducing acupuncture into mainstream antenatal care?
4.10.2.5 Analysis and data interpretation of in-depth interview and focus group transcripts

Data was analysed using thematic analysis techniques, (Boyatzis, 1998; Braun & Clarke, 2006), which in the first instance consisted of the principal researcher and associate investigator (HD) independently searching across transcripts for repeated patterns of meaning and key concepts (Braun & Clarke, 2006). Once identified, concepts were coded and collated into themes and subthemes, until no further development of themes was judged to be possible (Bradley et al., 2007). These were then reviewed in relation to the research questions and refined until “the overall story the analysis tells” emerged (Braun & Clarke, 2006, p87). Coded structures were then compared for the purposes of verification and discrepancy resolution, prior to the final coded format being decided upon (Bradley et al., 2007). Once finalised, a further independent assessment was conducted by principal supervisor Caroline Smith (CS2), to check the validity of findings in reference to interview transcripts. A ‘general inductive approach’ was utilised for analysis, as this method enables “research findings to emerge from the frequent, dominant, or significant themes inherent in raw data” (Thomas, 2006, p238), that although considered within the context of the study objectives, “arise directly from the analysis of the raw data, not from a priori expectations or models” (Thomas, 2006, p239). The qualitative interpretivist paradigm was also employed, as this method additionally enables the uncovering of meaning through reflections stimulated by the interactive dialogue between researchers and participants (Ponterotto, 2005).

4.10.2.5.1 Reflexivity and the ‘trustworthiness’ of findings

A common criticism of qualitative research is the notion that findings are “merely a collection of personal opinions subject to researcher bias” (Noble & Smith, 2015, p34). One such source of possible bias is a consequence of the researcher occupying the status of an ‘insider’ during the research investigation, whereby there is a sharing of a “characteristic, role, or experience under study with the participants” (Dwyer & Buckle, 2009, p55). Arguments in relation to this positioning however also suggest that whilst the objectivity of the
researcher may be questioned, sharing of commonalities may also enable
greater access to the breadth and depth of participants’ experiences, as a
consequence of being perceived to be ‘one of them’ (Dwyer & Buckle, 2009).
Similarly, it has additionally been argued that the status of ‘outsider’ is also not
without drawbacks, as while greater ‘objectivity’ may be afforded from this
positioning, researchers may be denied access to deeply personal experiences of
participants, due to participants’ perceptions that these are beyond the
comprehension of the researcher. Dwyer and Buckle (2009) more realistically
argue that researchers can occupy both insider and outsider status during the
research process, as according to Rose (1985) “There is no neutrality. There is
only greater or less awareness of one’s biases” (Dwyer & Buckle, 2009, p55).
In consideration of these arguments however, strategies were incorporated to
strengthen the ‘trustworthiness’ of findings (Noble & Smith, 2015). Firstly, a
reflexive “internal dialogue and critical self-evaluation” (Berger, 2015, p220)
process was incorporated by the principle researcher, to continually monitor
her positionality, as well as how her biases and beliefs may have impacted upon
the research (Berger, 2015) as a consequence of: 1) sharing the common
experiences of being a mother and an acupuncture recipient with some of the
study participants, 2) having pre-existing biases and beliefs about acupuncture
effectiveness and 3) interacting with acupuncture recipients over the period of
the RCT invariably influenced “the direction of the research from start to finish”
(Couture, 2012, p91). Secondly, bracketing was employed to ‘set aside’ these
factors, as much as possible, so that the data could be viewed away from these
influences (Fischer, 2009). Lastly, the potential inclusion of other biases by the
principal researcher was also monitored during data analysis, interpretation
and reporting stages, by the supervisory panel.
4.12 Summary

In this chapter the mixed-methods methodologies employed for the evaluation of acupuncture as an adjunct therapy for antenatal depression were provided, along with the rationale for the choice of these methods. The quantitative findings from stage one for the published and purposively designed questionnaires are reported in chapter five, and biomarkers analysis in chapter six. The stage two thematic findings from in-depth interviews with acupuncture recipients and focus groups with midwives are provided in chapter seven. In accordance with the chosen strategy of enquiry of complementarity, focus group findings were integrated with the emergent themes obtained from the in-depth interview data, so as to not only to provide 'elaboration, enhancement, illustration or clarification' (Greene et al., 1989) of the findings from the in-depth interviews with the perspectives provided by the midwives, but also to ensure the overall qualitative findings are presented as a cohesive 'whole'. Similarly, this pragmatic approach (Creswell, 2003) of complementarity was also utilised to integrate the findings generated from both stage one and two of this mixed-methods research design (Johnson & Onwuegbuzie, 2004), and this collective assessment is provided in chapter eight.
Chapter 5

Findings from Stage One – Results from the Randomised Controlled Trial
5.1 Introduction

In this chapter, the outcomes of the RCT with respect to screening, enrolment, randomisation and study attrition are provided, along with group allocation analysis of baseline demographics, pre- and post-intervention mood and quality of life score changes and birth and six-week postnatal findings.

5.2 Study Feasibility, Baseline Demographics, Mood and Quality of Life

5.2.1 Summary of Screening, Recruitment, Randomisation, Study Attrition and Adverse Events

In accordance with the recommendations of the revised CONSORT statement (Moher, Schulz, & Altman, 2005, p40), a flow diagram that details the “passage of participants through an RCT”, is provided (Figure 5.1), so as to enable both transparent and standardised reporting.

Additional detail regarding the RCT process is as follows. Recruitment was commenced on February 9, 2015 and terminated on August 6, 2016. The two predominant reasons for the exclusion of the majority of the 374 women screened were ‘not meeting inclusion criteria’ (141), and ‘not displaying interest in participation’ (107). The most successful recruitment strategy utilised was the mental health team referral list provided by midwives, with approximately only three other women being recruited from the study flyer / poster. After the randomisation of the 57 recruits, 19 women were equally distributed to one of the three groups.

Eleven women withdrew before completing the entire treatment regime, representing an overall percentage loss of 19.3%, which was less than the 30% incorporated into the power calculation. Only one woman withdrew from the treatment as usual group, after the fifth session, due to not being able to manage the commitment in addition to the extra appointments required as a consequence of developing gestational diabetes.
Figure 5.1 Randomised Controlled Trial Enrolment Flow Diagram

Excluded (n=317)
- Not meeting inclusion criteria (n=141)
- No response / not interested / declined with no reason provided (n=107)
- Dislike of study / randomisation (n=6)
- Wanted antenatal acupuncture (n=2)
- Needle phobic (n=7)
- Too busy / ill children / child minding issues / no transport / moved (n=46)
- Unwell / severe hyperemesis gravidarum (n=5).

Assessed for eligibility (n=374)

Randomised (n=57)

Allocation

Treatment as usual
- Received allocated intervention (n=19)

Depression specific acupuncture
- Received allocated intervention (n=19)

Progressive Muscle Relaxation
- Received allocated intervention (n=19)

Follow up

Treatment as usual
- Completed intervention (n=18)
- Discontinued intervention (n=1) after session 5/8, too busy to continue

Depression specific acupuncture
- Completed intervention (n=17)
- Discontinued intervention (n=2): after session 1/8, GP advice that acupuncture is unsafe in pregnancy (n=1); after session 2/8, child minding difficulties (n=1)

Progressive Muscle Relaxation
- Completed intervention (n=11)
- Discontinued intervention (n=8): after session 1/8, dislike of guided relaxation (n=1); after session 1/8 and 2/8, too busy and child minding difficulties (n=2); after session 3/8, too busy and didn’t find effective (n=1); after session 5/8, moved out of the area (n=1); after session 7/8, birthed pre-term (n=1); after session 1/8 and 5/8, no reason provided (n=2)

Intention to treat (ITT) / per-protocol (PP) analysis

Treatment as usual
- ITT - analysed (n=19), excluded from analysis (n=0)
- PP - analysed (n=18), excluded from analysis (n=0)

Depression specific acupuncture
- ITT – analysed (n=19), excluded from analysis (n=0)
- PP - analysed (n=17), excluded from 6 wks postnatal analysis only (n=2): forms not returned

Progressive Muscle Relaxation
- ITT – analysed (n=19), excluded from analysis (n=0)
- PP - analysed (n=11), excluded from analysis (n=0), postnatal follow-up provided by 1 non-completer (n=12)
Two women withdrew from the acupuncture group. One after the first session after receiving advice from her general practitioner that acupuncture was unsafe, as it induces labour. Whilst attempts were made to reassure this participant that acupuncture points thought to facilitate cervical ripening in the later stages of pregnancy, had been omitted from the protocol, these were unsuccessful. The other participant withdrew after the second session, due to no longer having access to free child-minding facilities.

A much higher discontinuation rate was noticeable in the PMR group, with eight women not completing the intervention. Three of these participants withdrew after the first session. One stated a dislike of guided relaxation as being the reason for withdrawal. Another indicated being too busy, as well as having difficulty accessing suitable child-minding options, and in the case of the third, no reason was provided. Another participant withdrew after the second session, also stating being too busy, as well as having difficulty with child minding options. An additional withdrawal occurred after session three, with 'being too busy', as well as not finding the therapy effective, being the reasons provided. Two participants also withdrew after session five, with one doing so due to moving out of the area, whereas in the case of the other, no reason was provided. The final non-completer was unable to continue, due to birthing prior to the administration of her final session in week eight.

Follow-up data was requested from all non-completers, however only two women in the PMR group provided additional forms, at the week four timepoint.

No adverse events resulting from the acupuncture intervention were reported by participants or co-managing midwives. In addition, the principal researcher did not observe any bruising or bleeding at acupuncture point locations. It may be that the intentionally incorporated strategies to avoid strong needling techniques, such as not searching for ‘de-qi’ sensations, shallow insertions where possible, and fine gauge needles, may facilitated this outcome.

5.2.2 Group Characteristics at Baseline

There were no group differences observed in any characteristics collected at baseline (Tables 5.1- 5.6).
5.2.2.1 Baseline demographics

Baseline demographics are provided (Table 5.1). The mean age of participants at trial entry was 28.76 years. Most of the women were born in Australia (75.4%), with six of these participants also identifying as Aboriginal or Torres Strait Islander. Of the fourteen women born overseas, countries of origin were: New Zealand (3), Africa (3), Bangladesh/India (2), Eastern Europe (2), America (2), the Middle East (1) and South East Asia (1). Forty-seven women indicated being married or in de facto relationships (82.5%), and the remaining ten (17.5%), single or partnered, but not living with their partner.
### Table 5.1 Baseline Demographic Characteristics of Trial Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at trial entry</td>
<td>27.37 ± 3.64</td>
<td>28.95 ± 6.75</td>
<td>29.95 ± 4.82</td>
<td>57</td>
<td>0.317</td>
</tr>
<tr>
<td>Australian born</td>
<td>13 (68.4%)</td>
<td>15 (78.9%)</td>
<td>15 (78.9%)</td>
<td>43</td>
<td>0.685</td>
</tr>
<tr>
<td>Indigenous or TSI Australian born</td>
<td>3 (15.8%)</td>
<td>2 (10.5%)</td>
<td>1 (5.3%)</td>
<td>6</td>
<td>0.572</td>
</tr>
<tr>
<td>Relationship status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or de facto</td>
<td>15 (78.9%)</td>
<td>15 (78.9%)</td>
<td>17 (89.5%)</td>
<td>47</td>
<td>0.616</td>
</tr>
<tr>
<td>Single or partnered &amp; not living together</td>
<td>4 (21.1%)</td>
<td>4 (21.1%)</td>
<td>2 (10.5%)</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Highest level of education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High School</td>
<td>4 (21.1%)</td>
<td>4 (21.1%)</td>
<td>8 (42.1%)</td>
<td>16</td>
<td>0.432</td>
</tr>
<tr>
<td>Vocational or further college education</td>
<td>12 (63.2%)</td>
<td>10 (52.6%)</td>
<td>7 (36.8%)</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Higher Education</td>
<td>3 (15.8%)</td>
<td>5 (26.3%)</td>
<td>4 (21.1%)</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working at trial entry</td>
<td>9 (47.4%)</td>
<td>12 (63.2%)</td>
<td>7 (36.8%)</td>
<td>28</td>
<td>0.263</td>
</tr>
<tr>
<td>Working full-time</td>
<td>4 (21.1%)</td>
<td>7 (36.8%)</td>
<td>5 (26.3%)</td>
<td>16</td>
<td>0.450</td>
</tr>
</tbody>
</table>

1. Alpha values are set at 0.05;
2. Data are mean ± (SD) or (%) of cases within groups;
3. TSI – Torres Strait Islander
Exploration of the levels of education attained amongst the cohort identified that the majority (50.9%) of women had completed vocational or further education college qualifications, with an additional 21%, also specifying having completed higher education degrees.

Just under half (49.1%) of the participants indicated being employed at trial-entry, of which 57% were working on a full-time basis. The majority of women fulfilled administration and retail related roles.

\textbf{5.2.2.2 Maternal characteristics}

Maternal characteristics are provided (Table 5.2). Forty-three of the participants were multiparous, of which 20 had one child, 17 had two, two had three, one had four, two had five and one had eight children. The remaining 14 women (24.6%) were to become mothers for the first time.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation (n=19 per group)</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primiparous</td>
<td>6 (31.6%)</td>
<td>6 (31.6%)</td>
<td>2 (10.5%)</td>
<td>14</td>
<td>0.220</td>
</tr>
<tr>
<td>Multiparous</td>
<td>13 (68.4%)</td>
<td>13 (68.4%)</td>
<td>17 (89.5%)</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Mean number of birthed children</td>
<td>2.08 ± 1.26</td>
<td>2.00 ± 1.8</td>
<td>1.71 ± 1.05</td>
<td>0.743</td>
<td></td>
</tr>
<tr>
<td>Currently using CM</td>
<td>15 (78.9%)</td>
<td>17 (89.5%)</td>
<td>16 (84.2%)</td>
<td>48</td>
<td>0.673</td>
</tr>
<tr>
<td>Current pregnancy IVF/assisted reproductive technology assisted</td>
<td>0 (0.0%)</td>
<td>2 (10.5%)</td>
<td>0 (0.0%)</td>
<td>2</td>
<td>0.126</td>
</tr>
</tbody>
</table>

**Sex of unborn**

<table>
<thead>
<tr>
<th>Known</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 (63.2%)</td>
<td>7 (36.8%)</td>
<td>5 (26.3%)</td>
</tr>
<tr>
<td>17 (89.5%)</td>
<td>9 (47.4%)</td>
<td>8 (42.1%)</td>
</tr>
<tr>
<td>16 (84.2%)</td>
<td>7 (36.8%)</td>
<td>9 (47.4%)</td>
</tr>
<tr>
<td>45</td>
<td>23</td>
<td>22</td>
</tr>
</tbody>
</table>

**Maternity leave plans**

| Intend to take leave | 9 (47.4%) | 10 (52.6%) | 7 (36.8%) | 26 | 0.211 |

**Time planned (months)**

| 6 months or less | 5 (55.6%) | 5 (50.0%) | 1 (14.3%) | 11 | 0.407 |
| Over 6 months    | 3 (33.3%) | 3 (30.0%) | 5 (71.4%) | 11 |
| Unsure           | 1 (11.1%) | 2 (20.0%) | 1 (14.3%) | 4  |

**Breastfeeding history / intention**

| Previous child received breastmilk at 6 weeks postpartum (exclusive / mixed) | 9 (47.4%) | 7 (28.0%) | 9 (47.4%) | 25 | 0.414 |
| Planning to breast feed | 16 (84.2%) | 19 (100.0%) | 19 (100.0%) | 54 | 0.176 |

1 Alpha values are set at p=0.05;
2 Data are mean ± (SD) or (%) of cases within groups;
3 The sexes of the two sets of twins (monozygotic females and dizygotic, male and female) were known at baseline, however were not able to be included in the group analysis, due to database limitations preventing the inclusion of the sex of the second twin. Consequently, the additional male in the acupuncture group, and the second female in treatment as usual, is not included in this analysis.
A large proportion of the women (84%) indicated having utilised CM and therapies during this pregnancy, however the vast majority of this occurrence was attributed to the use of pregnancy multivitamin supplementation. Other nutraceuticals consumed by a minority of the women included vitamin D, and iron. Twelve women (21%) had accessed physiotherapy, chiropractic / osteopathy, acupuncture, yoga or massage. Only one woman in the PMR group had utilised acupuncture.

With respect to IVF / assisted reproductive technology (ART) use, two women in the acupuncture group (10.5%) reported their current pregnancies had been supported in this way. Of these women, one had previously conceived one other pregnancy using IVF / ART, whereas the other, had conceived two of her previous pregnancies using these technologies.

Forty-five participants (79%) reported knowing the sex of their unborn child(ren). Amongst these participants, two sets of twins were being carried, a dizygotic set and a monozygotic set of females. The twin boy in the acupuncture group, and the additional girl in treatment as usual were not included in the data analysis provided in Table 5.2.

At the time of trial entry, the majority of the 28 working women (93%) had plans regarding maternity leave. With respect to the amount of leave intended, 15.4% stated being unsure of timeframes, 42.3% indicated they would be taking less than 6 months, and the remaining 42.3%, over 6 months.

A high proportion of the cohort also indicated their intention to breastfeed their current unborn child (94.7%). Breastfeeding outcomes of the most previously born child of multiparous women were additionally assessed, of which it was found that twenty-five (58.1%) of these women were still breastfeeding their baby in some capacity at six-weeks postpartum.

5.2.2.3 Previous history of depression

Data are provided regarding participants’ personal and family histories of experiencing depressive episodes (Table 5.3). It was of interest to note that the majority of participants (75.4%) indicated other family members also suffered
from mental health concerns. This percentage may have however been even higher, as one participant in the treatment as usual group had very little knowledge of her family of origin. Out of the entire cohort, only two women (3.5%) had no previous history of depression prior to their current pregnancy. In both cases, the women were multiparous, with one living child.

_Depression experienced outside of the perinatal period_

A large proportion of the women (87.7%) reported experiencing adolescent onsets for their index episodes, with the mean age of occurrence being $17.22 \pm 5.46$.

When queried regarding the number of non-perinatal related depressive episodes experienced from the time of first onset, several women indicated having difficulty providing estimates, as they felt they had suffered either one long continuous but fluctuating episode or many episodes of variable and often short length. Nonetheless estimates were provided from which the mean number was seen to range from $7.65 \pm 8.21$ in PMR, to $10.88 \pm 18.58$ in the acupuncture group. The majority of women (44%) indicated experiencing episode lengths of greater than six months.

With respect to the severity of episodes, the largest proportion of women (82%) reported phases of mixed intensity. Questioning regarding previous management techniques revealed that five women (10%) had never utilised any treatment approach, six (12%) utilised psychotherapy / counselling or antidepressants as monotherapies and 19 (38%), combined antidepressants with psychotherapy / counselling. Eighteen women (36%) additionally incorporated complementary methods with conventional approaches, such as: meditation / mindfulness, exercise, lifestyle modifications and confiding in friends & family.
### Table 5.3 Previous History of Depression Among Trial Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Awareness of family history of mental health issues</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=19 per group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 (78.9%)</td>
<td>14 (73.7%)</td>
<td>14 (73.7%)</td>
<td>43</td>
<td>0.699</td>
<td></td>
</tr>
<tr>
<td><strong>Non-perinatal period experiences of depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number experiencing non-perinatal episodes</td>
<td>17 (89.5%)</td>
<td>17 (89.5%)</td>
<td>16 (84.2%)</td>
<td>50</td>
<td>0.850</td>
</tr>
<tr>
<td>2^Index episode age of onset</td>
<td>16.76 ± 3.36</td>
<td>18.65 ± 6.79</td>
<td>16.19 ± 5.68</td>
<td>50</td>
<td>0.404</td>
</tr>
<tr>
<td>Approximate no of non-perinatal depressive episodes</td>
<td>7.65 ± 8.21</td>
<td>10.88 ± 18.58</td>
<td>9.19 ± 9.48</td>
<td>50</td>
<td>0.770</td>
</tr>
<tr>
<td><strong>Average episode(s) length</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 6 months</td>
<td>7 (41.2%)</td>
<td>7 (41.2%)</td>
<td>6 (37.5%)</td>
<td>20</td>
<td>0.983</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>8 (47.1%)</td>
<td>7 (41.2%)</td>
<td>7 (43.8%)</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Varied or continuous but fluctuating</td>
<td>2 (11.8%)</td>
<td>3 (17.6%)</td>
<td>3 (18.8%)</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td><strong>Description of depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild / Moderate</td>
<td>0 (0.0%)</td>
<td>2 (11.8%)</td>
<td>3 (18.8%)</td>
<td>5</td>
<td>0.161</td>
</tr>
<tr>
<td>Severe</td>
<td>3 (17.6%)</td>
<td>0 (0.0%)</td>
<td>1 (6.3%)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>14 (82.4%)</td>
<td>15 (88.2%)</td>
<td>12 (75.0%)</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No treatment</td>
<td>1 (5.3%)</td>
<td>0 (0.0%)</td>
<td>4 (21.1%)</td>
<td>5</td>
<td>0.058</td>
</tr>
<tr>
<td>Psychotherapy / counselling</td>
<td>2 (12.5%)</td>
<td>0 (0.0%)</td>
<td>1 (8.3%)</td>
<td>3</td>
<td>0.708</td>
</tr>
<tr>
<td>Anti-depressants</td>
<td>0 (0.0%)</td>
<td>2 (11.8%)</td>
<td>1 (8.3%)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Psychotherapy / anti-depressants</td>
<td>8 (50.0%)</td>
<td>6 (35.3%)</td>
<td>5 (41.7%)</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Other^3</td>
<td>1 (6.3%)</td>
<td>1 (5.9%)</td>
<td>0 (0.0%)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Other combined with 1 or more conventional approaches</td>
<td>5 (31.1%)</td>
<td>8 (47.1%)</td>
<td>5 (41.7%)</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

1. p value
<table>
<thead>
<tr>
<th>Previously experienced antenatal depression (AND)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number experiencing AND episodes</td>
</tr>
<tr>
<td>9 (47.4%)</td>
</tr>
<tr>
<td>9 (47.4%)</td>
</tr>
<tr>
<td>11 (57.9%)</td>
</tr>
<tr>
<td>29</td>
</tr>
<tr>
<td>0.523</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average length of episode(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 months or under</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>5 (45.5%)</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>0.076</td>
</tr>
<tr>
<td>More than 4 months</td>
</tr>
<tr>
<td>6 (66.7%)</td>
</tr>
<tr>
<td>6 (66.7%)</td>
</tr>
<tr>
<td>6 (54.5%)</td>
</tr>
<tr>
<td>18</td>
</tr>
<tr>
<td>Unspecified, unsure or varied</td>
</tr>
<tr>
<td>3 (33.3%)</td>
</tr>
<tr>
<td>1 (11.1%)</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild / Moderate</td>
</tr>
<tr>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>3 (33.3%)</td>
</tr>
<tr>
<td>3 (27.3%)</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>0.716</td>
</tr>
<tr>
<td>Severe</td>
</tr>
<tr>
<td>3 (33.3%)</td>
</tr>
<tr>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>1 (9.1%)</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>Mixed</td>
</tr>
<tr>
<td>4 (44.4%)</td>
</tr>
<tr>
<td>4 (44.4%)</td>
</tr>
<tr>
<td>7 (63.6%)</td>
</tr>
<tr>
<td>15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>No treatment</td>
</tr>
<tr>
<td>1 (5.3%)</td>
</tr>
<tr>
<td>4 (21.1%)</td>
</tr>
<tr>
<td>3 (15.8%)</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>0.436</td>
</tr>
<tr>
<td>Psychotherapy / counselling</td>
</tr>
<tr>
<td>3 (37.5%)</td>
</tr>
<tr>
<td>1 (20.0%)</td>
</tr>
<tr>
<td>2 (10.5%)</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>0.351</td>
</tr>
<tr>
<td>Anti-depressants</td>
</tr>
<tr>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>Psychotherapy / anti-depressants</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>3 (37.5%)</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>1 (20.0%)</td>
</tr>
<tr>
<td>1 (12.5%)</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>Other combined with 1 or more conventional approaches</td>
</tr>
<tr>
<td>4 (50.0%)</td>
</tr>
<tr>
<td>3 (60.0%)</td>
</tr>
<tr>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previously experienced postnatal depression (PND)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number experiencing PND episodes</td>
</tr>
<tr>
<td>12 (63.2%)</td>
</tr>
<tr>
<td>8 (42.1%)</td>
</tr>
<tr>
<td>12 (63.2%)</td>
</tr>
<tr>
<td>32</td>
</tr>
<tr>
<td>0.536</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of PND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild /Moderate</td>
</tr>
<tr>
<td>3 (25.0%)</td>
</tr>
<tr>
<td>3 (37.5%)</td>
</tr>
<tr>
<td>5 (41.7%)</td>
</tr>
<tr>
<td>11</td>
</tr>
<tr>
<td>0.141</td>
</tr>
<tr>
<td>Severe</td>
</tr>
<tr>
<td>1 (8.3%)</td>
</tr>
<tr>
<td>2 (25.0%)</td>
</tr>
<tr>
<td>5 (41.7%)</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>Mixed</td>
</tr>
<tr>
<td>8 (66.7%)</td>
</tr>
<tr>
<td>3 (37.5%)</td>
</tr>
<tr>
<td>2 (16.7%)</td>
</tr>
<tr>
<td>13</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>No treatment</td>
</tr>
<tr>
<td>1 (5.3%)</td>
</tr>
<tr>
<td>3 (15.8%)</td>
</tr>
<tr>
<td>1 (5.3%)</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>0.152</td>
</tr>
<tr>
<td>Psychotherapy / counselling</td>
</tr>
<tr>
<td>1 (9.1%)</td>
</tr>
<tr>
<td>1 (20.0%)</td>
</tr>
<tr>
<td>2 (18.2%)</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>0.427</td>
</tr>
<tr>
<td>Method</td>
</tr>
<tr>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Anti-depressants</td>
</tr>
<tr>
<td>Psychotherapy / anti-depressants</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Other combined with 1 or more conventional approaches</td>
</tr>
</tbody>
</table>

1 Alpha values are set at p=0.05;
2 Data are mean ± (SD) or (%) of cases within groups;
3 Other - meditation / mindfulness, exercise, lifestyle modifications, confiding in friends & family; either with or without the addition of conventional management approaches.
**Depression experienced during pregnancy**

Over half of the cohort (51%) had previously experienced AND. Some of these affected women were primiparous, with pregnancies not resulting in live births. With respect to the length of the episodes experienced, the majority of women (62.1%) reported durations lasting longer than four months. As was also seen with non-perinatally experienced depression, most (51.7%) suffered episodes of mixed severity. Choices of therapeutic approach for management were similar, however it was noted that proportionally more women did not seek any treatment (27.6%); less utilised antidepressants either as monotherapies (3.4%) or combined with psychotherapy/counselling (10.3%); rates of combined conventional approaches with complementary therapies was similar (31.0%); and some exclusively chose complementary approaches (10.3%). It is possible that some women had experienced dissatisfaction with conventional approaches since the time of first onset, as well as safety concerns regarding antidepressant use during pregnancy.

**Depression experienced during the postnatal period**

The incidence of previously experienced PND was also high, with 32 women (74.4%) being affected. Of these, 21 reported experiencing one episode, whereas the remaining 11 indicated having had more than one experience. As was the case with both non-perinatal and AND, the majority of women reported episodes of mixed severity (40.6%). Managements strategies employed were again similar to those previously discussed. What was interesting to note was that rates of antidepressant usage, either as a monotherapy (21.9%), or combined with psychotherapy/counselling (21.9%), had proportionally increased when compared to pregnancy. This may reflect less safety concerns, especially if women also chose not to breast feed. Rates of usage were however still proportionally lower than seen in the non-perinatal period.
5.2.2.4 Current antenatal depressive episode

Data collected in relation to the current antenatal depressive episode is provided (Table 5.4). It was notable that there was a sharp increase in the proportion of women indicating risk of self-harm from 7 (12.3%) at the time of the first antenatal appointment, to 25 (43.9%), at trial entry. A number of women confessed to the principal researcher that they had been reluctant to disclose to midwives the extent of their difficulties, for fear of losing custody of their children. Consequently, a proportion of the increase seen, could be attributed to this factor alone.

Management for mental health concerns was examined at both time points. At the time of the first antenatal appointment, 13 women (22.8%) were medicated. At the time of trial entry, a slight increase in the number of women utilising medication was observed (26.3%), with one women in acupuncture and one in treatment as usual commencing pharmacotherapy. The increase may have occurred as a consequence of mental health team referral. The majority (86.7%) of medicated women were taking drugs of only one class, which was either a serotonin reuptake inhibitor (SSRIs, 3) or selective serotonin and norepinephrine reuptake inhibitor (SSNRIs, 8). Two women were taking combined drug therapies, consisting of an SSRI with an antipsychotic, and a SSNRI combined with an anticonvulsive.

Other than medication, midwives reported seven women (12.3%) were accessing psychotherapy / counselling services as monotherapies, and two other women (3.5%), were ‘self-treating’ or utilising social services. By the time of trial entry, two additional women utilised ‘other’ strategies such as naturopathy / herbal medicine, and yoga and meditation.
Table 5.4 Characteristics of the Current Antenatal Depressive Episode Experienced by Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Midwife screening</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2Edinburgh depression scale score (EPDS)</td>
<td>12.63 ± 4.90</td>
<td>14.32 ± 5.00</td>
<td>13.94 ± 3.92</td>
<td>57</td>
<td>0.546</td>
</tr>
<tr>
<td>Gestation age of screening EPDS</td>
<td>16.74 ± 3.36</td>
<td>17.7 ± 2.09</td>
<td>15.90 ± 3.16</td>
<td>57</td>
<td>0.175</td>
</tr>
<tr>
<td>Referral to mental health team</td>
<td>17 (89.5%)</td>
<td>16 (84.2%)</td>
<td>19 (100.0%)</td>
<td>52</td>
<td>0.216</td>
</tr>
<tr>
<td><strong>Risk of self-harm</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At midwife screening</td>
<td>2 (10.5%)</td>
<td>3 (15.8%)</td>
<td>2 (10.5%)</td>
<td>7</td>
<td>0.850</td>
</tr>
<tr>
<td>Trial enrolment</td>
<td>10 (52.6%)</td>
<td>7 (36.8%)</td>
<td>8 (42.1%)</td>
<td>25</td>
<td>0.607</td>
</tr>
<tr>
<td><strong>Management at midwife booking</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychotherapy / counselling</td>
<td>2 (10.5%)</td>
<td>3 (15.8%)</td>
<td>2 (10.5%)</td>
<td>7</td>
<td>0.850</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>3 (16.7%)</td>
<td>5 (26.3%)</td>
<td>5 (25.0%)</td>
<td>13</td>
<td>0.751</td>
</tr>
<tr>
<td>Other</td>
<td>2 (10.5%)</td>
<td>0 (0.00%)</td>
<td>0 (0.00%)</td>
<td>2</td>
<td>0.106</td>
</tr>
<tr>
<td><strong>Management at trial entry (gestation 24)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antidepressants</td>
<td>4 (21.1%)</td>
<td>6 (31.6%)</td>
<td>5 (26.3%)</td>
<td>15</td>
<td>0.762</td>
</tr>
<tr>
<td>Other</td>
<td>1 (5.3%)</td>
<td>1 (5.3%)</td>
<td>2 (10.5%)</td>
<td>4</td>
<td>0.764</td>
</tr>
</tbody>
</table>

1Alpha values are set at p=0.05;  
2 Data are mean ± (SD) or (%) of cases within groups;  
3Antidepressants include other medications prescribed for mental health concerns such as antipsychotic and anticonvulsants;  
4Other - two participants in the PMR group indicated accessing social services and ‘self-treating’;  
5Participants indicated that up until enrolling in the study they had utilised naturopathy & herbal medicine, meditation/relaxation techniques and yoga for mental health concerns.
5.2.2.5 Risk factors for the development of mental health disorders

Examination of risk factors for the development of mental health concerns is provided (Table 5.5). At trial commencement, the majority of participants reported having someone to confide in (73.7%), as well as adequate financial support (68.4%). Less than half however felt emotionally supported (49.1%). Further details provided in this regard revealed that whilst some of these women felt their partners did not understand the complexity of their difficulties, other family members or friends were sometimes able to fulfil this role. A smaller proportion (10.5%) felt that it was only on rare occasions that they had someone to turn to, and in addition, a further 15.8% never felt they had support.
Table 5.5 Presence of Known Risk Factors for Mental Health Disturbance Amongst Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=19 per group)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently feeling financially supported</td>
<td>14 (73.7%)</td>
<td>11 (57.9%)</td>
<td>14 (73.7%)</td>
<td>39</td>
<td>0.743</td>
</tr>
<tr>
<td>Currently feeling emotionally supported</td>
<td>8 (42.1%)</td>
<td>11 (57.9%)</td>
<td>9 (47.4%)</td>
<td>28</td>
<td>0.505</td>
</tr>
<tr>
<td>Currently have someone to confide in</td>
<td>14 (73.7%)</td>
<td>14 (73.7%)</td>
<td>14 (73.7%)</td>
<td>42</td>
<td>0.287</td>
</tr>
</tbody>
</table>

**Alcohol consumption**

<table>
<thead>
<tr>
<th></th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>0 (0.0%)</td>
<td>1 (5.3%)</td>
<td>0 (0.0%)</td>
<td>1</td>
</tr>
<tr>
<td>Quit</td>
<td>17 (89.5%)</td>
<td>16 (84.2%)</td>
<td>16 (84.2%)</td>
<td>49</td>
</tr>
</tbody>
</table>

**Cigarette use**

<table>
<thead>
<tr>
<th></th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>6 (31.6%)</td>
<td>2 (10.5%)</td>
<td>3 (15.8%)</td>
<td>11</td>
</tr>
<tr>
<td>Quit</td>
<td>5 (26.3%)</td>
<td>10 (52.6%)</td>
<td>10 (52.6%)</td>
<td>25</td>
</tr>
<tr>
<td>²Current daily use</td>
<td>9.53 ± 10.58</td>
<td>10.00 ± 0.00</td>
<td>11.00 ± 8.54</td>
<td>11</td>
</tr>
<tr>
<td>Number of years of smoking</td>
<td>10.91 ± 5.32</td>
<td>6.38 ± 5.60</td>
<td>9.46 ± 6.05</td>
<td>36</td>
</tr>
</tbody>
</table>

**Recreational drug use**

<table>
<thead>
<tr>
<th></th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quit</td>
<td>8 (42.1%)</td>
<td>5 (26.3%)</td>
<td>7 (36.8%)</td>
<td>20</td>
</tr>
<tr>
<td>If quit for how many years did you use</td>
<td>2.72 ± 3.34</td>
<td>1.82 ± 2.03</td>
<td>1.36 ± 1.00</td>
<td>20</td>
</tr>
</tbody>
</table>

**If quit, how long since last use**

<table>
<thead>
<tr>
<th></th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>One year or less</td>
<td>3 (37.5%)</td>
<td>1 (20.0%)</td>
<td>2 (28.6%)</td>
<td>6</td>
</tr>
<tr>
<td>Between 1-5 years</td>
<td>4 (50.0%)</td>
<td>3 (60.0%)</td>
<td>1 (14.3%)</td>
<td>8</td>
</tr>
<tr>
<td>More than 5 years</td>
<td>1 (12.5%)</td>
<td>1 (20.0%)</td>
<td>4 (57.1%)</td>
<td>6</td>
</tr>
</tbody>
</table>

¹Alpha values are set at \(p=0.05\)
²Data are mean ± (SD) or (%) of cases within groups
Examination of alcohol consumption amongst participants revealed that only one woman in the acupuncture group was consuming alcohol at trial entry. At that time, her average weekly consumption was 0.04 drinks per week. The majority of participants (87.5%) ceased consuming alcohol upon becoming aware of their current pregnancy.

A number of participants reported smoking cigarettes at trial entry (19.3%). The mean number of cigarettes smoked per day was 10.02 ± 8.43. Twenty-five women reported quitting for their current pregnancy (43.9%).

No participant reported illicit recreational drug use during their current pregnancy. However, 35% reported quitting prior to this time point, of which six quit within the last year. On average, the number of years of use was 2.02 ± 2.38 for the cohort.

5.2.2.6 Participants’ knowledge of and previous experience with acupuncture

Data relating to women’s experiences of acupuncture are provided (Table 6.6). Of the cohort, 17 women (29.8%) had previously received treatment. The most frequently cited reason for seeking treatment was pain relief, particularly in regard to headaches and injuries (71%). Other reasons for attendance included infertility / IVF support (11.7%), labour induction (11.7%), hyperemesis (5.8%), and assistance with quitting smoking (5.8%).

When queried in relation to their experiences of acupuncture, 13 women (76.5%) reported they had found the therapy helpful for the condition for which they sought treatment. Three (17.6%) were however unsure if treatment had been beneficial and one (5.9%) individual had found it ineffective, as after having six sessions, she still did not go into spontaneous labour.

With respect to expectations prior to the receipt of treatment, only four women (25%) indicated having had positive expectations of benefits, with the majority instead stating either having no expectations, uncertainty regarding possible benefits or being hopeful of receiving benefit. Surprisingly, three (7.5%) of the
40 women who had not previously received acupuncture, also had not heard of it before the study.

Based upon the p values generated for the between group evaluations of baseline assessments, it would appear that randomisation successfully distributed various potential confounding influences evenly between groups.

Previous knowledge of PMR amongst participants was not collected.

### Table 5.6 Knowledge and Previous Experience of Acupuncture Amongst Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation (n=19 per group)</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total no.</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never had acupuncture, but had heard of it</td>
<td>9 (47.4%)</td>
<td>14 (73.7%)</td>
<td>14 (73.7%)</td>
<td>37</td>
<td>0.368</td>
</tr>
<tr>
<td>Previously utilising acupuncture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number utilising by group</td>
<td>9 (47.4%)</td>
<td>4 (21.1%)</td>
<td>4 (21.1%)</td>
<td>17</td>
<td>0.123</td>
</tr>
<tr>
<td>How many times in total by group</td>
<td>3.67 ± 3.87</td>
<td>4.25 ± 5.25</td>
<td>10.00 ± 10.49</td>
<td>0.250</td>
<td></td>
</tr>
<tr>
<td>Experience of acupuncture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Found it helpful</td>
<td>7 (77.8%)</td>
<td>3 (75.0%)</td>
<td>3 (75.0%)</td>
<td>13</td>
<td>0.852</td>
</tr>
<tr>
<td>Unsure</td>
<td>1 (11.1%)</td>
<td>1 (25.0%)</td>
<td>1 (25.0%)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Expectation prior to treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None / unsure / hopeful for benefit</td>
<td>7 (87.5%)</td>
<td>3 (75.0%)</td>
<td>2 (50.0%)</td>
<td>12</td>
<td>0.368</td>
</tr>
<tr>
<td>Positive expectation of benefit</td>
<td>1 (12.5%)</td>
<td>1 (25.0%)</td>
<td>2 (50.0%)</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

1 Alpha values are set at p=0.05;
2 Data are mean ± (SD) or (%) of cases within groups.
5.2.3 Change in Mood and Quality of Life Scale Scores of Study Participants

The end of intervention and six-week postnatal assessments of participants’ mood and quality of life scale scores are provided (Tables 5.7 to 5.12). Recruitment was not sufficient large enough to analyse outcomes incorporating stratification for antenatal models of care, hence analysis was performed only in regard to outcomes as a consequence of group allocation.

5.2.3.1 Primary outcome measure – the EPDS

End of intervention and six weeks postnatal EPDS score outcomes were assessed using three data analysis techniques: 1) ITT one-way ANOVA that utilised the method of the ACM to impute missing data (n=57, Appendix AB); 2) a per-protocol one-way ANOVA of data sets from completers (n=46); and 3) a linear mixed model repeated measures analysis incorporating all collected data from all participants (completers and non-completers). Per-protocol one-way ANOVA and linear mixed-model repeated measures were post-hoc performed analyses. Findings are provided (Tables 5.7 to 5.9).

1) Intention to treat one-way ANOVA

End of intervention, and six weeks postnatal mean ITT EPDS scores are provided by group allocation (Table 5.7). EPDS scores at trial entry were similar between groups, with the mean for the cohort being 17.54 ±3.50. At the mid-intervention timepoint, scores in all groups had decreased from baseline. By the end of the intervention, significant differences between groups were observed (p<0.001), with lower EPDS scores being seen for acupuncture versus treatment as usual (p<0.001), MD -5.84 (95% CI -9.10 to -2.58), and acupuncture versus PMR (p=0.030), MD -3.42 (95% CI -6.64 to -0.20). Scores in the acupuncture group in addition fell below the cut-off indicative of probable depression (12/13).

At the six-week postnatal follow-up, which in most cases was approximately 15 weeks after the final session at gestation week 31, between group differences
were no longer significant. In addition, scores in all groups were below the cut-off indicative of probable postpartum depression.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>1p value (n=19 per group)</th>
<th>Effect size 2, 3 (mean difference [MD]) 95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline EPDS</td>
<td>17.84 ± 3.88</td>
<td>17.05 ± 3.24</td>
<td>17.74 ± 3.48</td>
<td>0.758</td>
<td></td>
</tr>
<tr>
<td>Session 4 – Mid intervention</td>
<td>13.63 ± 4.61</td>
<td>13.58 ± 4.26</td>
<td>16.21 ± 4.76</td>
<td>0.135</td>
<td></td>
</tr>
<tr>
<td>Session 8 – End of intervention</td>
<td>12.37 ± 3.40</td>
<td>8.95 ± 4.34</td>
<td>14.79 ± 4.08</td>
<td>5&lt;0.001 6-5.84 [-9.10 to -2.58] 0.030 -3.42 [-6.64 to -0.20]</td>
<td></td>
</tr>
<tr>
<td>Six weeks postnatal EPDS</td>
<td>11.16 ± 4.39</td>
<td>9.21 ± 5.76</td>
<td>10.58 ± 6.23</td>
<td>0.539</td>
<td></td>
</tr>
</tbody>
</table>

1Alpha values are set at p=0.05;
2Acupuncture vs treatment as usual;
3Acupuncture vs PMR;
4ACM – ‘average closest match’;
5Significant findings – group comparison; acupuncture vs treatment as usual; acupuncture vs PMR;
6Significant findings – acupuncture vs treatment as usual, acupuncture vs PMR.
2) Per-protocol one-way ANOVA

End of intervention, and six weeks postnatal per-protocol one-way ANOVA analysis is provided by group allocation (Table 5.8). At the end of intervention, EPDS scores significantly differed between groups (p=0.002), with the comparison between acupuncture (9.18 ± 4.53) and treatment as usual (14.78 ± 4.20) yielding a p value of p=0.002. As was the case for the ITT analysis, the six-week postnatal follow-up EPDS scores were no longer significantly different between groups. Standard deviations were however seen to increase, as a consequence of the extra variability incorporated from the reduced number of completed data sets.

Table 5.8 Per-Protocol One-Way ANOVA Comparative Analysis of Intervention Primary Outcome EPDS Scores

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>²p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1 – Baseline</td>
<td>(n=19 per group)</td>
<td>17.05 ± 3.24</td>
<td>17.74 ± 3.48</td>
<td>0.758</td>
</tr>
<tr>
<td></td>
<td>¹17.84 ± 3.88</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Session 4 – Mid intervention</td>
<td>³(n=15)</td>
<td>13.71 ± 4.47</td>
<td>16.21 ± 4.76</td>
<td>0.208</td>
</tr>
<tr>
<td></td>
<td>13.73 ± 5.12</td>
<td>13.73 ± 5.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Session 8 – End of intervention</td>
<td>(n = 11)</td>
<td>9.18 ± 4.53</td>
<td>14.78 ± 4.20</td>
<td>⁴0.002</td>
</tr>
<tr>
<td></td>
<td>(n = 17)</td>
<td>12.46 ± 4.55</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>11.18 ± 5.85</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = 12)</td>
<td>11.18 ± 5.85</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Six weeks postnatal</td>
<td>(n = 15)</td>
<td>9.33 ± 6.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = 18)</td>
<td>10.67 ± 6.40</td>
<td></td>
<td>0.729</td>
</tr>
</tbody>
</table>

¹ Data are mean ± SD; ² Alpha values are set at p=0.05; ³ Data missing for one individual in the PMR group, other week 4 forms were provided by this individual; ⁴ Significant finding - acupuncture vs treatment as usual, p = 0.002.
3) Linear mixed model repeated measures analysis

The findings for linear mixed model repeated measures analysis are provided (Table 5.9). End of intervention between group comparisons demonstrated significantly lowered scores in the acupuncture group in both the ITT (p=0.023), and per-protocol analysis (p=0.017). Differences were however no longer significant at the six-week postnatal time point.

Table 5.9 Linear Mixed Model Repeated Measures Analysis of Intervention Primary Outcome EPDS Scores

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 8 – End of intervention</td>
<td>3Between group difference over the 3 antenatal collection points - subject variance -7.25 ± 2.06</td>
<td>40.023</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACM Imputed ITT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per-protocol</td>
<td>Between group difference over the 3 antenatal collection points - subject variance -7.75 ± 2.27</td>
<td>50.017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Six weeks postnatal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACM Imputed ITT</td>
<td>Between group difference over the 4 collection points (incl. 6 weeks postnatal - subject variance -7.17 ± 2.08)</td>
<td>0.170</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per-protocol</td>
<td>Between group difference over the 4 collection points (incl. 6 weeks postnatal - subject variance -7.59 ± 2.30)</td>
<td>0.113</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Alpha values are set at p=0.05;  
2 ACM – ‘average closet match’;  
3 Data are mean ± SD;  
4, 5 Significantly reduced scores in the acupuncture group.
5.2.3.2 Secondary outcomes measures – DASS-21, K6 & WHOQoL-BREF

Per-protocol one-way ANOVA analyses were additionally conducted at the same time points for the DASS-21, K6 & WHOQoL-BREF. Linear mixed model repeated measures analyses over the four-data collection time points, were also performed. Results indicating significance were further explored by the calculation of effect sizes. Findings are provided (Tables 5.10 to 5.12).

5.2.3.2.1 The DASS-21

Data is provided for the DASS-21 (Table 5.10). No between group differences were observed for any sub-component of the DASS-21 at baseline or the session four timepoint. By the end of intervention, group comparisons for the stress component of the DASS-21 did significantly differ (p=0.002), with scores in the acupuncture group being reduced in comparison to both treatment as usual, p=0.002, MD -4.83 (95% CI -7.65 to -2.01), and PMR, p=0.026, MD -4.18 (95% CI -7.25 to -1.11).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>p value</th>
<th>Effect size (mean difference [MD]) 95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1 - Baseline</strong></td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress</td>
<td>412.63 ± 3.13</td>
<td>13.47 ± 3.47</td>
<td>12.11 ± 3.14</td>
<td>0.430</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>7.79 ± 2.37</td>
<td>8.47 ± 3.89</td>
<td>8.00 ± 4.00</td>
<td>0.827</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>8.90 ± 3.21</td>
<td>11.37 ± 4.50</td>
<td>9.31 ± 3.59</td>
<td>0.110</td>
<td></td>
</tr>
<tr>
<td><strong>Session 4 - Mid intervention</strong></td>
<td>(n = 16)</td>
<td>(n = 17)</td>
<td>(n = 19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress</td>
<td>13.25 ± 3.34</td>
<td>11.18 ± 3.28</td>
<td>12.74 ± 4.66</td>
<td>0.279</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>8.00 ± 3.10</td>
<td>8.18 ± 3.50</td>
<td>8.32 ± 5.02</td>
<td>0.974</td>
<td></td>
</tr>
</tbody>
</table>
### Depression

<table>
<thead>
<tr>
<th>Session 8 – End of intervention</th>
<th>(n = 11)</th>
<th>(n = 17)</th>
<th>(n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress</td>
<td>7.69 ± 2.89</td>
<td>9.00 ± 4.14</td>
<td>10.26 ± 4.75</td>
</tr>
<tr>
<td>Anxiety</td>
<td>7.82 ± 4.64</td>
<td>4.41 ± 4.36</td>
<td>7.28 ± 4.51</td>
</tr>
<tr>
<td>Depression</td>
<td>6.91 ± 2.95</td>
<td>5.06 ± 3.36</td>
<td>7.72 ± 4.11</td>
</tr>
</tbody>
</table>

### Six weeks postnatal

<table>
<thead>
<tr>
<th>(n = 12)</th>
<th>(n = 15)</th>
<th>(n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress</td>
<td>8.25 ± 4.41</td>
<td>6.53 ± 5.45</td>
</tr>
<tr>
<td>Anxiety</td>
<td>3.50 ± 4.17</td>
<td>3.00 ± 5.13</td>
</tr>
<tr>
<td>Depression</td>
<td>5.25 ± 4.45</td>
<td>4.53 ± 5.00</td>
</tr>
</tbody>
</table>

Linear mixed model repeated measures analysis for between group differences for the **stress component of the DASS 21** over the 4 collection points (incl. 6 weeks postnatal) subject variance – 4.95 ± 0.59

1 Alpha values are set at p=0.05;
2 Acupuncture vs treatment as usual;
3 Acupuncture vs PMR;
4 Data are mean ± SD;
5 Statistically significant - acupuncture vs treatment as usual p = 0.002, acupuncture vs PMR p = 0.026;
6 Significant findings – acupuncture vs treatment as usual, acupuncture vs PMR;
7 Significantly lower scores seen in the acupuncture group after the incorporation of all data.
As was the case for the EPDS, between group differences at the six-week postnatal follow-up for the stress subcomponent of the DASS-21 were no longer significant. Findings from the linear mixed model repeated measures analysis over the four collection timepoints (including six-week postnatal), were however significantly different (p=0.006), with the lowest overall scores again being seen in the acupuncture group.

5.2.3.2.2 The Kessler 6

Data is provided for the K6 (Table 5.11). No between group differences were observed at baseline, with the mean score for the cohort being 20.0 ± 3.86. After this time, scores were consistently seen to lower in all groups. By week six, a significant difference was noted (p=0.011), with the lowest scores being seen in the acupuncture group. Whilst significance was lost after session seven, the lowest score remained in the acupuncture group. At the end of intervention time point however, between group differences were again significant (p=0.001), with scores in the acupuncture group being significantly lower when compared to treatment as usual (p<0.001), MD -6.42 (95% CI -10.05 to -2.79).

As was also the case for the DASS-21, whilst the findings for the K6 at the six-week postnatal collection time point were no longer significant between groups, the linear mixed model repeated measures analysis over the four collection time points (including six-week postnatal) was (p<0.001), with the lowest overall all scores again being seen in the acupuncture group.
Table 5.11 Per-Protocol One-Way ANOVA and Linear Mixed Model Repeated Measures Comparative Analysis of Intervention Secondary Outcome K6 Scores

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total</th>
<th>( ^{p} \text{ value} )</th>
<th>( ^{2,3} \text{Effect size} )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td></td>
<td>(mean difference [MD]) 95%CI</td>
</tr>
<tr>
<td>Baseline</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>57</td>
<td>( ^{4}19.11 \pm 3.43 )</td>
<td>20.47 \pm 4.56 19.42 \pm 3.56</td>
</tr>
<tr>
<td>Session 2</td>
<td>(n=18)</td>
<td>(n=18)</td>
<td>(n=19)</td>
<td>55</td>
<td>18.22 \pm 2.29</td>
<td>18.01 \pm 4.15 17.32 \pm 3.58</td>
</tr>
<tr>
<td>Session 3</td>
<td>(n=15)</td>
<td>(n=17)</td>
<td>(n=19)</td>
<td>51</td>
<td>17.00 \pm 4.79</td>
<td>17.71 \pm 4.88 16.95 \pm 5.01</td>
</tr>
<tr>
<td>Session 4</td>
<td>(n=14)</td>
<td>(n=17)</td>
<td>(n=19)</td>
<td>50</td>
<td>16.65 \pm 4.27</td>
<td>16.29 \pm 4.38 19.42 \pm 4.32</td>
</tr>
<tr>
<td>Session 5</td>
<td>(n=14)</td>
<td>(n=17)</td>
<td>(n=19)</td>
<td>50</td>
<td>16.07 \pm 4.12</td>
<td>14.24 \pm 5.19 17.95 \pm 4.60</td>
</tr>
<tr>
<td>Session 6</td>
<td>(n=12)</td>
<td>(n=17)</td>
<td>(n=18)</td>
<td>47</td>
<td>16.08 \pm 4.32</td>
<td>12.59 \pm 4.52 17.89 \pm 5.81</td>
</tr>
<tr>
<td>Session 7</td>
<td>(n=12)</td>
<td>(n=17)</td>
<td>(n=18)</td>
<td>47</td>
<td>15.42 \pm 4.96</td>
<td>13.06 \pm 5.06 16.61 \pm 5.45</td>
</tr>
<tr>
<td>Session 8</td>
<td>(n=11) 6(n=16)</td>
<td>(n=18)</td>
<td></td>
<td>45</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

134
<table>
<thead>
<tr>
<th></th>
<th>(n = 12)</th>
<th>(n = 15)</th>
<th>(n = 18)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13.92 ± 5.87</td>
<td>11.67 ± 5.09</td>
<td>14.00 ± 6.37</td>
<td>0.467</td>
<td>-2.33 [-7.11 to 2.45]</td>
</tr>
<tr>
<td>11.75 ± 4.43</td>
<td>11.67 ± 5.09</td>
<td>14.00 ± 6.37</td>
<td>0.467</td>
<td>-2.25 [-7.09 to 2.59]</td>
</tr>
<tr>
<td>15.55 ± 4.68</td>
<td>11.75 ± 4.43</td>
<td>18.17 ± 4.19</td>
<td>0.096</td>
<td>-6.42 [-10.05 to -2.79]</td>
</tr>
<tr>
<td>0.096</td>
<td>0.001</td>
<td>&lt;0.001</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>0.001</td>
<td>-</td>
<td>&lt;0.001</td>
<td>0.096</td>
<td>0.001</td>
</tr>
<tr>
<td>0.001</td>
<td>-</td>
<td>&lt;0.001</td>
<td>0.096</td>
<td>0.001</td>
</tr>
<tr>
<td>0.001</td>
<td>-</td>
<td>&lt;0.001</td>
<td>0.096</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Linear mixed model repeated measures analysis for between group difference over the 4 collection points (including 6 weeks postnatal) - subject variance - 9.31 ± 2.09

5.2.3.2.3 The WHOQoL-BREF

Data is provided for the WHOQoL-BREF (Table 5.12). No significant between group differences were observed for any domain, or combined score of the WHOQoL-BREF at baseline, mid-intervention, end of intervention, or six-week postnatal. A non-significant trend was however observed, whereby acupuncture group scores over time, were consistently higher than either control.

---

1 Alpha values are set at p=0.05;
2 Acupuncture vs treatment as usual;
3 Acupuncture vs PMR;
4 Data are mean ± SD;
5 Acupuncture vs PMR p=0.09, acupuncture vs treatment as usual p=0.09;
6 Week 8 data missing for one acupuncture participant;
7 Acupuncture vs treatment as usual p <0.001; acupuncture vs PMR p = 0.096;
8 Significantly lower scores seen in the acupuncture group after the incorporation of all data.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>p value</th>
<th>Effect size [mean difference [MD]] 95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1 - Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Relationships</td>
<td>59.00 ± 22.08</td>
<td>57.26 ± 23.10</td>
<td>53.26 ± 19.87</td>
<td>0.707</td>
<td>34.96 [-79.43 to 9.51]</td>
</tr>
<tr>
<td>Environment</td>
<td>63.28 ± 13.27</td>
<td>61.63 ± 15.90</td>
<td>63.63 ± 13.95</td>
<td>0.902</td>
<td>-34.96 [-79.43 to 9.51]</td>
</tr>
<tr>
<td>Psychological</td>
<td>46.47 ± 13.91</td>
<td>43.21 ± 10.78</td>
<td>47.32 ± 15.11</td>
<td>0.610</td>
<td>-11.42 [-57.94 to 35.10]</td>
</tr>
<tr>
<td>Physical Health</td>
<td>43.26 ± 12.13</td>
<td>40.68 ± 7.61</td>
<td>41.95 ± 10.02</td>
<td>0.735</td>
<td></td>
</tr>
<tr>
<td><strong>Combined Score</strong></td>
<td>208.68 ± 49.32</td>
<td>202.79 ± 36.66</td>
<td>206.16 ± 46.78</td>
<td>0.920</td>
<td></td>
</tr>
<tr>
<td><strong>Session 4 - Mid intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Relationships</td>
<td>61.69 ± 21.17</td>
<td>61.35 ± 24.41</td>
<td>48.68 ± 16.95</td>
<td>0.114</td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td>65.06 ± 16.61</td>
<td>69.18 ± 15.04</td>
<td>63.95 ± 11.43</td>
<td>0.530</td>
<td></td>
</tr>
<tr>
<td>Psychological</td>
<td>50.50 ± 13.24</td>
<td>48.65 ± 11.75</td>
<td>47.74 ± 13.94</td>
<td>0.820</td>
<td></td>
</tr>
<tr>
<td>Physical Health</td>
<td>43.82 ± 10.59</td>
<td>48.29 ± 11.20</td>
<td>41.00 ± 11.56</td>
<td>0.155</td>
<td></td>
</tr>
<tr>
<td><strong>Combined Score</strong></td>
<td>221.06 ± 50.66</td>
<td>227.47 ± 51.00</td>
<td>201.37 ± 43.17</td>
<td>0.245</td>
<td></td>
</tr>
<tr>
<td><strong>Session 8 - End of intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Relationships</td>
<td>68.27 ± 15.13</td>
<td>68.77 ± 23.40</td>
<td>58.78 ± 17.87</td>
<td>0.264</td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td>74.09 ± 14.61</td>
<td>75.88 ± 17.36</td>
<td>65.06 ± 16.26</td>
<td>0.129</td>
<td></td>
</tr>
<tr>
<td>Psychological</td>
<td>55.27 ± 12.59</td>
<td>59.65 ± 11.62</td>
<td>52.89 ± 14.43</td>
<td>0.312</td>
<td></td>
</tr>
<tr>
<td>Physical Health</td>
<td>46.18 ± 14.03</td>
<td>50.94 ± 12.10</td>
<td>43.56 ± 12.80</td>
<td>0.242</td>
<td></td>
</tr>
<tr>
<td><strong>Combined Score</strong></td>
<td>243.82 ± 48.49</td>
<td>255.24 ± 56.10</td>
<td>220.28 ± 46.76</td>
<td>0.130</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.138</td>
<td>-34.96 [-79.43 to 9.51]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.917</td>
<td>-11.42 [-57.94 to 35.10]</td>
</tr>
</tbody>
</table>
Six weeks postnatal (n = 12) (n = 15) (n = 18)

<table>
<thead>
<tr>
<th></th>
<th>(n = 12)</th>
<th>(n = 15)</th>
<th>(n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Relationships</td>
<td>65.58 ± 21.84</td>
<td>73.80 ± 18.19</td>
<td>62.56 ± 15.80</td>
</tr>
<tr>
<td>Environment</td>
<td>72.67 ± 19.90</td>
<td>79.27 ± 17.09</td>
<td>68.50 ± 16.39</td>
</tr>
<tr>
<td>Psychological Health</td>
<td>54.33 ± 16.00</td>
<td>61.67 ± 15.26</td>
<td>51.44 ± 15.11</td>
</tr>
<tr>
<td>Physical Health</td>
<td>49.08 ± 12.30</td>
<td>53.47 ± 11.24</td>
<td>45.67 ± 15.44</td>
</tr>
<tr>
<td>Combined Score</td>
<td>241.67 ± 61.30</td>
<td>268.20 ± 51.70</td>
<td>228.17 ± 47.11</td>
</tr>
</tbody>
</table>

Utilising a cut-off score of ≥60 within the individual domains as an indicator of a ‘perceived quality of life’ (Silva, Soares, Santos, & Silva, 2014), it was observed that the domain ‘environment’ was consistently above this threshold, in all three groups from baseline. It was also observed that the ‘social relationship’ domain scores reached this threshold, in all groups, by six-weeks postnatal. The acupuncture group however, was the only group to obtain a score of ≥60, in the ‘psychological well-being’ domain, over the timeframe of the intervention.

5.2.4 End of Intervention, Pregnancy, Maternity and Six-Week Postnatal Outcomes

Assessment of secondary outcomes in pregnancy, birthing, maternity ward admission and six-week postnatal is provided (Tables 5.13 to 5.19). No significant between group differences were noted in any outcome measured apart from an increased utilisation of the Foley’s catheter (p=0.042) for induction of labour, in the treatment as usual group.

---

1 Alpha values are set at p=0.05;
2 Acupuncture vs treatment as usual;
3 Acupuncture vs PMR;
4 Data are mean ± SD.
5.2.4.1 End of intervention, pregnancy and maternity outcomes

1) Participant characteristics at the end of intervention

As some women were unable to adhere to the weekly eight-week schedule, gestation age at completion of the intervention was in some cases beyond the end of gestation week 31. Between group variability in mean gestation age of completion, as well as the total number of days in the intervention were consequently assessed to: 1) determine if there were any significant between group differences in this regard and, 2) provide details regarding the possible impact on resultant biomarker hormone concentrations (stage one - part C), of increasing gestation age (see chapter 5 and 7). Findings are provided (Table 5.13).

Table 5.13 Participant Characteristics at the End of Intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total</th>
<th>^p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestation age of completers at end of intervention</td>
<td>32.43 ± 1.19 (n=11)</td>
<td>32.35 ± 0.87 (n=17)</td>
<td>31.61 ± 1.14 (n=18)</td>
<td>46</td>
<td>0.065</td>
</tr>
<tr>
<td>Total days in intervention</td>
<td>56.55± 7.23 (n=11)</td>
<td>55.41± 5.92 (n=17)</td>
<td>51.39± 7.41 (n=18)</td>
<td>46</td>
<td>0.101</td>
</tr>
</tbody>
</table>

2) Pregnancy and labouring outcomes

Data is provided regarding pregnancy and labouring outcomes (Table 6.14). Medical records were accessed in relation to the recording of any obstetric complications. Assessment of this information revealed that 43 women (75.4%) had been affected, and in most cases, by more than one issue.

^1Alpha values are set at p=0.05;
^2Data are mean ± SD.
Table 5.14 Pregnancy and Labouring Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total</th>
<th>p value</th>
<th>Risk ratio (mean difference [MD])</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n =19 per group)</td>
<td></td>
<td></td>
<td>57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Obstetric complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total affected</td>
<td>14 (73.7%)</td>
<td>14 (73.7%)</td>
<td>15 (78.9%)</td>
<td>43</td>
<td>0.910</td>
<td>0.93 [0.14 to 6.37]</td>
<td>0.83 [0.15 to 4.54]</td>
</tr>
<tr>
<td>Gestational diabetes (total)</td>
<td>4 (21.1%)</td>
<td>4 (21.1%)</td>
<td>8 (42.1%)</td>
<td>16</td>
<td>0.249</td>
<td>0.39 [0.06 to 2.42]</td>
<td>0.94 [0.14 to 6.28]</td>
</tr>
<tr>
<td>Diet controlled</td>
<td>3 (15.8%)</td>
<td>4 (21.1%)</td>
<td>6 (31.6%)</td>
<td>13</td>
<td>0.498</td>
<td>0.62 [0.10 to 3.92]</td>
<td>1.33 [0.18 to 9.66]</td>
</tr>
<tr>
<td>Insulin required</td>
<td>1(5.3%)</td>
<td>0 (0.00%)</td>
<td>2 (10.5%)</td>
<td>3</td>
<td>0.348</td>
<td>0.37 [0.02 to 8.49]</td>
<td>0.59 [0.02 to 15.75]</td>
</tr>
<tr>
<td>High blood pressure/ pre-eclampsia</td>
<td>0 (0.00%)</td>
<td>2 (10.5%)</td>
<td>1(5.3%)</td>
<td>3</td>
<td>0.348</td>
<td>2.25 [0.12 to 40.66]</td>
<td>6.16 [0.23 to 165.83]</td>
</tr>
<tr>
<td>Small for gestational age / intrauterine growth restriction</td>
<td>0 (0.00%)</td>
<td>1(5.3%)</td>
<td>3 (15.8%)</td>
<td>4</td>
<td>0.152</td>
<td>0.67 [0.06 to 7.48]</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Premature rupture of membranes</td>
<td>3 (15.8%)</td>
<td>1 (5.3%)</td>
<td>0 (0.00%)</td>
<td>4</td>
<td>0.152</td>
<td>6.88 [0.25 to 186.68]</td>
<td>0.22 [0.01 to 4.80]</td>
</tr>
<tr>
<td>Pre-term birth</td>
<td>4 (21.1%)</td>
<td>2 (10.5%)</td>
<td>1 (5.3%)</td>
<td>7</td>
<td>0.320</td>
<td>2.25 [0.12 to 40.66]</td>
<td>0.42 [0.04 to 4.33]</td>
</tr>
<tr>
<td>Foetal distress / heart rate anomaly</td>
<td>6 (31.6%)</td>
<td>4 (21.1%)</td>
<td>2 (10.5%)</td>
<td>12</td>
<td>0.282</td>
<td>2.43 [0.28 to 20.82]</td>
<td>0.54 [0.09 to 3.37]</td>
</tr>
</tbody>
</table>
## Postpartum haemorrhage

<table>
<thead>
<tr>
<th></th>
<th>1 (5.3%)</th>
<th>1 (5.3%)</th>
<th>0 (0.00%)</th>
<th>2</th>
<th>0.596</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (26.3%)</td>
<td>8 (42.1%)</td>
<td>4 (21.1%)</td>
<td>17</td>
<td>0.336</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Labouring details

<table>
<thead>
<tr>
<th>Labouring details</th>
<th>738.04 ± 2.63</th>
<th>38.87 ± 1.73</th>
<th>38.68 ± 1.86</th>
<th>57</th>
<th>0.448</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestation age of onset</td>
<td>-</td>
<td>-0.19 [-1.60 to 1.22]</td>
<td>-0.83 [-2.43 to 0.77]</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of labour (hours)</td>
<td>3.87 ± 3.42</td>
<td>4.25 ± 3.35</td>
<td>4.31 ± 4.43</td>
<td>57</td>
<td>0.927</td>
<td>-</td>
</tr>
<tr>
<td>Induction required</td>
<td>5 (26.3%)</td>
<td>6 (31.6%)</td>
<td>8 (42.1%)</td>
<td>19</td>
<td>0.575</td>
<td>-</td>
</tr>
</tbody>
</table>

## Method of induction / augmentation

<table>
<thead>
<tr>
<th>Method of induction / augmentation</th>
<th>2 (10.5%)</th>
<th>5 (26.3%)</th>
<th>4 (21.1%)</th>
<th>11</th>
<th>0.455</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostin gel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artificial rupture of membranes</td>
<td>4 (21.1%)</td>
<td>5 (26.3%)</td>
<td>9 (47.4%)</td>
<td>18</td>
<td>0.182</td>
<td>-</td>
</tr>
<tr>
<td>Foley's catheter</td>
<td>0 (0.00%)</td>
<td>0 (0.00%)</td>
<td>3 (15.8%)</td>
<td>3</td>
<td>0.042</td>
<td>-</td>
</tr>
<tr>
<td>Intravenous Syntocinon</td>
<td>6 (31.6%)</td>
<td>4 (21.1%)</td>
<td>5 (26.3%)</td>
<td>15</td>
<td>0.762</td>
<td>-</td>
</tr>
</tbody>
</table>

## Pain relief required

<table>
<thead>
<tr>
<th>Pain relief required</th>
<th>15 (78.9%)</th>
<th>15 (78.9%)</th>
<th>16 (84.2%)</th>
<th>46</th>
<th>0.893</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total usage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

140
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Overall</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas</td>
<td>15 (78.9%)</td>
<td>14 (73.7%)</td>
<td>13 (68.4%)</td>
<td>42</td>
<td>0.762</td>
</tr>
<tr>
<td>Pethidine / morphine</td>
<td>5 (26.3%)</td>
<td>5 (26.3%)</td>
<td>4 (21.1%)</td>
<td>14</td>
<td>0.910</td>
</tr>
<tr>
<td>Epidural</td>
<td>5 (26.3%)</td>
<td>4 (21.1%)</td>
<td>4 (21.1%)</td>
<td>13</td>
<td>0.905</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birthing details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal vaginal</td>
</tr>
<tr>
<td>Assisted vaginal</td>
</tr>
<tr>
<td>Ventouse</td>
</tr>
<tr>
<td>Episiotomy</td>
</tr>
<tr>
<td>Forceps</td>
</tr>
<tr>
<td>Caesarean section (total)</td>
</tr>
</tbody>
</table>

**Elective**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Overall</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas</td>
<td>15 (78.9%)</td>
<td>14 (73.7%)</td>
<td>13 (68.4%)</td>
<td>42</td>
<td>0.762</td>
</tr>
<tr>
<td>Pethidine / morphine</td>
<td>5 (26.3%)</td>
<td>5 (26.3%)</td>
<td>4 (21.1%)</td>
<td>14</td>
<td>0.910</td>
</tr>
<tr>
<td>Epidural</td>
<td>5 (26.3%)</td>
<td>4 (21.1%)</td>
<td>4 (21.1%)</td>
<td>13</td>
<td>0.905</td>
</tr>
</tbody>
</table>

**Birthing details**

| Normal vaginal | 15 (78.9%) | 14 (73.7%) | 16 (84.2%) | 45 | 0.729 |
| Assisted vaginal | 4 (21.1%) | 3 (15.8%) | 0 (0.00%) | 7 | 0.120 |
| Ventouse | 1 (5.3%) | 1 (5.3%) | 0 (0.00%) | 2 | 0.596 |
| Episiotomy | 4 (21.1%) | 3 (15.8%) | 0 (0.00%) | 7 | 0.120 |
| Forceps | 2 (10.5%) | 0 (0.00%) | 0 (0.00%) | 2 | 0.126 |

**Caesarean section (total)**

| Elective | 0 (0.00%) | 1 (5.3%) | 0 (0.00%) | 1 | 0.216 |
| Emergency | 0 (0.00%) | 1 (5.3%) | 3 (15.8%) | 4 | - |

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The most frequently occurring single complication affecting just over a quarter of the participants (28.1%), was the development of gestational diabetes (GD). The majority of these affected women (81.2%) were managed by diet modification alone. Whilst not significant, it was noted that twice as many women in the treatment as usual group (8) were diagnosed than in acupuncture or PMR (4). Foetal distress and or heart rate anomalies were the second most frequently occurring single complication (21.1%). Detection of this issue during routine screening prior to or during labour, was a common reason for the induction and or augmentation, so as to hasten birth. The third most frequently occurring single complication was birthing preterm, which impacted 12.3% of the cohort.

1 Alpha values are set at p=0.05;  
2 Acupuncture vs treatment as usual;  
3 Acupuncture vs PMR;  
4 Data was obtained from e-records and paper files when available, or participants, when not available; some participants experienced more than one obstetric complication;  
5 Both sets of twins were birthed before 37 weeks gestation, one in treatment as usual, 1 in acupuncture, with the male twin dying shortly after birth due to a congenital heart malformation;  
6 Other included increased body mass index (BMI), advanced maternal age (AMA), and mental health disturbances resulting in induction of labour or planned caesarean section date being brought forward;  
7 Data are mean ± SD;  
8 A significant association was noted between the use of Foley’s catheter in treatment as usual group when compared to both active treatment arms
In addition to foetal distress, other factors listed as reasons for medical induction included advanced maternal age, increased body mass index, emotional distress and being ‘post-date’. Including women whose babies were exhibiting signs of foetal distress, approximately one in every three women required the intervention (33.3%). A variety of methods were employed, with some women requiring multiple approaches. The frequency of utilisation of these methods was similar amongst groups, apart from a significantly higher rate of Foley’s catheter use in the treatment as usual group. A large proportion of the women accessed pain relief medication during labour (80.7%), with 73.7% using gas (42), 24.6% opioids (14), and 22.8% epidural medication (13). In many cases, Syntocinin was also used for augmentation of labour. Overall the mean gestation age of birthing was prior to 40 weeks (38.53 ± 2.61), and the average length of labour, 4.14 ± 3.70 hours.

Assessment was also made in regard to mode of birth, with the majority of women (45) achieving normal vaginal deliveries (75.4%). Seven (12.3%) women required medically assisted vaginal birth, which in all cases included episiotomies. Two of these women additionally required the use of forceps, and another two, Ventouse extraction. Five women additionally delivered their babies via caesarean section (C-section, 8.8%). In one case, the procedure was elective, whereas in the other four, emergency procedures.

3) Baby outcomes

Data is provided regarding the outcomes for babies (Table 5.15). Including the two sets of twins, 59 babies were born. Sadly, the twin boy in the dizygotic set died at birth, due to congenital heart defects. Consequently 58 live births occurred.

The mean birthweight of the infants of 3.27 ± 0.68 kilograms, was slightly lighter than the reported 2004 Australian national average (3.37 kilograms) (Linacre, 2007), and may be reflective of the tendency amongst cohort to birth early. The mean Apgar scores of 8.84 ± 0.60 and 8.93 ± 0.33 at 1 and 5 minutes respectively, were also within the range typically regarded as indicating good health. Neonatal intensive care unit admissions (NICU) were however
substantial, with thirteen babies requiring admission, representing 22.8% of the cohorts’ infants. Reasons for admissions were classified according to the subcategories provided in Table 5.15, for which occurrences within each category, were generally infrequent. Whilst the duration of time babies spent in NICU did not significantly differ between groups, the mean number of days in the treatment as usual group (16.00 ± 18.39), was almost three times that observed for the acupuncture (6.60 ± 8.23) and PMR (6.33 ± 5.43).

Table 5.15 Birthing and Infant Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total</th>
<th>(^1)p value</th>
<th>(^2,3)Risk ratio (mean difference [MD])</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n = 19 per group)</td>
<td></td>
<td></td>
<td></td>
<td>57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant details</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (52.6%)</td>
<td>10 (52.6%)</td>
<td>9 (47.4%)</td>
<td>29</td>
<td>0.932</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>9 (47.4%)</td>
<td>9 (47.4%)</td>
<td>10 (52.6%)</td>
<td>28</td>
<td>0.932</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>4 ± 3.13 ± 0.60</td>
<td>5 ± 3.40 ± 0.59</td>
<td>6 ± 3.30 ± 0.81</td>
<td>57</td>
<td>0.476</td>
<td>-0.10 [-0.63 to 0.43]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.27 [-0.72 to 0.18]</td>
<td></td>
</tr>
<tr>
<td>(^7)Apgar scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 min</td>
<td>9.00 ± 0.00</td>
<td>8.72 ± 0.75</td>
<td>8.78 ± 0.73</td>
<td>55</td>
<td>0.335</td>
<td>-0.06 [-0.65 to 0.53]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>5 min</td>
<td>9.00 ± 0.00</td>
<td>8.78 ± 0.55</td>
<td>9.00 ± 0.00</td>
<td>55</td>
<td>0.056</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Neonatal intensive care unit admissions (NICU)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total occurrences</td>
<td>6 (31.6%)</td>
<td>5 (26.3%)</td>
<td>2 (10.5%)</td>
<td>13</td>
<td>0.274</td>
<td>2.43 [0.28 to 20.82]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.93 [0.18 to 4.90]</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Score 1</td>
<td>Score 2</td>
<td>Score 3</td>
<td>Score 4</td>
<td>Score 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
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<td>---------</td>
<td>---------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Feeding / weight gain difficulty</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhaled meconium and or need for oxygen</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scoring positive for or monitored for Neonatal Adaptation Syndrome</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-term birth</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion required</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foetal heart rate abnormality</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevated white blood cell count</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring of abnormality detected at ultrasound</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post gestational diabetes mellitus exposure monitoring</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous labour analgesia usage monitoring</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Length of NICU stay</strong></td>
<td>6.33 ± 5.43</td>
<td>6.60 ± 8.23</td>
<td>16.00 ± 18.39</td>
<td>57</td>
<td>0.395 [-9.40 [-19.26 to 0.46]</td>
<td>0.27 [-5.39 to 5.93]</td>
<td></td>
</tr>
</tbody>
</table>
1 Alpha values are set at p=0.05;  
2 Acupuncture vs treatment as usual;  
3 Acupuncture vs PMR;  
4 Data are mean ± SD;  
5 The weight of the male twin that died at birth was excluded from analysis;  
6 An average weight was calculated for the female twins (725 g + 1134 g);  
7 Medical records were unavailable for two participants (1 ACU, 1 UC);  
8 Neonatal Adaptation Syndrome - a spectrum of symptoms that may be experienced in newborns as a consequence of withdrawal from maternal exposure to some anti-depressant / anti-psychotic medications;  
9 Mild dilated renal pyectosis (acupuncture); cyst on the lung (acupuncture).
4) Maternity ward post-birth breastfeeding outcomes

Data is provided on post-birth breastfeeding outcomes (Table 5.16). Forty-nine participants (85.9%) breast fed their babies soon after birth, with 46 (80.7%) of these continuing to breastfeed at discharge.

Analysis of the type of infant feeding provided demonstrated that 63.2% of women were exclusively breastfeeding, 22.8% were combining breast feeds with formula, and 14% were utilising formula feeding alone.

Table 5.16 Maternity Ward Post-Birth Breastfeeding Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total</th>
<th>p value</th>
<th>²,³ Risk ratio (mean difference [MD])</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n =19 per group)</td>
<td></td>
<td></td>
<td>57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast feeding details</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initiated</td>
<td>17 (89.5%)</td>
<td>15 (78.9%)</td>
<td>17 (89.5%)</td>
<td>49</td>
<td>0.559</td>
<td>0.94 [0.07 to 11.97]</td>
<td>0.27 [0.04 to 2.02]</td>
</tr>
<tr>
<td>At discharge</td>
<td>17 (89.5%)</td>
<td>14 (73.7%)</td>
<td>15 (78.9%)</td>
<td>46</td>
<td>0.455</td>
<td>0.93 [0.14 to 6.37]</td>
<td>0.27 [0.04 to 2.02]</td>
</tr>
<tr>
<td>Breast exclusive</td>
<td>15 (78.9%)</td>
<td>11 (57.9%)</td>
<td>10 (52.6%)</td>
<td>36</td>
<td>0.205</td>
<td>1.80 [0.34 to 9.40]</td>
<td>0.27 [0.05 to 1.40]</td>
</tr>
<tr>
<td>Breast and formula</td>
<td>2 (10.5%)</td>
<td>4 (21.1%)</td>
<td>7 (36.8%)</td>
<td>13</td>
<td>0.151</td>
<td>0.49 [0.08 to 3.04]</td>
<td>2.13 [0.25 to 17.93]</td>
</tr>
<tr>
<td>Formula only</td>
<td>2 (10.5%)</td>
<td>4 (21.1%)</td>
<td>2 (10.5%)</td>
<td>8</td>
<td>0.559</td>
<td>2.43 [0.28 to 20.82]</td>
<td>2.13 [0.25 to 17.93]</td>
</tr>
</tbody>
</table>

¹ Alpha values are set at p=0.05;
² Acupuncture vs treatment as usual;
³ Acupuncture vs PMR
5) Management of mental health at hospital discharge

Data is provided on the management of mental health at hospital discharge (Table 5.17). At the time of booking in with the midwives, thirteen women reported being medicated. By the time of trial entry, two additional women had commenced medication (PMR [1], acupuncture [1]). At hospital discharge however, two women in the same group allocations had ceased their medication. Consequently, overall, no change in usage was observed.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Treatment as usual</th>
<th>Total</th>
<th>p value</th>
<th>Risk ratio (mean difference [MD])</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management approach</td>
<td>(n = 19 per group)</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental health related medication usage</td>
<td>3 (15.8%)</td>
<td>5 (26.3%)</td>
<td>5 (26.3%)</td>
<td>13</td>
<td>0.671</td>
<td>0.80 [0.12 to, 5.21]</td>
<td>2.29 [0.37 to 14.25]</td>
</tr>
<tr>
<td>Psychotherapy / counselling</td>
<td>10 (52.6%)</td>
<td>10 (52.6%)</td>
<td>8 (42.1%)</td>
<td>28</td>
<td>0.755</td>
<td>1.72 [0.35 to 8.51]</td>
<td>0.90 [0.19 to 4.17]</td>
</tr>
<tr>
<td>4Other</td>
<td>5 (26.3%)</td>
<td>4 (21.1%)</td>
<td>5 (26.3%)</td>
<td>14</td>
<td>0.910</td>
<td>0.80 [0.12 to 5.21]</td>
<td>0.70 [0.11 to 4.48]</td>
</tr>
</tbody>
</table>

1 Alpha values are set at p=0.05;  
2 Acupuncture vs treatment as usual;  
3 Acupuncture vs PMR;  
4 Other = social services, exercise & socialisation.
The utilisation of psychotherapy / counselling services was not assessed at trial entry, however an increased number of women accessing these services from seven at midwife booking in (12.3%), to 28 (49.1%) at hospital discharge was observed. This was likely to be a direct effect of mental health team referral throughout pregnancy.

Data relating to the accessing of ‘other’ services for the management of mental health concerns was collected at booking in, throughout the intervention period, and at hospital discharge. Overall, an increase was seen in the number of women accessing these services from two (3.5%) at midwife booking in, to fourteen (24.6%) at hospital discharge. Some of the additional services accessed resulted from mental health team referral, and were comprised of social services, such as ‘Focus on Families’. In other cases, additional techniques were added in by women as self-help strategies, such as exercise and socialisation.

5.2.4.2 Analysis of six-week follow-up outcomes

At six-weeks postnatal, data was collected regarding breastfeeding and postnatal depressive outcomes.

1) Breastfeeding outcomes at six-weeks postnatal

Data are provided regarding breastfeeding outcomes at six-weeks postnatal (Table 5.18). With respect to breastfeeding, it was interesting to observe that information provided on the six-week postnatal follow-up form regarding the initiation of breastfeeding in hospital, contradicted that provided from medical records. Specifically, less women (40) reported initiating breastfeeding in hospital (70.2%), compared to the number (49) specified on medical records (85.9%).

At the six-week postnatal follow-up time point, sixteen women had ceased breastfeeding (40%), with three of these women indicating stopping in the first week, five in the third, two in the fourth and six, in the fifth. Of those women continuing to breastfeed, 70.8% (17) were exclusively breastfeeding. The mean number of feeds provided at this time was $8.91 \pm 2.56$ per day.
Table 5.18 Breast Feeding Outcomes at Six-Weeks Postnatal

<table>
<thead>
<tr>
<th>Six-week postnatal details (provided by participants)</th>
<th>Progressive Muscle Relaxation (n=12)</th>
<th>Acupuncture (n=15)</th>
<th>Treatment as usual (n=18)</th>
<th>Total (n=45)</th>
<th>p value</th>
<th>Risk ratio (mean difference [MD]) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast feeding initiated</td>
<td>12 (100%)</td>
<td>12 (80.0%)</td>
<td>16 (88.9%)</td>
<td>40</td>
<td>0.259</td>
<td>0.75 [0.06 to 9.87]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.10 [0.00, 2.50]</td>
</tr>
<tr>
<td>Ceased by 6 weeks postpartum</td>
<td>5 (41.7%)</td>
<td>7 (46.7%)</td>
<td>4 (22.2%)</td>
<td>16</td>
<td>0.220</td>
<td>4.67 [0.72 to 30.11]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.84 [0.13 to 5.26]</td>
</tr>
<tr>
<td>Ongoing at 6 weeks postpartum</td>
<td>7 (58.3%)</td>
<td>5 (33.3%)</td>
<td>12 (66.7%)</td>
<td>24</td>
<td></td>
<td>0.20 [0.03 to 1.35]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.94 [0.17 to 5.25]</td>
</tr>
<tr>
<td>Breast exclusive</td>
<td>4 (33.3%)</td>
<td>4 (26.7%)</td>
<td>9 (50.0%)</td>
<td>17</td>
<td>0.312</td>
<td>0.40 [0.06 to 2.63]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.33 [0.15 to 11.50]</td>
</tr>
<tr>
<td>Breast and formula</td>
<td>3 (25.0%)</td>
<td>1 (6.7%)</td>
<td>3 (16.7%)</td>
<td>7</td>
<td></td>
<td>0.83 [0.07 to 9.69]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.25 [0.01 to 5.72]</td>
</tr>
<tr>
<td>Average no. of feeds per day</td>
<td>8.71 ± 2.14</td>
<td>9.00 ± 2.00</td>
<td>49.00 ± 3.16</td>
<td>44</td>
<td>0.973</td>
<td>0.00 [-2.08 to 2.08]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.29 [-1.55 to 2.13]</td>
</tr>
</tbody>
</table>

2) Depressive mood at six-weeks postnatal

Data relating to participants’ mood at six-week postnatal is provided (Table 6.19). Twenty-six (57.8%) of the 45 women providing feedback indicated having felt symptoms of depression at some stage since birthing. Of these, seventeen indicated currently feeling depressed (37.8%) at the time of the six-week postnatal follow-up.

1 Alpha values are set at p=0.05;
2 Acupuncture vs treatment as usual;
3 Acupuncture vs PMR;
4 Details regarding the number of feeds, not provided by one participant in treatment as usual.
The lengths of time and the number of women feeling depressed were categorised into four main categories, including: ‘on and off’ (6), for ‘a few days in total’ (4), ‘between 1-3 weeks’ (6) and, ‘since the birth of my baby’ (10). Whilst no between group differences were noted with respect to the mean number of days the postnatal depressive episodes were experienced for, the period of time in the treatment as usual group (29.19 ± 17.37), was noticeably longer when compared to PMR (16.67 ±15.14) and acupuncture (16.34 ± 15.58).

In regard to the severity of the depression experienced, seven women indicated feeling mild depression, five, moderate, two severe and twelve mixed. Management strategies utilised were similar to those accessed during pregnancy. Four women reported utilising psychotherapy / counselling; six, antidepressants; six ‘other’ methods; one psychotherapy combined with antidepressants and one, psychotherapy combined with ‘other’. ‘Other’ methods included: active efforts to change mindset, for example by realising the children needed a functional mother; moving closer to family support; reaching out for help from friends and family; identifying relationship issues and resolving these; switching the baby to formula feeding, as breastfeeding was the issue; and mediation and relaxation techniques.

Overall, the number of women utilising techniques to manage their mental health concerns had reduced from discharge to the postnatal period as follows: medicated women decreased from 13 to six; women accessing psychological and or counselling reduced from 28 to four; and those accessing ‘other’ services, from 14 to six.
### Table 5.19 Depressive Mood at Six-Weeks Postnatal

<table>
<thead>
<tr>
<th>Six-week postnatal details (provided by participants)</th>
<th>Progressive Muscle Relaxation (n=12)</th>
<th>Acupuncture (n=15)</th>
<th>Treatment as usual (n=18)</th>
<th>Total (n=45)</th>
<th>p value</th>
<th>Risk ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeling depressed in the postnatal period</td>
<td>9 (75.0%)</td>
<td>9 (60.0%)</td>
<td>8 (44.4%)</td>
<td>26</td>
<td>0.246</td>
<td>1.67 [0.29 to 9.71]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.56 [0.08 to 3.86]</td>
<td></td>
</tr>
<tr>
<td>Feeling depressed at 6 weeks postnatal</td>
<td>6 (50.0%)</td>
<td>5 (33.3%)</td>
<td>6 (33.3%)</td>
<td>17</td>
<td>0.484</td>
<td>0.80 [0.12 to 5.40]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.60 [0.10 to 3.72]</td>
<td></td>
</tr>
<tr>
<td>Length of episode (days)</td>
<td>16.67 ±15.14</td>
<td>16.34 ± 15.58</td>
<td>29.19 ± 17.37</td>
<td>26</td>
<td>0.199</td>
<td>-12.85 [-26.91 to 1.21]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.33 [-14.11 to 13.45]</td>
<td></td>
</tr>
<tr>
<td>Description of depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>3 (25.0%)</td>
<td>2 (13.3%)</td>
<td>2 (11.1%)</td>
<td>7</td>
<td>0.168</td>
<td>1.33 [0.10 to 17.55]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.43 [0.04 to 5.06]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>4 (33.3%)</td>
<td>1 (6.7%)</td>
<td>0 (0.0%)</td>
<td>5</td>
<td></td>
<td>8.54 [0.31 to 236.89]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.11 [0.01 to 2.40]</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>0 (0.0%)</td>
<td>1 (6.7%)</td>
<td>1 (5.6%)</td>
<td>2</td>
<td></td>
<td>2.83 [0.15 to 52.74]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>2 (16.7%)</td>
<td>5 (33.3%)</td>
<td>5 (27.8%)</td>
<td>12</td>
<td></td>
<td>1.04 [0.15 to 7.22]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.00 [0.37 to 24.17]</td>
<td></td>
</tr>
</tbody>
</table>

| Management method employed                           |                                     |                    |                          |              |         |            |        |
| Psychotherapy / counselling                          | 2 (28.6%)                           | 0 (0.00%)          | 2 (33.3%)                | 4            | 0.398   | 0.44 [0.02 to 10.34] |
|                                                      |                                     |                    |                          |              |         | 0.25 [0.01 to 5.87] |
| Anti-depressants                                     | 1 (14.3%)                           | 3 (60.0%)          | 2 (33.3%)                | 6            |         | 1.33 [0.10 to 17.55] |
|                                                      |                                     |                    |                          |              |         | 3.67 [0.27 to 49.29] |
| Other                                                | 3 (42.9%)                           | 1 (20.0%)          | 2 (33.3%)                | 6            |         | 1.33 [0.10 to 17.55] |
|                                                      |                                     |                    |                          |              |         | 0.16 [0.01 to 3.56] |
| Psychotherapy + Antidepressants                       | 0 (0.00%)                           | 1 (20.0%)          | 0 (0.00%)                | 1            |         | 8.54 [0.31 to 236.89] |
|                                                      |                                     |                    |                          |              |         | Not estimable |
| Psychotherapy + Other                                | 1 (14.3%)                           | 0 (0.00%)          | 0 (0.00%)                | 1            |         | 0.45 [0.02 to 12.49] |

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5.2.4.3 Analysis of the Being a Mother Scale (BAM-13)

The final assessment conducted at six-weeks postnatal was the administration of the BAM scale. Mean scores obtained ranged from 8.13 ± 6.38 in the acupuncture group, to 12.92 ± 7.61 in PMR, with scores above the cut-off score of 9 being suggestive of probable early parenting distress. Whilst mean groups scores were not statistically significant different, scores in the acupuncture group were lower and below the cut-off of 9.

In the following section, findings from the semi-structured feedback forms (stage one, section B) assessing the receipt of the interventions, as well as changes to quality of sleep are presented.

1 Alpha values are set at p=0.05;
2 Acupuncture vs treatment as usual;
3 Acupuncture vs PMR;
4 Data are (%) of cases within groups or mean ± SD;
5 Other – reframing, moving closer to family support, support from friends and family, resolving relationship and or issues with the infant & utilising meditation and relaxation techniques.
5.2.5 Stage One Section B - Semi-Structured Questionnaires Assessing Intervention Experiences and Quality of Sleep

Women were provided with semi-structured questionnaires designed to gain feedback regarding experiences of treatment, as well as overall quality of sleep. The assessments were administered at the mid and end of intervention time points, after completion of sessions four and eight respectively. The analysis technique utilised to interpret the responses was summative qualitative content analysis, for which the findings are presented in detail, in sections 5.2.5.1 and 5.2.5.2 below. Women randomised to either treatment arm generally indicated finding treatments helpful, as well as different to their expectations. Overall, the benefits described from acupuncture appeared to be longer lasting, more cumulative and better able to positively impact upon mood.

5.2.5.1 Summative content analysis of intervention experiences

Findings from the summative content analysis of the interventions is provided (Table 5.20).

*Progressive muscle relaxation*

At the mid-intervention time point, participants used the following positive descriptions of their experiences of PMR: mind emptying/clearing; relaxing; calming; helpful; made me better able to deal with stress and unwind; enjoyed one hour of peace to myself; felt lighter, fresher, happier, more motivated; enabled perspective and provided me with a new self-help technique. The descriptions were then divided into categories to facilitate examination of outcomes, based on the following criteria. If for example, feeling relaxed was described for the timeframe of the session, or a short-time afterwards, comments such as these were placed into the respective categories of: ‘relaxing / beneficial – one hour’ or ‘relaxing / beneficial – short-term’. If the women additionally indicated for example, feeling relaxed and or a sense of calmness in combination with another positive observation, such as the sessions provided timeout, or the gaining a skill that could be utilised at home, comments such as these were placed in the category of ‘beneficial overall experience’. Finally, if
references were made to an overall improvement to mental health, such as feeling better able to cope with life stress, being better able to control emotions and manage anxiety and depression or improved mood, descriptions such as these were placed in the category of ‘benefit to overall mental health’. These same categories were also utilised for the examination of the acupuncture recipient responses, so as to be able to make comparisons between the two groups.

With respect to expectations regarding what PMR would entail, eleven women indicated that their experiences had been different to what they had expected, with six reporting being surprised to gain any benefit, even if it was only short-lived. The other five women indicated that they were: not anticipating how much effort and focus would be required to perform the technique; surprised that it worked this time, when in the past, it hadn’t; expecting to be randomised to acupuncture; not expecting the technique to provide an opportunity to gain perspective of life, though it did; and disappointed that PMR had been unable to reduce stress or depression, as that had been what they had anticipated.

In terms of feeling whether the four sessions had been helpful, eleven women stated that they had, with typical responses being: gaining assistance with stress; feeling relaxed; aiding sleep; and clearing of the mind. Of the four that reported mixed benefits, all stated that the downside was that outside of the hour, no tangible changes to mental health had occurred.
Table 5.20 Summative Content Analysis – Intervention

<table>
<thead>
<tr>
<th>Group allocation</th>
<th>PMR</th>
<th>Acupuncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid-intervention question 1</td>
<td>(n=16, 9 SM, 3 CL, 4 OB)</td>
<td>(n=17, 8 SM, 3 CL, 6 OB)</td>
</tr>
<tr>
<td>1. If you were randomized to receive acupuncture or Progressive Muscle Relaxation, could you please describe your experience of receiving the intervention so far</td>
<td>Not beneficial (1)</td>
<td>Not beneficial (0)</td>
</tr>
<tr>
<td></td>
<td>Relaxing / beneficial – the hour (2)</td>
<td>Relaxing / beneficial – the hour (0)</td>
</tr>
<tr>
<td></td>
<td>Beneficial overall experience (4)</td>
<td>Beneficial overall experience (3)</td>
</tr>
<tr>
<td></td>
<td>Benefit to overall mental health (5)</td>
<td>Benefit to overall mental health (10)</td>
</tr>
<tr>
<td>End of intervention question 1</td>
<td>(n=11, 6 SM, 2 CL, 3 OB)</td>
<td>(n=17, 8 SM, 3 CL, 6 OB)</td>
</tr>
<tr>
<td>If you were randomised to receive acupuncture or Progressive Muscle Relaxation, could you please describe your overall experiences of receiving the intervention?</td>
<td>Sometimes beneficial (1)</td>
<td>Not beneficial (0)</td>
</tr>
<tr>
<td></td>
<td>Beneficial – the hour (1)</td>
<td>Relaxing / beneficial – the hour (0)</td>
</tr>
<tr>
<td></td>
<td>Beneficial – short-term (1)</td>
<td>Relaxing / beneficial – short-term (1)</td>
</tr>
<tr>
<td></td>
<td>Beneficial – overall experience (4)</td>
<td>Beneficial overall experience (3)</td>
</tr>
<tr>
<td></td>
<td>Benefit to overall mental health (4)</td>
<td>Benefit to overall mental health (13)</td>
</tr>
<tr>
<td>Mid-intervention question 2</td>
<td>(n=16, 9 SM, 3 CL, 4 OB)</td>
<td>(n=17, 8 SM, 3 CL, 6 OB)</td>
</tr>
<tr>
<td>2. Has your experience so far differed from your expectation? If so, in what way?</td>
<td>Yes (11)</td>
<td>Yes (10)</td>
</tr>
<tr>
<td></td>
<td>No (2)</td>
<td>No (3)</td>
</tr>
<tr>
<td></td>
<td>No expectation (1)</td>
<td>No expectation (2)</td>
</tr>
<tr>
<td></td>
<td>Unanswered (2)</td>
<td>Yes and no (2)</td>
</tr>
<tr>
<td>End of intervention questions 2</td>
<td>(n=11, 6 SM, 2 CL, 3 OB)</td>
<td>(n=17, 8 SM, 3 CL, 6 OB)</td>
</tr>
<tr>
<td>Did your overall experience differ from your expectations? If so, in what way?</td>
<td>Yes (5)</td>
<td>Yes (9)</td>
</tr>
<tr>
<td></td>
<td>No (2)</td>
<td>No (4)</td>
</tr>
<tr>
<td></td>
<td>No expectation (4)</td>
<td>No expectation (2)</td>
</tr>
<tr>
<td></td>
<td>Yes and no (0)</td>
<td>Yes and no (2)</td>
</tr>
<tr>
<td>Mid-intervention question 3</td>
<td>(n=16, 9 SM, 3 CL, 4 OB)</td>
<td>(n=17, 8 SM, 3 CL, 6 OB)</td>
</tr>
<tr>
<td>3. Have you found acupuncture of Progressive Muscle Relaxation helpful so far and if so, in what way?</td>
<td>Yes (11)</td>
<td>Yes (17)</td>
</tr>
<tr>
<td></td>
<td>Yes and no (4)</td>
<td>Yes and no (0)</td>
</tr>
<tr>
<td></td>
<td>Unanswered (1)</td>
<td>Unanswered (0)</td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>Unsure</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----</td>
<td>--------</td>
</tr>
<tr>
<td>End of intervention question 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you found acupuncture or Progressive Muscle Relaxation helpful and if so, in what way?</td>
<td>Yes (9)</td>
<td>Unsure (1)</td>
</tr>
<tr>
<td>Mid-intervention question 4</td>
<td>Yes (10)</td>
<td>No (4)</td>
</tr>
<tr>
<td>4. At this stage, would you consider having the therapy again and if so, why?</td>
<td>Yes (16)</td>
<td>No (0)</td>
</tr>
<tr>
<td>End of intervention question 4</td>
<td>Yes (7)</td>
<td>No (1)</td>
</tr>
<tr>
<td>Would you consider having the therapy again and if so, why?</td>
<td>Yes (17)</td>
<td>No (0)</td>
</tr>
<tr>
<td>Mid-intervention question 5</td>
<td>Yes (12)</td>
<td>No (1)</td>
</tr>
<tr>
<td>At this stage, would you recommend the therapy to your friends and if so, why?</td>
<td>Yes (15)</td>
<td>No (0)</td>
</tr>
<tr>
<td>End of intervention question 5</td>
<td>Yes (9)</td>
<td>Unsure (1)</td>
</tr>
<tr>
<td>Would you recommend the therapy to your friends and if so, why?</td>
<td>Yes (16)</td>
<td>No (0)</td>
</tr>
</tbody>
</table>

The positives however were that for three of the four women, the hour to themselves was helpful, and in the other case, that learning the technique was a benefit, to 'take a moment' in the future.

---

*SM - Standard Midwifery, CL - Caseload Midwifery, OB - Obstetrician Care*
Similarly, with respect to having the therapy again, ten stated they would. Two were however unsure, with one further elaborating that she believed sessions would have to occur every three to four days, alongside meditation to achieve any longer-term benefit. Four also stated they wouldn’t seek PMR out again due to: having now learnt the technique and therefore no longer needing to learn it; having difficulty with focusing the mind and also, wishing instead to have acupuncture.

With respect to recommending the therapy to friends and family, twelve women indicated they would; two indicated that they would selectively recommend it, depending upon the dilemma faced, and whether the person was able to relax. One stated she wasn’t sure and another, that she wouldn’t recommend it, without further elaboration in either case.

At the end of the intervention, the eleven women that completed the eight sessions provided similar positive descriptions regarding their overall experiences, such as: a forced stop; a reset button that released the stress of previous week before the stress of the new week begun; the enabling of better emotional control and composure; and a wonderful feeling for the hour, until you returned to your everyday life. All of the participants indicated that after the eight sessions, they had experienced some benefits. One reported not always being able to benefit from each session however, as there were times when she was unable to relax, whereas another two indicated the benefits were only short-lived, either for the hour or shortly afterwards. Four other women felt they had gained overall benefits from the experience, with the remaining four describing that they had noticed positive changes to mental health.

Similarly, to the mid-intervention time-point, most of the women (5) reported the intervention being different to their expectations; due to either having a belief that it wouldn’t help at all, but it did or that it wouldn’t be enjoyable, but it was. Four also reported having no expectations, which was an interesting higher occurrence, than previously provided at the mid time point. The majority of women also reported that the experience was helpful overall (9); that they’d
have the therapy again (7); and that they would recommend it to friends and family (9).

No real discernible differences were noted between mid and end of intervention responses. What was noticeable however was the higher drop out by the end of the intervention. Field diary notes were consulted in regard to the individuals that did drop out to examine the reasons provided. These were found to comprise of a combination of having too many commitments, especially if the pregnancy had become of higher risk, and not feeling the benefit outside of the hour taken for the session.

Despite some overall disappointment in outcomes, the majority of participants felt PMR to be a worthwhile experience, with 31% (5/16) at the mid-intervention and 36% (4/11) at the end of intervention time point believing PMR had provided in an overall positive change to their mental health.

**Mental health orientated acupuncture**

At the mid-intervention time point, participants used similar positive descriptions of their experiences of receiving acupuncture. Examples are provided in Table 5.21 below.

Thirteen of the seventeen women indicated the benefits they experienced were beyond the short-term, of which ten noticed positive changes to mental health. Four however also reported that at this stage, benefits were relatively short-term.

Nine of the women stated their experiences were different to their expectations, with reasons provided being comprised of: expecting no benefit and being surprised at obtaining relief, as well as expecting needling to be painful, however finding that it wasn’t. Two women additionally indicated having mixed expectations, with one stating she did expect to be relaxed after treatment; however, she did not expect acupuncture to work so well for mental health concerns, and the other, that she had no expectation regarding treatment effects, however, was unaware acupuncture could be used for mental health.
All seventeen women indicated that they had found their experience of acupuncture helpful and that they would (or already had) recommend(ed) it to friends and family, with a couple of women clarifying that it may depend on the condition being experienced and whether or not the person was open-minded to non-mainstream treatments. Only one woman at this stage indicated being unsure if she would have the therapy again.

At the end of the intervention, seventeen women completed the eight sessions and provided similar positive descriptions regarding their overall experiences, with examples being: very helpful, I got more out of it than I expected; very relaxed, generally not as ‘wired’; amazing, life changing, while things still stress me out, I feel more able to cope; extremely impressed with the outcome; unexpected results, better mood and reduced stress and anxiety; as the sessions progressed I was more organised, found it easier to prioritise, was more able to think more clearly and have more positive energy and thoughts; and I loved it, it changed my outlook and temper.
Table 5.21 Examples of Women’s Descriptions of the Beneficial Effects of Acupuncture

<table>
<thead>
<tr>
<th>Acupuncture group</th>
<th>Women’s description of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>I looked forward to it, I felt calmer after each session</td>
<td></td>
</tr>
<tr>
<td>I felt lighter</td>
<td></td>
</tr>
<tr>
<td>I learnt of a new therapy that is good for health, it improved sleep, back pain like a miracle and helped me to feel more relaxed</td>
<td></td>
</tr>
<tr>
<td>I found it assisted coping with stressful situations and to be able to handle things better</td>
<td></td>
</tr>
<tr>
<td>It kept the ‘wig-outs’ at bay</td>
<td></td>
</tr>
<tr>
<td>I’m very grateful as I’m finding it working</td>
<td></td>
</tr>
<tr>
<td>It’s wonderful as physical and emotional needs have been supported and I gained perspective of my trigger</td>
<td></td>
</tr>
<tr>
<td>I have more energy and don’t feel angry anymore</td>
<td></td>
</tr>
<tr>
<td>It opened my mind up to the benefits</td>
<td></td>
</tr>
</tbody>
</table>

By this stage only one woman indicated feeling only short-term benefits, three reported overall benefits and thirteen specifically mentioned statements that were indicative of improvements to mental health. Also, akin to the mid-intervention time point, all of the women found acupuncture beneficial, and stated they would recommend it to friends and family, with only one specifying that it may depend upon the individual. All also wished to have the therapy again, whereas at the mid time point, one woman was still unsure.

Overall, when the two therapies were compared, it appeared women found the acupuncture intervention to be more beneficial, with greater numbers wishing to have it again and recommend it to their friends and family. One other notable difference was that there was a higher percentage of women in the acupuncture group indicating at both time points, improvement to mental health, that is 10/17 (59%) for acupuncture versus 5/15 (33%) for PMR at the mid-intervention time point and 13/17 (77%) for acupuncture versus 4/11 (36%) for PMR at the end of intervention time point.
Following is the summative content analysis of overall between group changes to sleep.

5.2.5.2 Summative content analysis of quality of sleep

In Table 5.22 the findings from the summative content analysis of between group changes to sleep are provided.

As can be seen in Table 5.22, the vast majority of the participants complained of poor sleep. At the mid-intervention time point, only two women indicated sleeping without disturbance, one in treatment as usual, and the other in the PMR group, with no apparent insomnia or pregnancy related issues impacting at that time. Only one other woman indicated obtaining adequate rest in the acupuncture group, even though she also stated that her sleep was disturbed.

Reasons for reported disruptions encompassed a broad range of issues across psychological, physical and environmental domains. Many women described taking a considerable time to fall asleep, due to: stress, worry, anxiety, having many things to consider in regard to work and future plans, as well as not being able to ‘switch off’ their minds. Others also cited physical complaints such as heartburn, muscle aching and joint pain, sciatica, and frequent visits to the toilet being the main reasons for restlessness and waking at night.

Numerous women also indicated that upon waking, they had great difficulty falling back to sleep. Some women also mentioned that young children waking and partners going off to work, prevented them from catching up on sleep in the early morning. For the vast majority, it was a combination of psychological and physical disturbances that resulted in very poor quality of sleep.
### Table 5.22 Summative Content Analysis of Between Group Intervention

#### Changes to Sleep Quality

<table>
<thead>
<tr>
<th>Mid-intervention</th>
<th>PMR (n=16, 9 SM&lt;sup&gt;a&lt;/sup&gt;, 3 CL&lt;sup&gt;b&lt;/sup&gt;, 4 OB&lt;sup&gt;c&lt;/sup&gt;)</th>
<th>Acupuncture (n=17, 8 SM&lt;sup&gt;a&lt;/sup&gt;, 3 CL&lt;sup&gt;b&lt;/sup&gt;, 6 OB&lt;sup&gt;c&lt;/sup&gt;)</th>
<th>Treatment as usual (n=19, 11 SM&lt;sup&gt;a&lt;/sup&gt;, 3 CL&lt;sup&gt;b&lt;/sup&gt;, 6 OB&lt;sup&gt;c&lt;/sup&gt;)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep ok</td>
<td>1</td>
<td>Sleep ok</td>
<td>Sleep ok</td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td></td>
<td>Sleep disturbed but ok</td>
<td>Sleep disturbed but ok</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sleep disturbed / no change</td>
<td>Sleep disturbed / no change</td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>/ no change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>8</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>/ worsening</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>5</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>/ but improving</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End of intervention</td>
<td>PMR (n=11, 6 SM, 2 CL, 3 OB)</td>
<td>ACU (n=17, 8 SM, 3 CL, 6 OB)</td>
<td>TAU (n=19, 10 SM, 3 CL, OB)</td>
</tr>
<tr>
<td>Sleep ok</td>
<td>-</td>
<td>Sleep ok</td>
<td>Sleep ok</td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>-</td>
<td>Sleep disturbed but ok</td>
<td>Sleep disturbed but ok</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sleep disturbed / no change</td>
<td>Sleep disturbed / no change</td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>-</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>/ no change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>7</td>
<td>3</td>
<td>17</td>
</tr>
<tr>
<td>/ worsening</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep disturbed</td>
<td>4</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>/ but improving</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> SM - Standard Midwifery,  
<sup>b</sup> CL - Caseload Midwifery,  
<sup>c</sup> OB - Obstetrician Care
At this mid-intervention time point, two women in the treatment as usual and PMR groups stated that their disturbed sleep had not changed. Four in acupuncture group also indicated no changes had occurred by this time. Sixteen in the treatment as usual, eight in the PMR and two in the acupuncture group reported that disturbed sleep had been worsening with gestation age. Improvements to sleep quality were not reported for any of the women in the treatment as usual group, however, in both of the intervention groups, sleep quality did improve for five women in the PMR group and ten in the acupuncture group. Three women in the acupuncture group also stated that by the end of the four sessions, sleep was no longer disturbed and they were sleeping well.

By the end of intervention time point however, there were no longer any women in any group that indicated that they were sleeping well. Many women reported that their worsening sleep was due to an increasing need to go to the toilet during the night, as well as having more difficulty finding comfortable positions to lie in for any length of time. As had been the case at the mid-intervention time point, only one woman in the acupuncture group indicated that whilst her sleep was disturbed, she was still sleeping adequately well. Worsening of sleep however occurred across all three groups, with seven in the PMR, three in acupuncture and seventeen in treatment as usual indicating more difficulty. As was seen at the mid-intervention time point, improvements to sleep, whilst still disturbed also occurred, particularly for women in the intervention groups, with four women in PMR and eleven in the acupuncture group observing positive changes. Unlike the mid-intervention time point however, one woman in the treatment as usual group also reported some overall improvements to sleep quality.

In summary, the summative content analysis of between group intervention changes to sleep quality indicated that women in both of the treatment groups fared better than those in the treatment as usual group, as less experienced worsened sleep and more reported overall improvements to quality during the that time. It was also observed that women in the acupuncture group demonstrated greater overall improvements than women in the PMR group.
with less women reporting worsening [3/17 (18%) for acupuncture versus 7/11 (64%) for PMR], and more reporting improvements in quality [11/17 (65%) for acupuncture versus 4/11 (36%) for PMR].

The findings from these semi-structured questionnaires mirror those previously obtained for the quantitative mood score questionnaires, whereby it was demonstrated that the greatest overall improvements to both mood and quality of life were seen to occur in the acupuncture group. In addition, that improvements seen in the PMR group were less than those obtained from acupuncture, however, greater than those seen in the treatment as usual group.

In the next chapter, the quantitative findings from stage one section B, analysis of between group post-intervention changes in biomarkers are provided.

**5.3 Summary**

In this chapter, the findings from stage one of this mixed-methods study, that utilised both quantitative and qualitative RCT methodologies to explore the feasibility of utilising acupuncture for antenatal mental health concerns, were provided. In the chapter to follow, further examinations from the RCT, of pre- and post-intervention biomarker analysis will in addition be explored in this regard.
Chapter 6
Between Group Analysis of Pre-and Post-Intervention Differences in Participants’ Biomarkers Cortisol, DHEA and Oxytocin
In this chapter, the between group pre-and post-intervention analysis of changes to biomarkers cortisol, DHEA and OT are presented. All analysis was performed using SPSS software (version 24.0). Of the 57 randomised participants, 46 completed the intervention and provided both pre- and post-intervention samples, hence per-protocol analysis was conducted only on those participants who provided samples at each time point.

6.1 Analysis of Time of Sample Collection Variation

As previously discussed in chapter 4, in order to minimize the impacts of diurnal and pulsatile fluctuations upon hormone concentrations, within individual saliva collection times for both the pre- and post-time intervention samples were collected as closely as possible to the same time of day. Descriptive statistical analysis was performed (see chapter 4) to assess the overall variability of sample collection times. Findings presented in Table 6.1 demonstrate that whilst the longest time in between the two collections was 8 hours, the majority of participants had their two samples collected within one hour of each other (mean 0.7174 ± SD 0.49). As diurnal peaks and troughs also impact upon resultant cortisol and DHEA concentrations, the data set was additionally analysed to determine the average time of day of sample collection.

<table>
<thead>
<tr>
<th>Variable (hours)</th>
<th>Range</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean statistic ± (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post minus pre-sample collection time differences (n=46)</td>
<td>12.00</td>
<td>-4.00</td>
<td>8.00</td>
<td>0.7174 ± (0.4290)</td>
</tr>
</tbody>
</table>

Findings presented in Table 6.2 show that the majority of pre-intervention samples were collected at 12.21 pm, and post-intervention at 1.04 pm, hence the majority of samples were collected several hours past the greatest time of diurnal flux (Salimetrics, 2016).
Table 6.2 Descriptive Statistical Analysis of Average Time of Sample Collection

<table>
<thead>
<tr>
<th>Variable (hours. mins)</th>
<th>Range</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average pre-collection time</td>
<td>10</td>
<td>8</td>
<td>18</td>
<td>12.35</td>
<td>2.584</td>
</tr>
<tr>
<td>Average post collection time</td>
<td>10</td>
<td>9</td>
<td>19</td>
<td>13.07</td>
<td>2.265</td>
</tr>
</tbody>
</table>

6.2 Group Pre-and Post-Intervention Biomarker Ranges

A wide variation in pre-and post-intervention hormone levels were seen amongst individuals, both within groups, as well as between groups (see Table 6.3). In the case of OT, pre-intervention detection ranged from very low levels of 11.15 to as high as 203.87 pg/ml, with similarly broad ranges also being observed post-intervention, from 12.43 to 284.24 pg/ml. Large ranges were also seen for pre-and post-cortisol from 0.14 to 0.77 g/dL and 0.05 to 0.89 g/dL, and pre-and post DHEA from 14.91 to 315.52 pg/ml and 16.82 to 277.13 pg/ml respectively. A variety of flux was also seen with respect to individual post intervention hormone concentrations changes, with levels being seen to increase, decrease, as well as stay much the same (see Appendix AC).

Table 6.3 Participant Pre-and Post-Intervention Biomarker Concentration Ranges

<table>
<thead>
<tr>
<th>Concentration (lowest to highest) *</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-OT (pg/ml)</td>
<td>38.53 - 175.14</td>
<td>33.89 - 155.14</td>
<td>11.15 - 203.87</td>
</tr>
<tr>
<td>Post-OT (pg/ml)</td>
<td>23.60 - 119.59</td>
<td>23.47 - 284.24</td>
<td>12.43 - 149.22</td>
</tr>
<tr>
<td>Pre-cortisol (µg/dL)</td>
<td>0.18 - 0.37</td>
<td>0.14 - 0.76</td>
<td>0.14 - 0.77</td>
</tr>
<tr>
<td>Post-cortisol (µg/dL)</td>
<td>0.21 - 0.49</td>
<td>0.05 - 0.61</td>
<td>0.14 - 0.89</td>
</tr>
<tr>
<td>Pre-DHEA (pg/ml)</td>
<td>54.51 - 315.52</td>
<td>14.91 - 303.01</td>
<td>19.67 - 203.60</td>
</tr>
<tr>
<td>Post-DHEA (pg/ml)</td>
<td>30.98 - 277.13</td>
<td>16.82 - 138.12</td>
<td>19.34 - 205.63</td>
</tr>
</tbody>
</table>
6.3 Examination of Participant Pre- and Post-Intervention Cortisol to DHEA Ratios

As previously described, the calculation of a ratio of cortisol to DHEA concentration is proposed to be a superior method by which to assess the functionality of the HPA axis, as when the two hormones are assessed in reference to each other, they reportedly provide a more accurate indication of allostatic load (Maninger, Wolkowitz, Reus, Epel, & Mellon, 2009), as a consequence of their interactive and antagonistic nature (Guerry & Hastings, 2011). To this aim, pre-intervention and post-intervention cortisol: DHEA ratios were calculated for each individual (n=46). Mean group pre-and post-intervention cortisol: DHEA were calculated and plotted as bar charts so as to examine the overall distribution of the means and level of skewness. As can be seen in Figures 6.1 and 6.2, ratio means were not normally distributed.

In order to compare randomised group post-intervention cortisol: DHEA ratios to those obtained at baseline, the ratios were first logged transformed to...
provide normal distributions towards the mean, as can be seen in Figures 6.3 and 6.4.

6.4 Comparison of Individual Pre- and Post-Intervention Cortisol: DHEA Ratios

Upon determining that log transformation of the cortisol: DHEA ratio provided an improved distribution of the means towards the norm, logged individual pre- and post-intervention ratios were plotted in scatter plots to examine the overall distribution of participant ratios, as well as to assess for the presence of outliers; see Figures 6.5. A line of best fit was also calculated for each group and is provided in Figure 6.6.
6.5 Comparison of Between Group Post- to Pre-Intervention Cortisol: DHEA Ratio Changes

Between group changes in post to pre-intervention cortisol: DHEA ratio means is presented in Figure 6.7.
As can be seen in Figure 6.7, post-intervention cortisol: DHEA ratios appeared to increase in both the acupuncture and PMR group, with a more noticeable increase being seen in the acupuncture group when compared to the PMR group; whereas, post-intervention cortisol: DHEA ratios appeared to decrease in the standard care group.

6.6 Analysis of Between Group Post- to Pre-Intervention Cortisol: DHEA Ratio Changes

In order to analyse between group post- to pre-intervention changes to logged cortisol: DHEA ratios, it was considered that the simplest approach to minimise errors was the generalised linear model, in which changes to logged post-intervention cortisol: DHEA ratios were predicted by both logged pre-intervention cortisol: DHEA ratios, as well as randomised group allocation. Utilising this method, the logged post-intervention cortisol: DHEA ratios were the dependent variables that were then compared to group allocation (as a factor [BY]) and the logged pre-intervention cortisol: DHEA ratios (as a covariate [WITH]). Incorporated into this model, group allocation, logged pre-intervention cortisol: DHEA ratios and the intercept were all included.

As both cortisol and DHEA concentrations have been reported to vary as a function of gestation age, whereby cortisol levels increase (Allolio et al., 1990; Buss et al., 2012; DiPietro, Costigan, Kivlghan, Chen, & Laudenslager, 2011; Goland, Conwell, Warren, & Wardlaw, 1992; Harville et al., 2007), and DHEA levels decline (Bloch, Daly, & Rubinow, 2003; Goland et al., 1992; Monticone, Auchus, & Rainey, 2012; O’Leary, Boyne, Flett, Beilby, & James, 1991) over time, it was considered imperative to also incorporate into the model an adjustment for the number of days the participants were in the intervention, as some women were unable to complete the treatment regimen within the specified timeframe. Consequently, the gestation age at which the end of intervention sample was collected varied amongst individuals. Similarly, an adjustment for the presence of a male foetus was also incorporated, as the in-utero presence of this gender had been reported in one study to be associated with higher
maternal cortisol concentrations ((DiPietro, Costigan, Kivlighan, Chen, & Laudenslager, 2011), however, this findings was not replicated in another study (Buss et al., 2012).

Adjustments to the model were made by adding the presence of a male foetus as a factor (along with randomised group allocation [BY]), as well as the number of days in the intervention as a covariate (with logged pre-intervention cortisol: DHEA ratios [WITH]). In this model group allocation, logged pre-intervention cortisol: DHEA ratio, presence of a male foetus, days in the intervention and the intercept were included.

Findings are presented in Table 6.4 in which it can be seen that in the unadjusted model logged pre-intervention cortisol: DHEA ratios were significantly predictive of logged post-intervention cortisol: DHEA ratios (p=0.000), whereas randomised group allocation was not (p=0.065), however approaching significance. As the three-group analysis of post-intervention cortisol: DHEA ratios neared significance, an additional post-hoc exploratory analysis was performed by selectively removing cases belonging to each group at a time from the data set to enable between two group comparisons. Utilising this approach, as can be seen in Table 6.5, a significant difference in post-intervention cortisol: DHEA ratios was observed between the acupuncture and treatment as usual group (p=0.039), however not between the acupuncture and PMR group (p=0.179) nor the PMR and treatment as usual group (p=0.421). In all three cases, pre-intervention cortisol: DHEA ratios were significantly predictive of those obtained at post-intervention (p=0.000), whereas the intercept was significant in the acupuncture to treatment as usual group comparison (p=0.000) and acupuncture to PMR group comparison (p=0.022), but not for the treatment as usual to PMR group comparison (p=0.094).

In the adjusted model, logged pre-intervention cortisol: DHEA ratios were also shown to be significantly predictive of logged post-intervention cortisol: DHEA ratios (p=0.000), however group allocation (p=0.068), the number of days in the intervention (p=0.617) and the presence of a male foetus (p=0.211) were all found not to be. In both the unadjusted and adjusted models, the intercept was found to be significant (p=0.000). As neither the presence of a male foetus
(p=0.211) nor the number of days in the intervention (p=0.211) approached significance with respect to influence on post-intervention cortisol: DHEA rations in the unadjusted model, the between two group comparison was not conducted in the adjusted model.

**Table 6.4 Analysis of Between Group Post to Pre-Intervention Cortisol: DHEA Ratio Differences**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted model</th>
<th>Adjusted model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logged pre-intervention cortisol: DHEA ratio</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Group allocation</td>
<td>0.065</td>
<td>0.068</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.002</td>
<td>0.029</td>
</tr>
<tr>
<td>Presence of a male foetus</td>
<td>N/A</td>
<td>0.211</td>
</tr>
<tr>
<td>Days in the intervention</td>
<td>N/A</td>
<td>0.617</td>
</tr>
</tbody>
</table>

Dependent variable logged post-intervention cortisol: DHEA ratio; alpha levels were set at p≤0.05.

**Table 6.5 Dual Group Analysis of Unadjusted Post to Pre-Intervention Cortisol: DHEA Ratio Differences**

<table>
<thead>
<tr>
<th>Variable</th>
<th>ACU vs UC</th>
<th>ACU vs PMR</th>
<th>PMR vs UC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logged pre-intervention cortisol: DHEA ratio</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Group allocation</td>
<td>0.039</td>
<td>0.179</td>
<td>0.421</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.000</td>
<td>0.022</td>
<td>0.060</td>
</tr>
</tbody>
</table>

Dependent variable logged post-intervention cortisol: DHEA ratio; alpha levels were set at p≤0.05.

**6.7 Examination of Participant Pre-and Post-Intervention OT Concentrations**

Mean group pre- and post-intervention OT concentrations were plotted as bar charts to examine the distribution of the means and level of skewness, and as can be seen in Figures 6.8 and 6.9, ratio means were not normally distributed.
As the distribution of participant pre- and post-intervention OT concentrations were skewed, OT concentrations were log transformation of to examine determine whether distribution towards the mean could be improved. As can be seen in Figures 6.10 and 6.11 log transformation did provide more normally distributed means of participant OT concentrations.
6.8 Comparison of Individual Pre- and Post-Intervention OT Concentrations

Upon determining that log transformation of OT concentrations provided an improved distribution of the ratios towards the norm, logged individual pre- and post-intervention ratios were compared in dot plots to assess the overall distribution of OT concentrations, as well as for the presence of outliers (Figure 6.12). A line of best fit was also calculated for each group allocation, as provided in Figure 6.13.

Figure 6.12 Dot Plot of Pre- and Post-Plot of Intervention OT Concentrations

Figure 6.13 Line of Best Fit Dot Plot of Pre- and Post- Plot of Intervention OT Concentrations

6.9 Comparison of Between Group Pre- and Post-Intervention OT Concentration Differences

A histogram representation of the between group pre- and post-intervention mean OT concentrations differences is presented in Figure 6.14. As can be seen, mean post-intervention OT concentrations appeared to slightly increase for the acupuncture (ACU) and treatment as usual.
As can be seen, mean post-intervention OT concentrations appeared to slightly increase for the ACU and TAU groups and slightly decrease for the PMR group. Overall little pre- and post-intervention changes appeared to have occurred both within as well as between groups.

6.10 Analysis of Between Group Post to Pre-Intervention OT Changes

An identical analysis was performed to examine between group logged post-intervention to logged pre-intervention OT concentration differences in both the unadjusted model and the model adjusting for the presence of a male foetus and the number of days in the intervention (completing gestation age). Using this method, the dependent variable (logged post-intervention OT concentration), was compared to group allocation as a factor (BY), and logged pre-intervention OT concentration as a covariate (WITH). In the model, group allocation, logged pre-intervention OT concentration and the intercept were all included.

For consistency, the model was also adjusted the presence of a male foetus as a factor (along with randomised group allocation [BY]), as well as the number of days in the intervention as a covariate (with logged pre-intervention OT concentrations [WITH]). In the model group allocation, logged pre-intervention
OT concentrations, presence of a male foetus, days in the intervention and the intercept were all included.

Findings are presented in Table 6.6 in which it can be seen that in the unadjusted model pre-intervention OT concentration was significantly predictive of post-intervention OT concentrations (p=0.004), however randomised group allocation was not significantly predictive of post-intervention OT concentration (p=0.321). In the adjusted model, pre-intervention OT concentration was also seen to be significantly predictive of post-intervention OT concentration (p=0.002), however, group allocation (p=0.271), the number of days in the intervention (p=0.439) and the presence of a male foetus (p=0.159) were all found to be not significantly predictive of post-intervention OT concentration. In the unadjusted model, the intercept was significant (p<0.000), whereas in the adjusted model, this was no longer the case (p=0.076).

**Table 6.6 Analysis of Between Group Post to Pre-Intervention OT Concentration Differences**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted model</th>
<th>Adjusted model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention OT concentration</td>
<td>0.004</td>
<td>0.002</td>
</tr>
<tr>
<td>Group allocation</td>
<td>0.321</td>
<td>0.271</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.000</td>
<td>0.076</td>
</tr>
<tr>
<td>Presence of a male foetus</td>
<td>N/A</td>
<td>0.159</td>
</tr>
<tr>
<td>Days in the intervention</td>
<td>N/A</td>
<td>0.439</td>
</tr>
</tbody>
</table>

Dependent variable post-intervention OT concentration; significance levels set at p≤0.05

**6.11 Analysis of Correlation Between Mood Scores and Biomarkers of Depression and Stress**

An examination of whether any correlations were observable for the questionnaires or components of questionnaires that were found to be significantly improved in the acupuncture group and OT concentrations and cortisol: DHEA ratios, at both pre- and post-intervention time points, a non-parametric correlation analysis was conducted, for which the findings are
presented in Table 6.7. As can been seen in Table 6.7, no significant correlations between scores and biomarker measurements were observable.

**Table 6.7 Pre-Intervention Analysis of Correlation Between Mood Scores and Biomarkers of Depression and Stress**

<table>
<thead>
<tr>
<th></th>
<th>Log OT concentration</th>
<th>Log cortisol: DHEA ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPDS</td>
<td>0.809</td>
<td>0.410</td>
</tr>
<tr>
<td>Stress component of DASS-21</td>
<td>0.156</td>
<td>0.884</td>
</tr>
<tr>
<td>K6</td>
<td>0.662</td>
<td>0.056</td>
</tr>
<tr>
<td>Log OT concentration</td>
<td>-</td>
<td>0.101</td>
</tr>
<tr>
<td>Log cortisol: DHEA ratio</td>
<td>0.101</td>
<td>-</td>
</tr>
<tr>
<td><strong>Post-intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPDS</td>
<td>0.813</td>
<td>0.244</td>
</tr>
<tr>
<td>Stress component of DASS-21</td>
<td>0.985</td>
<td>0.454</td>
</tr>
<tr>
<td>K6</td>
<td>0.685</td>
<td>0.779</td>
</tr>
<tr>
<td>Log OT concentration</td>
<td>-</td>
<td>0.085</td>
</tr>
<tr>
<td>Log cortisol: DHEA ratio</td>
<td>0.085</td>
<td>-</td>
</tr>
</tbody>
</table>

Significance levels set at p≤0.05

**6.12 Analysis of between group oxytocin receptor density differences**

Attempts were made to conduct pre- and post-intervention oxytocin receptor expression analysis as described in the published manuscript (Ormsby et al., 2016), however due to the expression of this receptor being found to be very low in participants’ leucocytes, no accurate information regarding between group comparisons could be provided.

**6.13 Summary**

In this chapter examination of whether the progressive muscle relaxation or acupuncture intervention exerted influence on participants’ oxytocin, cortisol and DHEA biomarker concentrations was conducted in comparison to the standard care group. To this aim, participants’ pre- and post-intervention
salivary oxytocin, cortisol and DHEA concentrations were analysed with respect to post-intervention changes. As was seen, minimal post-intervention oxytocin concentration differences were observed amongst individuals, as well as between groups. With regard to post-intervention cortisol: DHEA ratios, minimal changes were also observed in the progressive muscle relaxation and standard care groups, with the post-intervention PMR ratios being seen to marginally increase, whereas, those in the standard care group were seen to decrease. A significant post-intervention cortisol: DHEA ratio change was however observed for the acupuncture group (p=0.039).

In the next chapter, an overall analysis of these findings, along with those obtained from the other components of this mixed-methods study, namely quantitative mood and quality of life questionnaire scores, as well as qualitative examination of the experiences of acupuncture recipients and midwives involved in the RCT will be conducted. The resultant integrated analysis of the individual components of the study will provide an overall picture of the findings of this study, as well as the possible role that acupuncture may provide as an additional therapeutic possibility for women experiencing depression during pregnancy.
Chapter 7

Qualitative Findings from In-Depth Interviews with Acupuncture Recipients and Focus Groups with Midwives
7.1 Introduction and Review

In the previous chapter, the findings from the quantitative examination of RCT changes to HPA and oxytocinergic biomarker activity were reported. In this chapter, the findings from in-depth interviews are presented along with relevant perspectives provided by the midwives.

7.2 Interview and Focus Group Participants

7.2.1 Characteristics of In-Depth Interview Participants

Ten acupuncture recipients were approached to be interviewed, however two were later unable to be contacted by the independent researcher, hence eight interviews, were conducted, taking approximately one hour each. The demographic details of interviewed women are provided in table 7.1. Participants’ ages ranged from 21 to 40. All women were married or living as a couple, the majority held a vocational qualification, and were employed on a full or part time basis. Most of the women had had no previous involvement with acupuncture. All women had previous histories of mental illness, with index episodes ranging from 5 – 26 years prior to the current pregnancy, as well as experience with using antidepressants and or counselling or psychotherapy. Three women were medicated at study onset, two with antidepressants of the SNRI class and the other, with an anti-epileptic for the management of bi-polar disorder.

7.2.2 Characteristics of focus group participants

As previously described, ward midwives were informed of the upcoming focus group sessions via email, as well posters in staff rooms. Data was not collected on what proportion of informed midwives attended the sessions. In total 16 midwives participated in the two separate focus groups conducted during the one-hour routine meeting time, with eight continuity of care model midwives attending the first and eight standard model of care midwives attending the second. Of those midwives in attendance, a portion had shared care with women enrolled in the RCT, whereas other were aware of the RCT via in-service
communication and posters displayed in the antenatal clinic. Demographic details were not collected from focus group participants.
Table 7.1 Demographic Details of Interviewed Women

<table>
<thead>
<tr>
<th>Participant Number &amp; Nationality</th>
<th>Age at study onset</th>
<th>Relationship status</th>
<th>Highest Level of Education</th>
<th>Employment Status</th>
<th>Number of children</th>
<th>Index Depressive Episode (age/phase)</th>
<th>Length of depressive history at study onset (years)</th>
<th>Medicated at study onset &amp; type</th>
<th>Previous use of acupuncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 New Zealander</td>
<td>27</td>
<td>Married or living as married</td>
<td>Vocational College</td>
<td>Full-time</td>
<td>1</td>
<td>22 / PND</td>
<td>5</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>2 Australian</td>
<td>22</td>
<td>Married or living as married</td>
<td>Vocational College</td>
<td>Not working</td>
<td>0</td>
<td>15 / Adolescence</td>
<td>7</td>
<td>Anti-epileptic for bi-polar disorder</td>
<td>No</td>
</tr>
<tr>
<td>3 Australian</td>
<td>21</td>
<td>Married or living as married</td>
<td>Vocational College</td>
<td>Full-time</td>
<td>0</td>
<td>12 / Adolescence</td>
<td>11</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>4 Australian</td>
<td>39</td>
<td>Married or living as married</td>
<td>Vocational College</td>
<td>Not working</td>
<td>2</td>
<td>25 / Non-perinatal</td>
<td>14</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5 Indigenous Australian</td>
<td>40</td>
<td>Married or living as married</td>
<td>Undergraduate Degree</td>
<td>Full-time</td>
<td>1</td>
<td>21 / Non-perinatal</td>
<td>19</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>6 Australian</td>
<td>27</td>
<td>Married or living as married</td>
<td>Year 10 High School</td>
<td>Part-time</td>
<td>2</td>
<td>14 / Adolescence</td>
<td>13</td>
<td>SSNRI Antidepressant</td>
<td>No</td>
</tr>
<tr>
<td>7 Australian</td>
<td>39</td>
<td>Married or living as married</td>
<td>Vocational College</td>
<td>Part-time</td>
<td>8</td>
<td>33 / Non-perinatal</td>
<td>6</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>8 Australian</td>
<td>36</td>
<td>Married or living as married</td>
<td>Vocational College</td>
<td>Part-time</td>
<td>1</td>
<td>10 / Adolescence</td>
<td>26</td>
<td>SSNRI Antidepressant</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Key: PND – Postnatal depression; SSNRI – Selective serotonin-norepinephrine reuptake inhibitors
7.3 Thematic Findings from In-Depth Interviews and Focus Groups – Overview

The overarching theme identified from the data was ‘feeling trapped between a rock and a hard place’, along with the three supporting themes ‘feeling stuck’, ‘give it a go’ and ‘gaining relief’. Several subthemes were also identified within each major theme, as represented in Figure 7.1.
“I think that when you Google depression and when it says how to fix it, I think acupuncture should be at the top because I don’t believe that anyone should be on prescription drugs for the rest of their life, because it doesn’t help you. It doesn’t cure you. It just takes half of your personality away...I definitely think acupuncture should be offered to everyone and it should be more commonly known, because I didn’t know about it until this study...”

(Georgia)
The overarching theme ‘feeling trapped between a rock and a hard place’ captured the dilemma women with antenatal depression faced when considering therapeutic options for the management of their symptoms whilst pregnant and the possible detrimental impacts of non-treatment or medication to both themselves and their offspring. Upon recognising their depressive episode, the women in this study articulated ‘feeling stuck’ due to the difficulties they faced ‘living with mental health issues’, as well as the knowledge that for them, previous experiences with conventional ‘treatment is hit and miss’ and additionally limited during pregnancy. When queried about reasons for joining the study, the women stated they were willing to try acupuncture and ‘give it a go’, as they knew they needed help, despite also having limited knowledge of what to expect, ‘I’d heard about acupuncture but ...’, as well as concerns, ‘I was uncertain’. Perceptions of beneficial effects expressed in ‘gaining relief’ encompassed women’s and close family or friend’s observations of positive changes after treatment, which were described as ‘a pleasant surprise’.

7.3.1 Theme One - ‘Feeling Stuck’

In ‘feeling stuck’, the women expressed the difficulty they faced, genuinely desiring to feel well and be better ‘partners’ and or ‘mothers’, yet not having access to options they felt were suitable to achieve this. In the subtheme ‘living with mental health issues’, discussions centred around past experiences with mental health concerns and awareness of triggers in, ‘it gets worse with change’. Previous attempts to recover utilising conventional approaches were described in ‘treatment is hit and miss’, with experiences being grouped into three subthemes, ‘some counsellors are good, some aren’t so good’, ‘feeling drugged’ and ‘I didn’t want to harm my baby’.

Living with mental health issues

Having a long history of depression was commonly reported, with previous onset for most occurring during hormonally laden times such as adolescence, “I’ve had depression since I was younger…. I was diagnosed with that when I
was about 13” (Annabel), and the perinatal period, “… had suffered postnatal previously” (Isabella). For others, stressful events served as triggers, such as current relationship difficulties, “My partner and I were in a really rocky place when we found out we were expecting…everything was...up in the air as to whether we were even going to stay together …” (Madison) and previous relationship demise, “I've been diagnosed with post-traumatic stress disorder in the past. It was after a breakup with my ex-partner” (Sarah).

‘It gets worse with change’

‘It gets worse with change’ was clearly identified as a major contributing factor to depression onset. For Annabel, ‘change’ triggered her index episode, “From primary school to high school I was depressed because everything changed. If my routine goes out of whack I can’t cope with it”, as well as her current antenatal depression. Others similarly reported that being pregnant had added considerable stress to their lives, creating both “anxiety and anticipation” (Isabella) of impending change, as well as the “few things at once” requiring attention, being “just a lot” (Bree) to manage. Realising “emotions were heightened while pregnant” (Bree), these women identified they were experiencing mental health difficulties when they couldn’t ‘cope’ with these changes.

Key areas of recognised pressure included career, housing and financial insecurity; pre-existing or pregnancy related relationship difficulties; co-morbid pregnancy ailments or complications and the possibility of postnatal depression. Women who had to maintain full-time work as well as long commutes to manage housing commitments, reported being “wound up from the work day” (Isabella). One feared job loss and was “too scared to tell work” about the pregnancy, until “they worked it out, because my belly was growing” (Bree). Co-morbidities such as back pain, sciatica, nausea and vomiting also worsened symptoms, as did obstetric complications:

“...I'd noticed myself spiralling downhill during the pregnancy and not being able to be happy and excited. I was very fearful throughout the whole
pregnancy. I still am in regards to what the outcome is going to be ... halfway through my pregnancy I found out one of my babies has hypoplastic left heart syndrome which can lead to a very tragic outcome. It still could. So it’s very hard to enjoy the pregnancy ... I found myself stressing continuously if I was going to maintain the pregnancy ... I had bleeding a couple of times early on ... I know what a normal pregnancy is supposed to feel like, and the happiness, the excitement and the joy and everything. This pregnancy just wasn’t like that ... it’s very fearful and constant thoughts of what if and what may go wrong, and often tears” (Sarah).

Concerns about managing in the postnatal period were also expressed, when “you’re feeling a little bit overwhelmed from either lack of sleep or emotions” (Sarah).

‘Treatment is hit and miss’

A major theme to emerge from discussions regarding experiences with conventional options was that of mixed success, with overall dissatisfaction predominating.

‘Some counsellors are good, some aren’t so good’

One participant reported positive experiences with counselling however felt it was no longer an option to pursue, “because I said what I needed to say and I felt a lot better about the situation” (Bree).

Another expressed mixed success with clearly more negative than positive outcomes, stating “some of them [counsellors] aren’t so good and some of them are good” however, “… for some reason once something changes they don’t know how to keep me on the same level” and in addition, “I didn’t find it all that helpful because of the way they sit there judging you all the time” (Annabel).

Others were even less positive, reporting that going along “to talk about it [depression] and work it out and that sort of stuff. Honestly, I don’t really think any of it helped too much” (Madison), and similarly:
“No. I didn’t find it helpful. Bringing up the things that happen and talking about it, I don’t find resolving. It just made it worse I think...it brought up memories that I didn’t even know I had...that upset me...if I’ve suppressed these feelings or memories, then I’ve suppressed them for a reason” (Georgia).

‘Feeling drugged’

Overall dissatisfaction with medication were also the predominantly expressed views. Only one participant appeared not to question taking medication, even though she had received conflicting advice. Her perinatal Psychiatrist had suggested “I’m someone who can never come off it...actually at the end of my last pregnancy – they increased my dose”. This had occurred after a general practitioner (G.P) had told her in the previous pregnancy to come “straight off my antidepressants because I was going to murder my baby”, however after doing that, she had had “a really hard time” (Odette).

Annabel similarly noticed some benefits from medication, however she also stated that she “didn’t like it”. She had experimented with taking only a “small dose at a time”, to try to balance herself out, and at the same time minimise unpleasant effects, which she also admitted was “… not the best way. It’s probably the easiest way”.

Other expressed much stronger views of dislike of medication, citing non-effectiveness and unpleasant side effects like blunted emotionality:

“I honestly don’t even think the medication was working. To me it doesn’t affect me. Well it does in a way that it holds you back. I feel it makes you a different person, like it takes away your opinions ... it was just I didn’t have a voice because I was just drugged up”, “… it takes half of your personality away ... it made me dull, so dull to be around. I was just this mute ... I didn’t feel that I was myself and I didn’t want that…”, “…and there are all of the side effects that came with it. It was just not good” (Georgia).

“One made me blink all the time. One made me yawn all the time...Lexapro or something like that, made me violently sick all the time” (Sarah).
‘I didn’t want to harm my baby’

In addition to unwanted side effects, uncertainty regarding foetal toxicity was a clearly expressed eliminator of medication for a number of the participants, as typified by Sarah’s statement:

“I had tried different medications in the past and didn’t really want to take anything while I was pregnant because I knew whatever you take obviously can affect the baby... That’s why I was really against medication I guess for depression during this pregnancy”.

Experienced limitations with Western medical approaches such as these expressed by participants in ‘treatment is hit and miss’, were similarly echoed by midwives in the focus groups:

“... women with depression and anxiety, a lot of them aren’t medicated. They’re reluctant to go to talk to anybody about it, GPs, they’re reluctant to go and see a psychologist, psychiatrist, be on medication. But if they knew that [acupuncture] was here they may see it as a good alternative” (MW Focus groups).

“...some women come off medication, antidepressants, anti-anxiety medication, what’s the option for them?” (MW Focus groups).

“modern medicine doesn’t give people what they need or what they want. They think they have all the answers but they don’t” (MW Focus groups).

7.3.2 Theme Two - ‘Give it a Go’

The inadequate and or unsuitable management of the participants symptoms using conventional approaches left the interviewed women in a difficult place in that they not only continued to experience unpleasant mood disturbances, they also felt a sense of frustration and anxiety regarding what else, if anything, they could do to better manage their symptoms. Not wanting “to have anxiety or depression at all” (Georgia), or “to be on tablets either” (Georgia), all of the women in this study arrived at a position of being willing to try acupuncture
and ‘give it a go’, in recognition of being “…at that point where I’m definitely not going to turn down help” (Bree). The theme ‘give it a go’ not only reflected the sense of frustration the women felt with their narrowed treatment options, but also the mixture of open-mindedness and or desperation with which the women approached treatment, as most had ‘heard about acupuncture but…’ had very little knowledge of what it entailed and unsurprisingly, also expressed some fears and anxieties about treatment in ‘I was uncertain’.

In the focus group sessions, the midwives also discussed this sense of desperation amongst the women. When discussion centred around cost being a possible barrier to women taking up acupuncture if it was available in mainstream care, a number of midwives expressed a view that whilst it may be an issue for some, “if they’re serious they would find their money for it”, as “most of our women … are pretty happy to pay for … a couple of sessions…”, as “when they’re desperate…they try anything” (MW Focus groups).

‘Heard about acupuncture but…’

Examination of the women’s pre-existing knowledge of acupuncture identified a range from having heard of it but “I never really knew anything about acupuncture” (Annabel) to familiarity with it for specific clinical applications, such as neck pain, stress relief, fertility and to “bring on labour or to help ease out labour when it finally comes” (Madison).

Apart from ‘bringing on labour’, the women generally “hadn’t really specifically heard anything about using it [acupuncture] during pregnancy” (Madison), with the exception of Madison, who had just recently been exposed to this possibility on a Facebook “mum’s group”, in which she discovered that “they were talking about that it’s safe during pregnancy”. Probing for knowledge of use for mental health issues similarly revealed little knowledge of or consideration of this possibility, apart from again in Madison’s case, in which she indicated she had “definitely heard that it was good for stress relief”.

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‘I was uncertain’

With respect to the utilisation of a predominantly unknown therapy that involved the use of needles, it was not surprising that some of the five acupuncture naïve women expressed apprehension prior to their first session in ‘I was uncertain’, as “I’d never had acupuncture before so I wasn’t really aware of what would happen and [I was] a bit nervous” (Georgia).

In regard to a fear of needles, a range of views was expressed from “I was very scared of the acupuncture because I don’t like needles” (Annabel), to “I didn’t expect it was going to hurt because I’ve never heard anyone complain that acupuncture hurts” (Madison).

Needle fear had also been communicated to the midwives when discussing the study with women, as a number indicated during focus group discussions, that some women were “sometimes a bit reluctant because of the needles”. As a consequence, it was concluded that acupuncture wouldn’t suit all antenatally depressed women, as “if you’ve got a fear of needles … they won’t go for it at all” (MW Focus groups).

Women reported that they were comfortable with the needles used in the technique, even the most needle phobic participant, who stated that “... the first couple of times that I got it done ... I got a bit scared”, but then when asked how it actually was, she stated “It was good”. She was asked to consider why her experience was so different to her fears and she suggested it was “because [it] doesn’t draw blood” (Annabel).

Additional positive feedback regarding being needled included:

“I knew enough about acupuncture to know that they don’t insert them really deep or anything like that” but “the first time...I’m wondering if this is going to sting a little bit, but no it was always fine”, “it was comfortable, yeah” (Madison); “I never ever, ever once felt a needle hurt me” (Georgia) and “honestly everything was great” (Isabella).
Similarly, in the focus groups, the midwives who themselves had experienced acupuncture reassured their colleagues, that “it doesn’t hurt” (MW Focus Groups).

A variety of pre-session views were also expressed regarding potential treatment benefits. A number approached the idea of acupuncture effectiveness from an ‘open minded’ point of view, being “Interested in the acupuncture and interested to see if you could be helped with depression during pregnancy” (Odette), and “I only just went into it with an open mind just hoping that something alternative would help apart from being medicated or having those feelings” (Isabella); however, for others, scepticism predominated:

“I did not have any kind of expectations. I didn’t think it would make me worse. I wasn’t optimistic that it would make me better. But I kept that to myself a bit. But I definitely didn’t think it would cure anything really” (Bree).

“I was very sceptical about acupuncture because I had done it before. I paid for acupuncture to be done 12 sessions previously for IVF. That never helped. So I was very sceptical that this would even help at all. I sort of went in thinking it probably wouldn’t help… I went in there thinking acupuncture, what a load of crap. It’s not going to help” (Sarah).

Nonetheless, despite the scepticism, there was also hope expressed that the acupuncture would help, “I had my doubts but I also sat down and went, look I want it to work” (Sarah).

Scepticism was also expressed in the focus groups, particularly in regard to how acupuncture could positively affect the body, with one midwife (MW) indicating that “I’m a bit of a cynic I guess” (MW Focus group). However, this was not the dominant view expressed, as the majority of midwives indicated that they had over the years, been actively “encouraging women to use” “…alternatives” such as acupuncture and naturopathy (MW Focus group).
7.3.3 Theme Three - ‘Gaining Relief’

The third major theme to emerge was ‘gaining relief’, in which the women described their largely unexpected positive experiences of acupuncture, as ‘a pleasant surprise’.

The individualised treatment tailoring comprising of an initial “good conversation about where I was at and what I was feeling and ... a general medical history”, followed by a weekly “good discussion about what was going on” and “if I was getting or feeling any better throughout” (Isabella), was noticed by participants, as well as the fact that “it was never the same process every week” (Georgia). Such an approach enabled the women to feel as though treatment was “specifically catered to me, what I needed and what pressure points on that particular day were going to help me” (Sarah).

‘A pleasant surprise’

With respect to how participants actually felt during and after the treatments, all indicated experiencing positive effects.

Sarah, who had received acupuncture for fertility and IVF support discerned gaining benefits from the study acupuncture that she had not experienced previously. When comparing the acupuncture she had received for fertility support in shopping malls, she stated the study acupuncture was very different, in that it “…wasn’t just like out of the textbook where okay this needle is going to do the same job for everybody”. Similarly, when recalling her experience of acupuncture for IVF, she stated:

“...you didn’t walk out of the session feeling any different...definitely didn’t help with ... me being able to relax“ whereas the acupuncture in this study “... actually allowed me to be able to temporarily switch my brain off or not go back to a certain thing that’s irritating me or upsetting me, or has helped me better to relax ...I definitely wasn’t expecting that” (Sarah).
In addition to relaxation, participants described experiencing other beneficial effects such as refreshment, calmness, an enhanced ability to cope and increased positivity and motivation:

“I felt a lot more relaxed … I don’t know how to explain it. You felt fresh for the new week… So instead of me going from being - cranky from the end of the last week to being able to cope again. So I could handle with the whole having to get our house ready for a baby … It was a stressful time” (Annabel).

“…it was like I just took a step back from what I used to…and I just let it go…I felt very at ease with certain things. I wasn’t worried about anything, like I was at a normal level of worry; not overreacting, heart palpitations, shaking type of stuff, yeah. I wasn’t on edge” (Georgia).

“… definitely … feeling really good … it must have brought me down a notch … I felt more positive and I know I felt more motivated again” (Eloise).

When questioned about how long the treatment effect lasted and whether the effects appeared to accumulate, women typically reported that yes “over time it grew into longer periods…” (Georgia).

“Well I was definitely able to relax during the sessions…and as I started to realise that I was getting benefits, even afterwards…” (Odette).

“… it’s sort of had some ongoing benefits … I found each time did allow me to extend how long a time period I could relax for” (Sarah).

A number of women described gaining a sense of lightness, “I kept feeling lighter … it really felt like a weight had been lifted off my shoulders” (Madison), “I just felt like I was not necessarily floating but just happy to go along with the rest of the day” (Sarah). At the time of the interview, Georgia described still feeling the benefits:

“I still find it lasting now … I’m much more yeah, just chilled out” and feeling “… relaxed … more energy and a lot more focused… I feel good within myself… I’m not as negative …I’m a lot happier … in my body I feel fantastic, yeah” (Georgia).
The midwives with experience of acupuncture predominantly concurred, stating, “it’s actually quite calming”, “very helpful”, “beneficial” and “what it does for you is incredible”. Only one indicated “I did use acupuncture once without much benefit, but I have no problem with trying again if I have any issues”. A number also indicated knowing “people who swear by it” (MW Focus Groups).

A number of the participants also reported noticing other seemingly unrelated improvements:

“I could take a deep breath and not hurt anymore, like I no longer had the pain in my chest ... sciatic nerve – had that really bad and she helped me with that, yeah, which was awesome ... I haven’t had one pain relief tablet since she started... I was just in pain with a lot of other things in my body, but during the course she has helped that even if she didn’t mean to” (Georgia)

“...that night afterwards I was getting up a lot less frequently to go to the toilet ... I was able to sleep more. I was able to have less dreams or less nightmares. I was able to turn my brain off and go to sleep, where normally I could lay there for three or four hours before I’m even able to get to sleep” (Sarah).

When specifically asked if partners, other family members and friends had noticed changes in them, participants typically indicated that yes, that had been the case:

“He's [partner] like you come out of these sessions and you....you always seem so much brighter ... I didn’t end up with postnatal depression....my partner has turned around quite a few times and said you know, I wonder if it was the acupuncture... he’s mentioned to a couple of our doctors ... and even just friends... she’s so bright and cheery. I wonder if it was because of that” (Madison)

“Oh, huge difference. He just said like “I can talk [to you]....he used to talk to me and I was always on the defence...he noticed it – even my children. I pick them up from school and ‘are you okay mum?’”. “Yeah, why?” “You’re happy, you’re happy” (Georgia)
The interviewer also purposely prompted women’s responses around the possibility that the benefits experienced were simply due to time out and having someone to talk too, however overall, participants were able to discern the differences:

“I tend to talk to people anyway so I don’t know that just the talking ... I’ve got quite a good support network so I think the talking and the therapy kind of combined were what helped” (Isabella).

“I definitely did relax more than if I was lying down” (Eloise)

Only one participant was unsure how much effect was just from time out for herself however, she also stated “…it made me calmer and more motivated, but overall, even if it was just...having the quiet time every week, it was...a positive experience and I’m glad I did it” (Odette).

Some of the midwives also raised the possibility that what was beneficial for the women was just “having that time to themselves” and “being cared for”, suggesting the hour with the acupuncturist may have helped the women to “slow down and think about themselves” and “fully relax, because they can stop thinking”, “let go ... revitalise”. Even though these potential effects were non-specific and unrelated to treatment, they were highlighted as likely to be really important for them as “sometimes they just feel rushed in and out of here and there is no personalisation of it all”. Further elaboration however also revealed that the midwives had received feedback in regard to specific positive effects from the recipients, stating they reported “enjoying it... finding it beneficial”, “very useful, helpful, very relaxed afterwards” and “feeling better...it definitely helped” (MW Focus groups).

In addition, the midwives themselves had also observed positive changes in the women as they came out of their sessions, suggesting they appeared to be “comfortable and happy with [the acupuncturists] care”, “very jovial” and “very happy when they’re leaving”. One midwife pointed out that “they’ve come in and made a special effort” to get to their appointments, which invariably involved child minding logistics, travel expenses and the juggling of others
commitments, yet “they're very happy when they're leaving ... so they're obviously getting something out of it” (MW).

In regard to continuing with the acupuncture, participants indicated wishing to “...keep going to the end of the pregnancy because ... the sessions have helped me this far... it was definitely worth it” (Sarah) and also a willingness to have acupuncture again. Typical statements included: “I will definitely go back after I have the baby” (Isabella) and “I'm looking forward to doing in the future” (Sarah). Sarah also indicated she thought it would be an invaluable resource in “NICU wards, because I think that would be very beneficial ... when you’re going through extra high times of stress... rather than looking at the medication route...”.

In regard to recommending acupuncture to other pregnant women, Bree stated she would “definitely recommend it....even if you're not stressed and having a really, really easy pregnancy....I found it very relaxing”, with Isabella agreeing, “I definitely think if it was available it would be great”.

Participants additionally discussed recommendations to friends, “I've told her [depressed friend] if she ever falls pregnant to do the acupuncture or to even go do it now... because I found it helped” (Annabel) and family members, “my daughter has really bad anxiety. She's medicated for it. I will be recommending it to my daughter” (Sarah).

When asked about whether acupuncture should just be “available for those who have a diagnosed concern” Isabella stated “Maybe if it was for everybody it would keep some people out of that category instead of getting into it and then seeking help”. Bree added that she felt it would be useful for general health maintenance, “not even pregnant, just in life... not even if [I] was that stressed, because I think it helped me immensely in just the growth of me”. Cost was however discussed as a barrier for some with Isabella indicating she would not have had as many treatments for that reason, however Sarah considered the “benefits far outweigh whatever cost or time is involved in getting it done".
Reflecting upon the many positive experiences gained from treatment, the participants indicated their views of acupuncture had changed, even amongst those that were the most sceptical, “I’m surprised at the benefits that I’ve gotten out of it because I honestly didn’t think it was going to work. I thought it was going to be a load of hogwash...” (Sarah) and Isabella, “I never really considered [it] would help me before but I think that it did. It kept me very level headed and allowed me to unwind really well...”. In addition, Georgia indicated that she was “very impressed”, and Madison stated “it really made me realise...this actually has some merit to it”.

The midwives similarly expressed their overall positive view, that acupuncture could be “a good solution for the women” as “it’s holistic. It’s not just physical, it’s mental”, and “every part of the person” is addressed, “the woman as a whole, not just a woman who is pregnant”. This was especially seen as important as the doctors were “always aware they’re running late with the clinic and they don’t like keeping other ladies waiting so they push what they classify as small issues like the emotional stuff out to the midwives”, with an attitude that “this is not an obstetric problem, so it’s got to go somewhere else”. The midwives pointed out that this perspective had been provided by their training and working knowledge, as “nothing works in isolation in a human being”.

The final sentiment expressed by participants was in relation to hope. Rather than feeling trapped between mood disturbance and exhausted therapeutic options, the participants indicated that acupuncture had provided them with “hope” (Sarah) for the future, as being able to “look forward to something when you’re depressed or want to get out of bed when you don’t want to get out of bed...is definitely valuable...that you know is going to help ... it’s definitely priceless”. In addition, the women expressed hope that the research findings would be assimilated into clinical practise, “I just hope that it goes ahead and works and people don’t stick their nose up just because they’re [acupuncturists] not like a doctor, you know?” (Georgia).

This latter viewpoint was also discussed by the midwives in the focus groups, in which they indicated that they hoped the RCT would provide “good results that
... prove that yes it is beneficial”, as they believed “evidence” was “the only thing that would convince” the doctors, and if that barrier could be overcome, if “we could actually prove that yes it is beneficial, you would have a much bigger uptake on it” (MWs Focus group).

Overall, the positive experiences of acupuncture treatment expressed by the women for antenatal mental health concerns were typified by the following overarching quote:

“\textit{I think that when you Google depression and when it says how to fix it, I think acupuncture should be at the top because I don’t believe that anyone should be on prescription drugs for the rest of their life, because it doesn’t help you. It doesn’t cure you. It just takes half of your personality away...I definitely think acupuncture should be offered to everyone and it should be more commonly known, because I didn’t know about it until this study...}” (Georgia).

**7.4 Summary**

In this chapter, the experiences of depressed pregnant women with respect to their long histories of mental illness and frustrated attempts to rectify the consequences of this using conventional treatment, was captured in the theme ‘feeling stuck’. Wanting to feel well yet also acknowledging their limited options, the participants in this study articulated in ‘give it a go’, how they became willing to try acupuncture, despite also having some fears regarding potential needle pain, uncertainty regarding what treatment would entail, and scepticism about whether acupuncture would make any difference. After completion of treatment, all of the interviewed women reported in ‘gaining relief’, both their surprise and appreciation, that they, as well as friends and family, had observed positive changes to their mood and overall quality of life. This unexpected outcome not only changed the way in which the women viewed acupuncture, it also provided them with a sense of hope for their futures, as they felt they now had an additional therapeutic possibility they could seek out in times of future need.
The views presented in the focus group sessions were also found to be in alignment with those provided from the in-depth interviews, with the midwives concurring that treatment options were frequently inadequate or undesirable to depressed pregnant women and also that there was a real need for additional options, particularly if they were natural therapies. In addition, the midwives also re-enforced that even though women may be fearful of, or uncertain of acupuncture, they felt many would give it a try, as ‘when they are desperate’, ‘they’ll try anything’. As the majority of the midwives held positive views of acupuncture, either as a result of personal experience or the receipt of positive feedback from recipients, they were genuinely encouraging of the acupuncture study and the women’s participation in it.

Another area of confirmed alignment was that the midwives had received encouraging feedback from the acupuncture recipients, that they were gaining benefits from the study that also reflected their own observations of positive changes in their demeanour. Based upon their existing knowledge of acupuncture, as well as their own observations of the study, the midwives concluded that acupuncture should be made more widely available to women experiencing mental health difficulties during pregnancy.

Findings from the in-depth interview study were published in ‘Women and Birth’ in 2017 (see appendix AD). An additional side study was also conducted in which maternity service managers and doctors caring for women suffering from depression during pregnancy were interviewed in regard to their opinions of acupuncture for antenatal depression. These findings were then incorporated in with those obtained from the midwives focus groups, and also published in ‘Women and Birth’ in 2017 (see appendix AE).

In the next chapter, the results from stage one, the quantitative questionnaire and biomarker analyses, will be integrated and presented along with the findings from stage two, the qualitative in-depth interviews and focus groups with midwives. Such an integration process is as previously discussed, a necessary component of any MMR research design, to ensure that the findings collected from each component of the pragmatic ‘best fit’ approach are
appropriately analysed in reference to each other, so as to provide the additional context required to accurately assess acupuncture as an additional therapeutic management option for antenatal depression.
Chapter 8
Integration of Findings - A ‘Restoration Towards Balance’
8.1 Strategies Employed for the Overall Analysis of the MMR Study Findings

In this chapter, the key findings from the individual components of stages one ( chapters 5 and 6) and two ( chapter 7), of this mixed-methods study design, are integrated in order to provide an overall analysis of the feasibility of utilising acupuncture for depression experienced during pregnancy.

The approach decided upon to integrate the findings from the separate mixed-methods components was pragmatism (see chapter 5), as in this method, different qualitative and quantitative data analysis techniques are able to be utilised on a ‘best fit’ basis (Creswell, 2003). The aim was to enable the broadest potential to answer (Johnson & Onwuegbuzie, 2004) the research question regarding the feasibility of acupuncture as an additional treatment for antenatal depression. In addition, the strategy chosen for the interpretation of data generated from the different analysis techniques, was ‘complementarity’ (see chapter 4), as in this method ‘elaboration, enhancement, illustration or clarification’ of the findings from one method, are intentionally provided by the investigation of the other (Bryman, 2006; Johnson & Onwuegbuzie, 2004). The overarching intention of this combined strategy was to provide, not only a broader understanding of the issues faced by women experiencing depression during pregnancy, but also specific detail in regard to the possible remedial role that acupuncture could provide.

8.2 Integration of Findings

The approach taken to integrate findings incorporated 1) the sequential integration of findings generated from various components of the mixed-methods study for the purpose of better informing the questions posed in later stages, for example in focus groups with midwives; 2) an exploration of study outcomes in order to identify overarching and emergent themes, and 2) an examination of emergent themes in reference to the overall feasibility of utilising acupuncture as an additional therapeutic possibility for depression.
experienced during pregnancy. Considerations relating to both aspects of this integrational analysis are provided below.

8.2.1 The Overarching Theme - A Restoration Towards Balance (Homeostasis)

A restoration towards balance (homeostasis) appeared to encompass the apparent beneficial effects gained from the acupuncture intervention and therefore was identified as the central theme.

A summary of the key findings in reference to this theme, a ‘restoration towards balance’ is provided as follows:

1) The significant improvement in multiple mental health questionnaire scores; as well as an indication of an overall improved quality of life in the acupuncture group, when compared to PMR and treatment as usual.

2) The positive feedback provided in the semi structured questionnaires that demonstrated that 77.0% of acupuncture recipients felt an overall positive change to mental health after treatment, compared to only 36.4% in the PMR group. In addition, that 100% of the acupuncture recipients indicated wishing to have the therapy again, versus 63.6% in PMR.

3) The greater proportion of acupuncture recipients reporting in the semi structured questionnaires, overall improvements to quality of sleep (64.7%), when compared to PMR (36.4%) and treatment as usual (5.5%).

4) The observed significant alteration to HPA axis activity in the acupuncture group when compared to treatment as usual, which may be suggestive of an attempted normalisation of a disrupted neuroendocrine system.

5) Feedback provided from acupuncture recipients during in-depth interviews that described multiple beneficial effects from treatment, including feelings of relaxation during and after the treatment process, an enhanced ability to cope with stress, and an improved psychological
state, resulting in feeling less overwhelmed, happier, more motivated and positive. These opinions were supported by quantitative mood score questionnaire findings.

6) Additional confirmation of observed beneficial effects from midwives during focus groups, in which they detailed that they 1) noticed improved dispositions in the women who had received acupuncture, 2) had received direct feedback from acupuncture recipients detailing the positive benefits they felt they had received from treatments and 3) had reasoned that busy overwhelmed women suffering from antenatal mental health concerns would not go to the trouble of finding time and space for treatments, ‘unless they were getting something out of it’.

8.2.2 A Restoration Towards Balance (Homeostasis) – Subthemes and Concepts

Several subthemes were also identified within the major theme that acupuncture provided a ‘restoration towards balance (homeostasis)’. These subthemes encompassed how acupuncture appeared to positively impact upon depression severity, by reducing and or buffering the effects of stress, increasing the ability to cope, and promoting an improved psychological state and overall well-being. Concepts within each subtheme were additionally identified (Table 9.1), including: ‘lightening the load’; taking me down a notch’ and ‘keeping me level headed’ (subtheme one, ‘reducing and or buffering the effects of stress’); ‘I can handle it’ (subtheme two, ‘increasing coping behaviours’) and ‘brightened me up’ (subtheme three, ‘promoting an improved psychological state and overall well-being’).
Table 8.1 A Restoration Towards Balance (Homeostasis) – Identified Themes and Concepts

<table>
<thead>
<tr>
<th>Major Theme</th>
<th>Subthemes</th>
<th>Concepts</th>
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<tbody>
<tr>
<td>A restoration towards balance (homeostasis)</td>
<td>Reducing and or buffering the effects of stress</td>
<td>Lightening the load Taking me down a notch Keeping me ‘level-headed’</td>
</tr>
<tr>
<td></td>
<td>Increasing the ability to cope</td>
<td>I can handle it</td>
</tr>
<tr>
<td></td>
<td>Promoting an improved psychological state and overall well-being</td>
<td>'Brightened me up'</td>
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Positively impacted upon depression severity

8.2.3 A Restoration Towards Balance (Homeostasis)

The definition of homeostasis according to the ‘Encyclopaedia Britannica’ (2018) is “any self-regulating process by which biological systems tend to maintain stability while adjusting to conditions that are optimal for survival.... The stability attained is actually a dynamic equilibrium, in which continuous change occurs yet relatively uniform conditions prevail.... When such a system is disturbed, built-in regulatory devices respond to the departures to establish a new balance; such a process is one of feedback control... If homeostasis is successful, life continues; if unsuccessful, disaster or death ensues.”

Such a concept has an equivalent in the ancient teachings of TEAM, which specifies that balance is maintained via the continuous adjustment and restoration of equal proportions of the two complementary yet intrinsically interconnected universal forces, yin and yang (Maciocia, 1989, p160; MacPherson, Hammerschlag, Lewith, & Schnyer, 2008). The notion of Yin and Yang is represented by the Chinese characters that symbolise the respective shaded and sunny sides of a hill. From this, the ideas are extended out to encompass all things, for example: activity, energy, warmth, expansion, masculinity and the immaterial are yang; whereas rest, matter, cold, contraction, female and the material are yin (Maciocia, 1989, ch.1). Just as in
Western medical thought, when disruptive forces are applied, either too intensely over a short period of time, or less intensely but for prolonged periods, the balance between yin and yang is lost. If this concept is applied to health, disease symptomology will ensue, which in its most basic form, will result in a yin or yang deficiency, or yin or yang excess (Maciocia, 1989). Schnyer, Birch and MacPherson described this process in medical terminology as “hypo function or diminished capacity of any physiological process and decreased resistance or a hyperfunction or obstruction of any physiological process and increased reactivity” (MacPherson et al., 2008, p160). As stated by Beinfield (1991) once “the cause of disease is understood as imbalance, then the goal of treatment is to recover balance” (p44), or homeostasis.

8.2.4 Acupuncture and Homeostasis

The substitution of the term 'balance' with 'homeostasis' in reference to acupuncture is not new. Plummer (1981) discussed that whilst the concept of homeostasis is typically applied to physiological effects, there is also the possibility for this concept to be applied to both postural, as well as psychological mechanisms. Plummer additionally suggested that “a feedback type of relationship probably exists between these forms of homeostasis, and any of the body-mind type of therapies (including acupuncture and T’ai chi ch’uan), thus have a three-fold effect on man, i.e. on his physiology, his posture and his mind” (p1).

Since this time, multiple authors have suggested the homeostatic influences of acupuncture on maintaining, and or restoring health (Ballegaard et al., 1993; Guimaraes, Pinge, Yamamura, & Mello, 1997; Kim et al., 2001; Leung, 2012; Li et al., 2015; Siedentopf et al., 2005; Xia, Ding, & Wu, 2012; Zhao et al., 2006; Žukauskas & Dapšys, 1991). For example, Siedentopf and co-workers (2005) stated that acupuncture “induces beneficial effects such as the promotion of homeostasis” (p68), and also that “acupuncture might modulate homeostasis in a different way for healthy subjects than for patients” (p72). Zhao and colleagues (2006) also stated that studies in rats demonstrate “that acupuncture
can contribute to the biochemical balance in the central nervous system and maintenance or recovery of homeostasis” (p28). In addition, they suggest, that “The notion that acupuncture exerts its therapeutic effects by restoring the balance of Yin and Yang to maintain homeostasis of the body is supported by other studies... in humans” (p32). Takahashi (2013) further suggested that “Acupuncture modulates the imbalance between the parasympathetic and sympathetic activity” (p8). The similarities between the parasympathetic functions of ‘rest and digest’ or ‘feed and breed’, and the qualities of yin; as well as the sympathetic ‘fight or flight’ response, and the activities of yang, were also suggested by Cabioğlu and co-workers (2012). This idea is however complicated by the concept that ‘within yin there is also yang and within yang there is also yin’ (Maciocia, 1989), as for example ‘yang’ functions also play a key role in ‘digesting and breeding’. Nonetheless, the overall perspective that acupuncture can exert broad ranging influences to autonomic nervous system functioning (Qian-Qian et al., 2013), is reflective in part of the theories of TEAM, that suggests that all bodily systems are inseparable and interinfluencing (MacPherson et al., 2008, p16), including those pertaining to psychological and emotional well-being. Consequently, adjustments applied towards restoration of balance in one system, will automatically also impact upon all other interconnecting systems (Beinfield & Korngold, 1991).

8.2.5 Acupuncture as a Homeostatic Mechanism for Improved Mental Health

The response of the neuroendocrine system to a “state of threatened homeostasis, whereby the organism, to preserve its internal equilibrium, reacts with an array of adaptive responses” (Tafet & Bernardini, 2003, p893), was discussed in chapter 3, in reference to mental health disturbances. Whilst the return of neurotransmitters, symptoms and mood scores to within normal ranges are established indicators of restored health, Slade and Longden (2015) also argued that “Recovery is best judged by the person living with the experience” (p1). Consequently, the combination of standardised
measurements, along with those enabling the exploration of individual perspectives, could potentially provide more comprehensive assessments.

In the sections to follow, findings are discussed in reference to the overall theme that acupuncture appeared to provide a ‘homeostatic restoration’ towards improved mental health, within the context of the three emergent subthemes: *reducing and or buffering the effects of stress; increasing the ability to cope; and promoting an improved psychological state and overall well-being*. Within each subtheme, study outcomes provided by the different mixed-methods assessments are integrated, and further discussed in relation to relevant literature.

Specifically, the subthemes are discussed in reference to the: a) findings from mood and quality of life measurements (stage one - part A); b) findings from examining biomarkers (stage one - part C); c) participant feedback in semi-structured questionnaires (stage one - part B) and d) acupuncture recipient interview findings and the observations and reflections of midwives (Stage 2).

### 8.3 Integration of Findings

#### 8.3.1 Theme One - Reducing and or Buffering the Effects of Stress

The subtheme identified within the overall theme that acupuncture appeared to initiate ‘a restoration towards balance or homeostasis, was suggestive in part, of ‘how’ acupuncture may have exerted this effect, and that is, as a consequence of ‘reducing and or buffering the effects of stress’. Within this subtheme, three concepts were additionally identified which included ‘lightening the load’, ‘taking me down a notch’ and ‘keeping me ‘level-headed’.

#### 8.3.1.1 Findings from stress assessment questionnaires

Examination of the mean scores subcomponent scores of the DASS-21 (Lovibond & Lovibond, 1995) demonstrated that in addition to experiencing depression, the majority of the cohort were also co-morbidly stressed at trial entry, with severity ratings falling into the moderate to severe categories. Such a
finding was in alignment with reports in the literature, that state that depression is frequently preceded by stressful events (Heim & Binder, 2012; Nemeroff & Vale, 2005; Tafet & Bernardini, 2003), as well as followed by the subsequent development of mood disorders (Tafet & Bernardini, 2003).

Post-intervention, mean DASS-21 stress scores were significantly lowered in acupuncture group (p=0.002), and corresponded to a fall from the ‘severe’ (13-16) to ‘normal’ (0-7) category. This finding was therefore suggestive that acupuncture may have provided ‘a restoration towards balance’, by returning recipients to a ‘normal’ level of stress. Whilst mean post-intervention DASS-21 stress scores were also reduced in the other two groups, changes were more modest, and in both cases, group means remained in the ‘moderate’ (10-12) classification.

Examination of studies evaluating acupuncture for the management of stress have provided similar findings. Bauer and colleagues (2010) demonstrated significant reductions in self-reported measurements of stress in 24 participants that had received six acupuncture treatments. The findings were however limited by the absence of randomisation and control groups, as well as the small sample size. Schroeder and colleagues (2017) also reported significantly reduced stress scores when verum acupuncture was compared to sham in a cohort of 111 college students. Similarly, studies evaluating acupuncture for chronic stress (de Oliveira & Scivoletto, 2017; Huang, Howie, & Robinson, 2012; Huang, Howie, Taylor, & Robinson, 2011), and stress associated with IVF, have provided further support of beneficial effects (Balk, Catov, Horn, Gecsi, & Wakim, 2010; Huang et al., 2011; Nandi, Shah, Gudi, & Homburg, 2014). Reviews examining acupuncture for PTSD, have in addition provided evidence of benefit (Grant et al., 2018; Hempel, Taylor, Solloway, & Shanman, 2014; Hollifield, 2011; Kim et al., 2013), however, the need for further research is also generally recommended.
8.3.1.2 Findings from examining biomarkers

The impacts of stress on HPA axis functioning (Herbert, 2013; Nemeroff & Vale, 2005; Seth et al., 2016; Tafet & Bernardini, 2003), and the corresponding relationship to mental health disturbances was discussed in detail in chapter 2. The mechanism via which the body attempts to restore homeostasis after exposure to such stressors is the ‘general adaptation syndrome’ response (Selye, 1950). In this system, during the initial phase, cortisol is increased in acute ‘alarm’, until after removal of the stressor. If stressors are prolonged, cortisol remains elevated in the ‘resistance or adaptation phase’. If stressors continue to be prolonged, an ‘exhaustion’ phase may also occur (Selye, 1950), in which blunted HPA axis activity and hyposecretion of cortisol may ensue (Miller, Chen, & Zhou, 2007). Clinical studies conducted on populations exhibiting psychological distress frequently report dysregulated HPA axis activity, with elevated, blunted and dysregulated cortisol secretion being seen (Glynn, Davis, & Sandman, 2013; Guerry & Hastings, 2011; Lazinski, Shea, & Steiner, 2008; Maninger, Wolkowitz, Reus, Epel, & Mellon, 2009). Dysregulated secretion of DHEA, the anabolic hormone antagonistic to the actions of cortisol (Guerry & Hastings, 2011; Maninger et al., 2009; Wilkinson & Goodyer, 2011), has also been reported in various populations experiencing psychological disorders (Maninger et al., 2009). When these hormones are assessed in reference to each other they reportedly provide an indicator of allostatic overload (McEwen, 2004), or “the cumulative physiological burden... of accommodating multiple stressors over time” (Maninger et al., 2009, p.78). Findings may however be more difficult to interpret, in cases of dysregulated secretion.

The observed variability in cortisol and DHEA responses have been postulated to occur as a consequence of the: time since onset of the stressor; nature of the threat; emotion elicited by the stress; controllability of the stress; individual psychiatric sequelae (Miller et al., 2007); age, gender, and demographic characteristics; and time of sample collection (Maninger et al., 2009). It was interesting to observe in this study, the significant increase in the mean post-intervention cortisol: DHEA ratio amongst acupuncture recipients (p=0.039).
This finding may suggest a regulatory homeostatic effect of acupuncture, on the HPA axis system. As the change in the ratio was an increase, it is possible that the majority of the cohort were in the ‘exhaustion’ phase of the ‘general adaptation syndrome’. This likelihood is supported by the lengthy timeframe from onset of difficulties experience by the majority, as evidenced by 1) exposure to early life social adversity (recorded on medical files), 2) adolescent onset of index episodes, and 3) the continuation of ongoing stressors (baseline DASS-21 stress subcomponent scores). Compounding these factors, family histories of mental health disturbances may have additionally predisposed participants to altered stress reactivity (Brummelte & Galea, 2016; Diego et al., 2004; Gentile, 2015; Glover et al., 2010; Seth et al., 2016).

Other studies are also suggestive that acupuncture may exert influences upon HPA axis functioning. In a 2008 study by Cabioglu and co-workers (as cited in Cabioglu, 2012) acupuncture was seen to increase cortisol levels in overweight patients that were also anxious. A study by Matzno and colleagues (2014) similarly reported an increase in cortisol after acupuncture for stress alleviation, which in addition correlated with reductions in self-reported stress scores. Magarelli and co-workers (2009) likewise reported that participants receiving acupuncture for the enhancement of IVF procedures demonstrated significantly higher cortisol and prolactin levels than controls, which the authors suggested reflected “a trend toward more normal fertile cycle dynamics” (p1870).

Further support regarding possible central nervous system effects of acupuncture have additionally been provided. Ng and colleagues (2008) reported findings supportive of beneficial exert of acupuncture on subfertility, as a consequence of inhibition of sympathetic nervous system activity (via the endorphin system), which in turn reduced stress and positively impacted upon uterine blood flow. Middlekauff and co-workers (2002) similarly proposed acupuncture inhibited sympathetic nervous system activity in advanced heart failure patients undergoing acute mental stress testing. In addition, a review by Cabioglu and colleagues (2012) provided further support from multiple animal and human studies that suggested acupuncture may modulate the effects of
stress by exerting influences to enkephalin, beta-endorphin, adrenocorticotropic hormone, cortisol, serotonin and dynorphin levels, as well as the oxytocinergic, serotonergic and opioid systems. In another synthesis of the literature, Qian-Qian and colleagues (2013) report on a number of mechanistic studies that demonstrate the ability of acupuncture to influence autonomic nervous system (ANS) functioning, as well as clinical efficacy on autonomic nerve-related disorders. The authors additionally suggest that brain imaging studies demonstrate “that acupuncture treatment not only activates distinct brain regions in different kinds of diseases caused by imbalance between the sympathetic and parasympathetic activities, but also modulates adaptive neurotransmitter in related brain regions to alleviate autonomic response” (p1).

8.3.1.3 Findings from participant feedback in semi-structured questionnaires

*Improvements to sleep quality as an outcome of stress alleviation*

Feedback provided from participants at baseline reinforced the findings of the DASS-21 stress component scores, that the majority of the cohort felt stress had been a substantial contributor to overall poor-quality sleep. In particular, women reported they were unable to ‘switch off their busy minds’ as they attempted to fall asleep, as well as fall back to sleep easily once awoken, due to their ‘overactive minds kicking back in’. Benefits observed from acupuncture with respect to reduced stress component scores, and the possible homeostatic restorative influence to HPA axis functioning, was also mirrored in feedback regarding sleep quality. Specifically, acupuncture recipients reported feeling that being less stressed enabled them a better quality of sleep. This improvement was still discernible, despite increasing nocturnal urination and physical discomfort with advancing gestation. Examples of noticed benefits included ‘feeling more relaxed’, which consequently facilitated not having to ‘work so hard’ to get to sleep, as well as an easy returning to sleep if awoken; due to their minds ‘no longer working on overdrive’. As was seen in chapter 6, some women in the PMR group (36%) also reported benefits to sleep, however,
the proportion benefiting was substantially less than in acupuncture (65%). Examples provided suggested that ‘feeling more relaxed’ and ‘better able to clear the mind’ prior to sleep had been helpful. Only one woman in the treatment as usual group (5.5%) reported a slight improvement to sleep, which was reasoned to be due to less disturbance from other children.

Stress alleviation as a consequence of receipt of the intervention
As had been the case with sleep quality, feedback provided from women who have received either intervention indicated that at baseline, stress had been a major component of their overall mental health concerns. After the treatment regime however, women in the acupuncture group (77%) reported feeling ‘generally not as wired’, ‘less stressed’ and ‘more relaxed’. Similar reports of benefits, such as a ‘reset button that released pressure from the week before, for the new week ahead’ were provided by a much smaller proportion of the PMR group (36%).

8.3.1.4 Findings from in-depth interviews and focus groups with midwives

Feelings of being stressed, as well as the impacts of these stressors upon participants were further explored in in-depth interview with acupuncture recipients. Findings confirmed those provided by the cohort in the semi-structured feedback forms, that due to pregnancy being ‘a very stressful time’, it had been a major factor in triggering and or compounding existing mental health concerns.

Examination of responses with respect to treatment demonstrated that the acupuncture recipients had found treatment stress alleviating. Specifically, women noticed being ‘taken down a notch’, in combination with ‘a weight being lifted’, which then enabled them to ‘take a step back’, ‘think more clearly’ and ‘gain perspective’ of day to day stresses. As a consequence, the women felt they were more able to ‘not take work stress home’, ‘remain level-headed’ and be ‘emotionally ok’.

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Taken together, these findings suggest that acupuncture not only appeared to reduce stress but also appeared to more broadly modulate or buffer the effects of stress.

8.3.2 Theme Two - Increasing the Ability to Cope

Findings were examined in relation to the overarching theme ‘a restoration towards balance’, the subtheme ‘increasing the ability to cope’ and the concept ‘I can handle it’. No specific questionnaire was employed to examine the capacity to cope, however a question in both the EPDS and BaM-13 did address this issue; although these were not assessed individually. Consequently, exploration of women’s improved capacity to cope as a consequence of the interventions was provided from semi-structured questionnaires and focus groups with midwives.

8.3.2.1 Findings from participant feedback in semi-structured questionnaires

Improvement to sleep quality and an enhanced capacity to cope

Amongst acupuncture recipients, no direct references were made in relation to how improvements to overall sleep quality had facilitated the women’s capacity to cope with life, however women did describe being ‘more rested’, and able to ‘wake up not tired and able to face the day’, which implied an improved capacity to manage the day ahead. Amongst PMR recipients, only a minority had indicated noticing any improvements to sleep, and of these, no references were made that appeared to suggest an enhanced ability to cope as a consequence of the intervention.

An improved ability to cope after acupuncture treatment

Responses provided by the cohort of acupuncture recipients in the semi-structured feedback forms further suggested that the receipt of acupuncture had enhanced capacities to cope with life’s difficulties. Three recipients made direct comments about feeling more able to cope, which in all cases relayed that whilst ‘stressful situations’ were ongoing, acupuncture treatment had provided
sufficient benefit to enable ‘coping with day to day life and activities’. Although no specific statements were made in relation to coping amongst the PMR recipients reporting improvements, one stated feeling ‘more in control of mind, body and emotion’, which possibly could be indicative of an improved capacity to cope.

8.3.2.2 Findings from in-depth interviews with acupuncture recipients and focus groups with midwives

Sentiments expressed by acupuncture recipients in the semi-structured questionnaires relating to the ability of acupuncture to assist with coping were akin to those conveyed in interview transcripts. Typical responses indicated that due to feeling ‘relaxed’ and ‘calmer’, the women were better able to cope with their own emotions, as well as the juggle of work stress, family commitments and the busyness of life. As a consequence, the women indicated having a much greater capacity to ‘just get on with the rest of the day’.

Similar reports of the ability of acupuncture to improve the capacity to cope with stressors have been provided in the literature. For example, improvements to coping have been detailed in studies examining acupuncture for pain reduction (Gamus, Meshulam-Atzmon, Pintov, & Jacoby, 2008; Hughes, 2007; Kukuk, Lungenhausen, Molsberger, & Endres, 2005; Norrbrink & Lundeberg, 2011); fibromyalgia alleviation (Singh, Wu, Hwang, & Khorsan, 2006); fertility assistance (de Lacey, Smith, & Paterson, 2009; Grant & Cochrane, 2014; Kovářová, Smith, & Turnbull, 2010); cancer-related surgery stressors and co-morbidities (Quinlan-Woodward et al., 2016); mental health (Russinova, Wewiorski, & Cash, 2002); and chronic illness or generalised well-being (Gould & MacPherson, 2001; Paterson & Britten, 2003).
8.3.3 Theme Three - Promoting an Improved Psychological State and Overall Well-Being

Findings were examined in relation to the overarching theme ‘a restoration towards balance’, the subtheme promoting an improved psychological state and overall well-being, and the concept ‘brightened me up’.

8.3.3.1 Findings from mood questionnaires

Anxiety

Mean scores for the anxiety component of the DASS-21 at trial entry demonstrated that in addition to feeling stressed, the majority of the cohort were also co-morbidly anxious. Such a finding was not surprising, with psychological stress being a known trigger for the subsequent development of various mood disorders (Tafet & Bernardini, 2003). As had been the case for the stress subcomponent scores, the greatest post-intervention reductions in anxiety scores were seen in the acupuncture group, falling from the ‘severe’ (8-9) to ‘mild’ (4-5) category. Reductions in the other two groups were also more modest, falling from ‘severe’ (8-9) to ‘moderate’ (6-7) in treatment as usual, and staying within in the ‘moderate’ category, in PMR.

Research investigating acupuncture for the treatment of anxiety disorders has also reported some positive findings. A synthesis of the literature by Errington-Evans (2012) lead the authors to suggest that whilst the quality of the evidence and heterogeneity of study designs was highly variable, “the volume of literature, consistency of statistically significant results, wide range of conditions treated and use of animal test subjects suggests very real, positive outcomes” (p277). Comparable conclusions were also drawn by the authors of two additional reviews. In the first, Maryam Hassanzadeh and colleagues (2017) reported after examining the findings of four RCTs incorporating 595 women, that “acupuncture is an effective technique in controlling the anxiety of infertile women” (p842). In the second, authors Amorim and co-workers (2018) stated after analysing 13 studies, that “there is good scientific evidence encouraging
acupuncture therapy to treat anxiety disorders as it yields effective outcomes, with fewer side effects than conventional treatment” (p31).

**Depression**

The greatest reductions in mean DASS-21 depression scores were also observed in the acupuncture group, with scores been seen to reduce from the ‘severe’ (11-13) to ‘mild’ (5-6) category. Reductions in depression scores in the other two groups were again more modest, remaining within the ‘moderate’ category for treatment as usual, and lowering from ‘moderate’ (7-9) to ‘mild’ (5-6) in PMR. These findings were also in alignment with those obtained for the EPDS, with mean scores in the acupuncture group being statistically lowest at the end of intervention (8.95 ± 4.34, p<0.001), as well as below the cut-off (12/13) of probable depression. Congruent findings of significantly reduced antenatal depression scores were also provided by Manber and colleagues (2004, 2010) in both their pilot and full-powered RCT, as a consequence of depression specific acupuncture treatment (see chapter 3). Further support for the possible role that acupuncture may provide, has in addition been suggested in several reviews assessing acupuncture for the treatment of depression (Bosch, van den Noort, Staudte, & Lim, 2015; Samuels, Gropp, Singer, & Oberbaum, 2008; Stub, Alræk, & Liu, 2011; Wang et al., 2008; Wu, Yeung, Schnyer, Wang, & Mischoulon, 2012).

**Distress**

Examination of post-intervention findings for the non-specific measure of psychological ‘distress’ the K6 (Kessler et al., 2002), provided similar findings, with scores in the acupuncture group significantly reducing (p<0.001) from the category of ‘severe mental disorder (20-30) to ‘likely to be well’ (6-11). As was the case with the other mood score questionnaires, mean scores were also seen to reduce in both the PMR and treatment as usual groups, however falls were again more modest and remained in the same classification as at baseline, that is ‘mild to moderate mental health disorder’ (12-19). Such a finding also aligned with that provided by da Silva and co-workers (2007) in which significant reductions in self-assessment scales scores for emotional distress, as well as the impact of these stressors upon participants, was seen to occur as a consequence
of acupuncture treatment in women suffering from emotional complaints during pregnancy.

**An improved psychological state**

When assessing these findings together, it appeared that the acupuncture provided in this study positively impacted upon antenatal depression, anxiety, stress and distress. Similar findings have also been reported in multiple examinations of acupuncture for mental health co-morbidities and or generalised psychological distress. In an individual study conducted by Courbassan and co-workers (2007) participants receiving auricular acupuncture demonstrated significantly lowered indicators of anxiety and depression in a sample of 286 women with substance use issues. Similarly, Arvidsdotter and colleagues (2013) reported that acupuncture appeared “to be beneficial in reducing anxiety and depression in primary care patients referred for psychological distress” (p308). A recent synthesis of literature by Huang and colleagues (2011) assessing the psychological well-being of women undergoing acupuncture treatment for IVF similarly concluded that whilst apparent benefits are probably multi-dimensional, they are also likely to be a consequence of “the amelioration of depression, anxiety and stress” (p386). Findings from the 2014 Veterans Affairs ‘evidence map’ also aligned, stating there was evidence of positive effect of acupuncture for the treatment of anxiety, depression and PTSD (Hempel et al., 2014).

**Overall well-being**

**Findings from the WHOQoL-BREF**

The possibility of even broader ranging positive impacts of acupuncture were suggested from WHOQoL-BREF findings. Although between group differences were not significant, the mean overall score at the six-week postnatal time point was highest in the acupuncture group, and in addition, this group was the only one to obtain an individual domain score that was indicative of psychological well-being. Chang and colleagues (2007) similarly described improvement to quality of life (QoL) after acupuncture treatment in a cohort of 119 patients with HIV. Findings demonstrated significant improvements from baseline to
emotional, spiritual/peace, physical, and mental health domains, as well as significant differences between groups in all assessments apart from the emotional domain. Improved quality of life after acupuncture treatment was also reported in a RCT assessing acupuncture for breast cancer related fatigue in a cohort of 302 participants (Molassiotis et al., 2012). Haddad and colleagues (2014) similarly assessed acupuncture in regard to therapeutic effect in cancer-related psychological symptoms, including depression, anxiety, sleep disturbance, and quality of life. The authors found the therapy to be well tolerated and clearly promising in the areas assessed, however firm conclusions were unable to be made as a consequence of study heterogeneity and the incomplete reporting of methodology.

Overall, the findings from the questionnaires suggest that acupuncture may have facilitated an increased ability to cope with life stressors, which in turn may have provided an improved psychological state and overall well-being, that then could have positively impacted upon depression severity. Other studies have similarly reported broad ranging impacts from acupuncture treatment. Cabioğlu and co-workers (2007) described benefits from electroacupuncture to phobias, anger, anxiety, obsession and paranoid symptoms, in co-morbidly obese patients with psychological disturbances. Grant and Cochrane (2014) likewise reported that acupuncture reduced anxiety and stress; lessened social and relationship concern; and improved psychological coping in women undergoing IVF treatment. Assessments of psychological well-being in women undergoing treatment to enhance pregnancy success have also reported that acupuncture improves the well-being of participants (Cochrane, Smith, Possamai-Inesedy, & Bensoussan, 2014; de Lacey et al., 2009; Nandi et al., 2014), as well as their ability to cope with stress (Cochrane et al., 2014; de Lacey et al., 2009). A review by Lee (2012) similarly described benefits from acupuncture to anxiety, sleep disturbances, depression and chronic pain. Findings such as these have additionally been reiterated in recent reviews, identifying positive effect of acupuncture for the treatment of anxiety, depression, PTSD, schizophrenia and insomnia, (McDonald & Janz, 2017), as well as trauma spectrum disorders (Jonas, Walter, Fritts, & Niemtzow, 2011).
8.3.3.2 Findings from examining biomarkers

The other biomarker assessed in this intervention was the anxiolytic, antidepressive hormone, oxytocin (OT), as, congruent to the observations for HPA axis activity, dysregulated (Parker et al., 2010), lowered (Anderberg & Uvnäs-Moberg, 2000; Frasch, Zetzsche, Steiger, & Jirikowski, 1995; Hickie, Naismith, Robillard, Scott, & Hermens, 2013; Ozsoy, Esel, & Kula, 2009; Porcelli et al., 2011; Scantamburlo et al., 2007; Skouteris et al., 2008; Zetzsche, Frasch, Jirikowski, Murck, & Steiger, 1996), elevated (Cyranowski et al., 2008; Holt-Lunstad, Birmingham, & Light, 2011; J. Liu et al., 2008; Meynen, Unmehopa, Hofman, Swaab, & Hoogendijk, 2007; Parker et al., 2010; Purba, Hoogendijk, Hofman, & Swaab, 1996; van Londen et al., 1997), and disrupted patterns of peripheral release (Cyranowski et al., 2008) have been reported amongst depressed participants under a variety of different observatory and experimental conditions. Whilst no post-intervention between groups differences were noted for this assessment, this finding was in contrast to reports of significant positive regulatory effects of acupuncture on the oxytocinergic system in 12 rodent and one human study (Jiaying et al., 2008; Jun, 1992; Lei & Liu, 2005; Liu, Song, Wang, & Lin, 1992; W. Liu, Song, Yang, Lin, & Wang, 1990; Luscher, Shen, & Sahir, 2011; Markham & Koenig, 2011; Song, Liu, Gu, & Lin, 1993; Song, Liu, Yang, Lin, & Zhu, 1990; Uvnas-Moberg, Bruzelius, Alster, & Lundeberg, 1993; Yang & Huang, 2008; Zhang et al., 2012). In addition, further indirect evidence was possibly provided in 11 human studies examining acupuncture for the preparation, induction or enhancement of labour, in which significantly reduced requirements for Syntocinon augmentation were reported in the nine studies (Aghamohammadi, Behmanesh, Zafari, & Tofighi, 2011; Aghdam & Daryabakhsh, 2012; Carr & Worth, 2001; Hantoushzadeh, Alhusseini, & Lebaschi, 2007; Hickie et al., 2013; Kashanian & Shahali, 2010; Gaudernack, Forbord & Hole 2006; Skilnand, Fossen, & Heiberg, 2002; Ziaei & Hajipour, 2006), as well as a trend toward less need in another (Fatemeh & Zahra, 2010). In the remaining study, acupuncture performed in addition to intra-venous Syntocinon also demonstrated significantly improved labour effectiveness rates (Jiaying et al., 2008).
Studies investigating the effects of acupuncture on other biomarkers associated with mental health disturbances have reported similar findings. Zhou and Wu (2007) demonstrated increased dopamine levels in acupuncture recipients when compared to controls, in a small cohort of depressed women in menopause. Pohl and Nordin (2002) similarly reported that electroacupuncture reduced depression scores, as well as levels of serum the neuropeptide Y, associated with depression, in a small sample of five women suffering from major depressive disorder. Reductions in pro-inflammatory cytokines associated with major depression, along with a restoration of a normal balance between immune modulatory Th1 and Th2 cells were also seen in 95 participants receiving electroacupuncture with major depressive disorder when compared to a control group of 30 individuals (Song, Halbreich, Han, Leonard, & Luo, 2009).

Examinations of biomarkers for broader ranging psychosocial benefits of acupuncture have also been assessed. For example Arranz and colleagues (2007) reported “impaired immune functions in anxious women (chemotaxis, phagocytosis, lymphoproliferation and NK activity) were significantly improved by acupuncture, and augmented immune parameters (superoxide anion levels and lymphoproliferation of the patient subgroup whose values had been too high) were significantly diminished” (p35). Hollifield (2011) suggested that whilst specific mechanistic studies of PTSD in human subjects are yet to be performed, “extant research shows that acupuncture has biological effects that are relevant to PTSD pathology” (p769). In another area of research, Bosch and co-workers (2015) suggested that observed benefits to sleep and emotions may be due to the ‘modulating and normalising’ effects of acupuncture on the limbic-paralimbic-neocortical network. In both cases, a homeostatic restorative effect had been suggested as the overall mechanism of action. In addition, recent syntheses of the literature go further to suggest that the observed broad ranging benefits of acupuncture treatment are not only due to influences to the autonomic nervous system, motor pathways of the nervous system, the immune and endocrine functioning (Karst & Fink, 2016), but connective tissue
(Langevin, Bouffard, Badger, Churchill, & Howe, 2006), and fascia (Bai et al., 2011; Finando & Finando, 2011; Ho, 2012) at the location of needle insertion.

8.3.3.3 Findings from participant feedback in semi-structured questionnaires

In this section, the examination of the semi-structured questionnaires in relation to the major theme ‘a restoration towards balance’, focused upon ‘promoting an improved psychological state and overall well-being’.

Enhanced well-being as a consequence of improved sleep quality
As had previously been discussed in relation to stress reduction, and enhanced coping, the ability of acupuncture to ‘greatly improve’ sleep, and the capacity to ‘rest during the day’, also appeared to have contributed to ‘an improved psychological state and overall well-being’. Participant responses’ that were reflective of this subtheme included reports that not only had disturbances such as ‘dreams or nightmares’ and ‘anxiety’ reduced, positive improvements to mental health such as feeling ‘more relaxed’, ‘physically and mentally rested’, ‘better able to get out of bed’, and ‘able to deal with everyday life’, had also been observed.

Enhanced well-being as a consequence of acupuncture treatment
Similarly, feedback from acupuncture recipients in relation to the intervention itself further re-enforced the overall theme ‘a restoration towards balance’, the subtheme ‘promoting an improved psychological state and overall well-being’, and the concept of ‘brightened me up’. Positive comments made were seen to encompass gratitude for the gaining of another self-efficacy resource, particularly one that had the capacity to address not only physical but also emotional needs; numerous descriptions of broad ranging psychosocial improvements, such as those previously described; and improvements to relationships with family and friends.

Analogous comments of improved psychosocial well-being were also provided by PMR recipients, such as finding the therapy ‘relaxing’; ‘calming’; ‘helpful with dealing with stress and unwinding’; as well as ‘providing of perspective’;
assisting to ‘feel lighter’, ‘fresher’, ‘happier’, and ‘more motivated’. However, the majority of this feedback related to short timeframes around the sessions, and in addition, were expressed only by a small proportion of the group.

The findings provided from this component of the study were also reflective of evidence in the literature. Beneficial effects of acupuncture to quality of sleep have also been examined in both mechanistic and clinical studies. For example in one study, Spence and colleagues (2004) combined mechanistic and clinical outcome measures and demonstrated that in a small sample of anxious adults with insomnia, five weeks of acupuncture resulted in a significant increase in melatonin secretion, significant improvements to a number of measures of sleep quality, and significant reductions in state and trait anxiety scores. Similar findings have also been observed in recent reviews assessing acupuncture effectiveness for insomnia. In the synthesis of the literature by Lin and co-workers (2016), acupuncture was shown to be an effective therapy for insomnia and insomnia related complications, by exerting beneficial effects on heart function, brain wave activity, the immune system, oxidative stress, and anxiety and depression. A comprehensive review by Kalavapalli and Singareddy (2007) reported that despite various study limitations, a consistent observation was that acupuncture provided significant improvement to insomnia. Similarly, a systematic review and meta-analysis provided by Shergis and colleagues (2016) also showed that whilst studies were heterogeneous and at risk of some bias, acupuncture was shown to be statistically superior to both sham acupuncture / placebo and pharmacotherapy as measured via the Pittsburgh Sleep Quality Index (PSQI). Additional studies more closely monitoring benefits to sleep have reported positive effects. Sok and colleagues (2003) reported in a review that after evaluating 11 studies that met the inclusion criteria, that “acupuncture may be an effective intervention for the relief of insomnia” (p375). With respect to studies evaluating insomnia in the context of mental illness, Reshef and colleagues (2013) reported the findings of a small pilot study of 20 patients suffering co-morbid insomnia and schizophrenia, that a significant effect of acupuncture across seven objective sleep variables was observed, and in addition, that psychopathology and emotional measures, such as depression and
anxiety levels also improved. A similar finding was reported in a review by Bosch and co-workers (2015), in which acupuncture was found to be effective in improving the quality of life in psychiatric patients, particularly in regard to quality of sleep.

8.3.3.4 Findings from in-depth interview with acupuncture recipients and focus groups with midwives

Acupuncture recipients similarly provided many positive descriptions during in-depth interviews of ‘an improved psychological state and overall well-being’ as a consequence of the intervention (see chapter 7). Responses were comparable to those provided in the semi-structured feedback forms regarding positive mood changes such as: ‘feeling calmer’, ‘more relaxed’, ‘lighter’, ‘more positive, ‘cheery, happier and content’. Reports of improvements to overall well-being were also analogous, such as being better able to ‘cope with day to day activities’; as well as be ‘more motivated again’, ‘level headed’, able to ‘concentrate’, ‘take a step back and gain perspective’, ‘be less down on myself’, and ‘avoid medical intervention’. Broader ranging improvements also reported to pain, bladder control, sleep and relationships were previously discussed in Chapter 7. The final sentiment expressed was hope that acupuncture would be made more readily available to all suffering from mental disturbances, so that it might prevent people ‘from needing to seek medical attention in the first place’.

Discussion amongst midwives during focus groups similarly re-iterated that feedback provided by acupuncture recipients was reflective of an ‘an improved psychological state and overall well-being’, with midwives reporting having been told directly by women in their care that they had found the therapy ‘beneficial’, ‘enjoyable’ and ‘relaxing’. Midwives observation of recipients similarly reinforced this subtheme, along with the concept ‘brightened me up’, as midwives reported amongst their colleagues that they themselves had noticed the women being ‘jovial when they’re leaving’.

Overall, the described benefits to mood, ability to cope, energy, motivation, and personal relationships were congruent with those reported to have occurred in
157 surveyed participants with serious mental illness after receiving acupuncture, and other CM approaches (Russinova et al., 2002). Similarly, broader ranging improvements across physical, psychological and social domains have also been reported in case studies, qualitative and mixed methods investigations and systematic reviews assessing acupuncture effects in general populations (Finston, 2009; Gould & MacPherson, 2001; Grant & Cochrane, 2014; Greene Prabhu, Walsh, Sirois, & McCaffrey, 2009; Lee et al., 2012; McDonald & Janz; Paterson et al., 2011; Paterson, Unwin, & Joire, 2010; Reshef et al., 2013; Rugg, Paterson, Britten, Bridges, & Griffiths, 2011; Smith, Ussher, Perz, Carmady, & de Lacey, 2011).

Whilst pain reduction, enhanced sleep quality and better bladder control were not the targeted focus of this protocol, non-specific benefits can arise as a consequence of the whole systems balancing approach taken in Chinese Medicine (Maciocia, 1989, 2006).

Whilst it was also clear that a reduced proportion of PMR recipients did obtain some benefits from the intervention, it was notable that for the majority of these, effects were shorter-lived and of insufficient magnitude to justify the effort of remaining enrolled in the clinical trial. However, other studies have reported significant benefits of PMR to both mood and quality of life, and consequently that this therapy may also provide ‘an improved psychological state and overall well-being’. Some examples include Zhao and co-workers (2012) reporting that after 12 weeks of PMR training, significant improvements to state anxiety, trait anxiety and depression, as well as health related quality of life domains were observed amongst 50 participants with endometriosis. In another study, significant benefits to quality of life were observed amongst 37 pregnant women utilising PMR combined with music, twice per day, for a period of 8 weeks (Akmeşe & Oran, 2014). Significant improvement to health related quality of life was also reported after 63 PMR sessions in a small cohort of 33 participants with multiple sclerosis (Ghafari et al., 2009). In these three studies, the duration and or number of sessions performed was greater than in this study, and this factor may therefore have contributed to the differences observed. Reviews of PMR studies have similarly reported benefits for the
management several conditions including antenatal stress, disturbed mood and perinatal outcomes (Beddoe & Lee, 2008); stress (Conrad & Roth, 2007; Varvogli & Darviri, 2011); anxiety, elevated blood pressure and heart rates (Varvogli & Darviri, 2011); psychological distress in cancer patients (Barrows & Jacobs, 2002); insomnia (Barrows & Jacobs, 2002; Morin et al., 1999); inflammatory arthritis, irritable bowel syndrome (Barrows & Jacobs, 2002); headaches (Barrows & Jacobs, 2002; Varvogli & Darviri, 2011); and the management of chemotherapy (Pelekasis, Matsouka, & Koumarianou, 2017). In addition, improved rehabilitation in cardiac patients and quality of life following bypass surgery have been reported (Varvogli & Darviri, 2011). Nonetheless, other reviews report contrasting findings including non-significant benefits for elevated blood pressure (Rainforth et al., 2007); limited benefit for anxiety, depression and quality of life in participants suffering from chronic obstructive pulmonary disease (COPD) (Baraniak & Sheffield, 2011); less effectiveness than cognitive and behavioural therapies for the treatment of both post-traumatic stress and obsessive–compulsive disorders (Montero-Marín, García-Camayo, López-Montojo, Zabaleta-del-Olmo, & Cuijpers, 2017); and inconclusive findings in regarding efficacy for pain reduction (Kwekkeboom & Gretarsdottir, 2006).

8.4 Overall Synthesis of Findings

Taken together, these findings, along with supportive evidence from the literature do suggest that acupuncture did provide a **homeostatic restoration towards balance**, by **reducing and or buffering the effects of stress**, which then had a subsequent effect on **improving overall psychological well-being** and **reducing depression severity**. A recent synthesis of literature by Karst and Fink (2016, p312) similarly concluded that acupuncture has far reaching influences in the body as a combined result of both physiological and non-specific effects including beliefs and practitioner–patient relationships, and therefore that acupuncture can be best described “as a biomedical information therapy”, able to address “the allostatic (information) systems of the body, such as the nervous system, the immune system, and the hormone system, in a manifold way”. This
holistic approach has been described as bidirectional in relation to balancing, and harmonizing body functions via the information systems of the body (Karst & Fink, 2016; Li et al., 2015), which if termed in another way, could be described as a return towards ‘homeostasis’.

According to the ancient Chinese medicine scholars, ‘a good acupuncture treatment is like the sun coming out from behind the clouds’.

In the next chapter, these integrated findings will be discussed in reference to the overall feasibility of acupuncture as an additional therapeutic possibility for depression experienced during pregnancy.
Chapter 9

Key Findings, Conclusion and Recommendations
The overarching aim of this study was to comprehensively examine acupuncture as an adjunct therapeutic possibility for depression experienced during pregnancy. In order to achieve this, a feasibility RCT was conducted to assess post acupuncture intervention changes to antenatal mood. It was also considered a valuable opportunity to more closely explore the issues faced by depressed pregnant women with respect to mood disturbances and treatments. Consequently, the scope of the investigation was broadened to include qualitative inclusions comprising of interviews with women and focus groups with midwives. In addition, as disrupted HPA axis and oxytocinergic system biomarker findings have frequently been reported in depressed perinatal populations, an additional assessment was made to determine whether the acupuncture intervention was able to exert a regulatory influence to cortisol: DHEA ratios and OT concentrations. This is the first mixed-methods evaluation of acupuncture for antenatal depression, in which qualitative and mechanistic effect explorations have been incorporated in with a RCT.

9.1 Summary of Key Findings

This study provided additional confirmation that acupuncture may be a suitable adjunct therapeutic possibility for the management of antenatal mood disturbances, as statistically significant reductions to depression, stress, and distress scores were observed after treatment, when compared to the PMR comparator and treatment as usual control groups. In addition, this is the first exploration to contribute towards new knowledge in regard to a putative regulatory mechanistic effect of acupuncture to HPA axis functioning, as end of intervention cortisol: DHEA ratios were seen to be significantly elevated in this group, when compared to treatment as usual. Further contributions towards new knowledge were provided from semi-structured and in-depth interviews with acupuncture recipients, in which findings demonstrated that due to difficulty finding suitable antenatal treatment options, these women were willing to try acupuncture, and in addition, that they found the therapy to be effective, and enjoyable. Lastly, these findings were re-enforcement during focus groups, as midwives agreed treatment options were limited for depressed
pregnant women, and in addition, that positive changes to mood after the receipt of acupuncture, were clearly observable.

**Mood score and quality of life evaluations**

Evaluation of post-intervention mood score findings demonstrated statistically significant reductions to depression, stress and distress indicators amongst acupuncture recipients, when compared to the attention comparator PMR and treatment as usual controls. In addition, mean scores also lowered into a range that was either considered 'normal', or no longer indicative of possible depression, stress or distress. These findings thus aligned with those previously published by (Manber, Schnyer, Allen, Rush, & Blasey, 2004; Manber et al., 2010) in both their pilot and full powered RCT, as well as (da Silva, 2007), in the quasi-randomised trial (see chapter 2), that suggested that acupuncture was a promising therapy for antenatal depression.

In regard to postnatal follow-up evaluations, differing treatment formats prevented comparisons being made between this study and the findings generated from the full-powered RCT by Manber and colleagues (2010), as in this larger study, treatments were continued into the postnatal period, whereby a significant assignment by time interaction was demonstrated only in the verum acupuncture group (Kent, 2011). In this study, the postnatal follow-up evaluation approximately 15 weeks after the final session demonstrated that differences between groups were no longer significant, with mean scores in both controls also being seen to reduce.

Assessment of adjustment to parenting was also made at this postnatal timepoint, using the BaM-13 scale. Whilst findings similarly revealed no significant differences between groups, the score was again lowest in the acupuncture group, and also the only one below the threshold indicative of likely parenting distress, therefore reflecting the same overall trend in findings.

It thus appeared that the positive changes to mood provided by acupuncture over the course of the intervention (gestation week 24 to 31-32), were no longer distinguishable at the 6-week postnatal follow-up. Such a result was
however not surprising in consideration of routine clinical recommendations for ongoing maintenance treatments to be conducted every 3 to 4 weeks, especially for chronic and complex conditions. It may however, also reflect regression towards the mean, as has been reported elsewhere (Streiner, 2001). Further factors that could have impacted findings include the possibility that in this cohort, the majority of concerns were pregnancy related; and or that parenting (Feldman, Weller, Zagoory-Sharon, & Levine, 2007; Levine, Zagoory-Sharon, Feldman, & Weller, 2007; Michalska et al., 2014), and breast-feeding (Grewen, Davenport, & Light, 2010) related OT releases may have effectively buffered postnatal depressive affects.

Whilst quality of life evaluations using the WHOQoL-26 also did not demonstrate differences between groups, this may have been a consequence of this tool being less able to discern differences amongst a cohort living in an affluent Western country. A quality of life assessment tool more applicable to this type of demographic may therefore, have been more appropriate. Despite this however, the indication of an overall improved quality of life at this postnatal timepoint amongst acupuncture recipients, did also confer with feedback provided from participants, that acupuncture did promote an improved psychological state and overall well-being.

The hypothalamic pituitary axis

Analysis of HPA axis biomarker concentrations demonstrated that, when compared to treatment as usual, cortisol: DHEA ratios in the acupuncture group significantly increased. This finding should however be interpreted with caution, due to being a post-hoc analysis in a small sample size. Such a finding possibly reflected a ‘homeostatic restoration towards balance’, of a potentially exhausted system, as a consequence of longer-term depression and chronic stress exposure (see chapter 8). Feedback provided by participants certainly supported this theory, as acupuncture recipients indicated that treatment had resulted in reduced or buffered feelings of stress, as well as an overall improved capacity to cope.
As was highlighted in chapter 3, a variety of assessments have provided heterogeneous findings in regard to cortisol and DHEA concentrations in depressed populations, which have been suggested to be reflective of broader HPA axis system disarray. Assessing the two antagonistic hormones in reference to each other has consequently been proposed to be a superior method for the discrimination of HPA system dysregulation, as well as for confirmation of depression (Maninger, Wolkowitz, Reus, Epel, & Mellon, 2009). Accordingly this approach was taken, even though findings in this regard are reportedly also varied, with studies demonstrating elevated (Goodyer, Herbert, & Altham, 1998; Kahl et al., 2006; Markopoulou et al., 2009; Michael, Jenaway, Paykel, & Herbert, 2000; Young, Gallagher, & Porter, 2002); flatter diurnal profiles (Mocking et al., 2015); and unchanged ratios (Jin et al., 2016; Markopoulou et al., 2009) in depressed populations, compared to patients in remission, and non-depressed controls. As the participants in this study were all depressed, it was not possible to determine the status of ratios in reference to normal populations. Findings were, however, compared to similarly assessed cortisol: DHEA ratio response to therapeutic interventions. Of the two studies identified, one demonstrated that elevated cortisol: DHEA ratios in patients with MDD did not change after cognitive therapy (Mocking et al., 2015); whereas in the other, cortisol: DHEA ratios were seen to be elevated in schizophrenic patients that responded to medication treatment. To date therefore, post intervention changes to cortisol: DHEA ratio findings are heterogeneous, and require further investigation.

The oxytocinergic system

Findings in regard to assessed OT concentrations demonstrated wide variability amongst participants, with flux being seen both within, as well as between individuals. Consequently, no post-intervention between group differences in OT concentrations were able to be discerned. Such an observation was in alignment with previously reported dysregulated OT releases in depressed populations (see chapter 3). Interestingly, a recent study by (Levine et al., 2007) also demonstrated that in non-depressed women, pregnancy and early post-partum sampling revealed wide variations in OT concentrations. Specifically, stable, increasing, decreasing and bidirectional fluctuations within individuals
were seen to occur over time. At this stage, clear understanding regarding serum OT concentrations in pregnancy and mental health disorders requires further research. Nonetheless, as other studies have demonstrated associations between mental health morbidity and altered OT concentrations, a much larger sample size may have been able to demonstrate such an outcome.

With respect to OT-R density, whilst (Light et al., 2010) were able to demonstrate slightly reduced leucocyte OT-R expression in new mothers with higher subclinical depression scores, OT-R expression in this study was found to be below detectable levels. Consequently, post-intervention differences between groups could not be assessed. It may be that the sampling method utilised (see chapter 4) may have contributed to this outcome, as the PAXgene collection tubes contained reagents to stabilise RNAs which only allowed for the uptake of 1.5 mls of blood, and this may have been insufficient.

**Qualitative evaluations**

Data generated from qualitative evaluations provided valuable insight into women’s experiences of receiving acupuncture for antenatal mental health concerns, as well as midwives’ perspectives regarding acupuncture for depressed pregnant women. An overall synthesis of key findings is provided.

**Feeling desperate and being willing to try acupuncture**

Feedback provided from participants aligned with previous reports suggesting that depressed pregnant women face extra difficulty deciding upon a path for the management of their symptoms (Battle et al, 2013; Epstein et al, 2014; Previti et al., 2014). For the women in this study, these difficulties culminated in a sense of ‘feeling trapped between a rock and a hard place’, as a consequence of three major factors. Firstly, previous experiences with conventional therapies, had on the whole, been unsatisfactory with respect to effectiveness, maternal side effects and provider relationships; and consequently, these women were reluctant to utilise these approaches. Secondly, potential medication harm to babies was regarded as an unacceptable risk for the majority. Lastly, limited options, in combination with the likelihood that impending pregnancy and
lifestyle changes would spiral their mental health out of control, left these women feeling desperate, and unsure of what to do.

Viewpoints provided such as these, closely mirrored those previously reported in other depressed perinatal populations (Bennett, Boon, Romans, & Grootendorst, 2007; Byatt et al., 2013a; Manber, Allen, & Morris, 2002). For example, the inability of conventional approaches to completely control symptoms (Cleare et al., 2015; Cohen et al., 2006; Dennis & Dowswell, 2013a; Epstein et al., 2014) was clearly re-enforced, as women already utilising both psychotropic drugs, and or psychosocial services, were still suffering from mental health disruptions. Similarly, this study also confirmed that perinatal women were reluctant to reuse conventional options, when previous management had been found to be inadequate (Battle et al., 2013), or associated with unpleasant medication (Mancini, Hardiman, & Lawson, 2005; Samples & Mojtabai, 2015), or trauma revisitation (Farber, Khurgin-Bott, & Feldman, 2009) side effects. In addition, reported disinclinations (Battle et al., 2013; Brummelte & Galea, 2016; O'Mahen & Flynn, 2008), or refusals to either take medication (Goodman, 2009), or attend psychosocial services, out of fears regarding foetal safety (Epstein et al., 2014; Ride & Lancsar, 2016), and or being judged by providers (Byatt et al., 2013a), were again corroborated in this study. Furthermore, comments made by some women supported previous findings that conflicting safety information (O'Mahen & Flynn, 2008; Ververs, van Dijk, Yousofi, Schobben, & Visser, 2009), and the disparate opinions of providers (Ververs et al., 2009), further hampered the already difficult decision regarding whether or not to take medication (Einarson, 2013).

Feedback provided by midwives similarly reiterated that treatment options were limited, and in addition that current services were poorly utilised, as women in their care frequently weren't medicated, nor willing to seek. Further confirmation in this regard was recently provided in a study by this author, in which interviewed mental health and obstetric providers also stated that options were limited for these women, as “medication... is far less — far, far less effective than is made out to be”, and “…nobody wants to see a psychiatrist. They’re not even enthusiastic about seeing a psychologist” (Ormsby, Dahlen, Ee,
Keedle, & Smith, 2018, p171). An additional possible reason for reluctance to acknowledge difficulties suggested by midwives, was that the women were fearful of losing parenting rights. Direct communications between the author and participants re-enforced this opinion, as many women revealed they had intentionally downgraded the extent of their difficulties during midwives’ assessments for this reason. Other studies have similarly reported that custody fears result in a lack of disclosure (Byatt et al., 2013a; Henshaw, et al., 2013).

In consideration of such difficulties, it was not surprising these women were willing to ‘give acupuncture a go’, despite also having little knowledge of it, as well as some fear regarding needles. Reasons provided reflected those reported elsewhere, including the hope of gaining benefit (Collinge, Wentworth, & Sabo, 2005; Russinova, Wewiorski, & Cash, 2002; Thomson, Jones, Evans, & Leslie, 2012), in combination with reassurances of safety (MacPherson, Thomas, Walters, & Fitter, 2001), positive reports of effect, and recommendations from friends, family and health professionals (Adams, 2006).

Although acupuncture is already utilised by perinatal and other mentally unwell populations for assistance with mental health concerns (Adams et al., 2009; Adams, Sibbritt, & Lui, 2012; Collinge et al., 2005; Frawley et al., 2013; MacPherson, Sinclair-Lian, & Thomas, 2006; Russinova et al., 2002), and in addition, increasingly accessed for pregnancy related complaints (Adams et al., 2009; Adams, Sibbritt, & Lui, 2011), it was of interest to note that only one quarter of participants had previously utilised it, and also, that only one participant had heard of it as beneficial for stress management.

Perceptions of benefits gained and hope for the future

After receiving treatment, the women in this study reported ‘gaining relief’ from symptoms, which they felt was both ongoing, and enabling of a better capacity to manage their stressful lives. Encouragingly, these positive changes to mental health symptomology, were also discerned by friends, family members and midwives. Specifically, the women reported benefits to mood, energy, motivation, sleep quality, interpersonal relationships and the ability to cope.
These findings, similarly mirrored improvements reported after acupuncture and other CM approaches in 157 participants with serious mental illness (Russinova et al., 2002). Further improvements to bladder control, and various types of pain also described, whilst not directly targeted, are potential outcomes of therapies that address whole systems, such as TEAM (Maciocia, 1989; Maciocia, 2006). Indeed, case studies, qualitative and mixed methods investigations, and systematic reviews assessing acupuncture effects in general populations likewise report broad ranging improvements across physical, psychological and social domains (Finston, 2009; Gould & MacPherson, 2001; Grant & Cochrane, 2014; Greene Prabhu, Walsh, Sirois, & McCaffrey, 2009; Lee et al., 2012; McDonald & Janz, 2017; Paterson et al., 2011; Paterson, Unwin, & Joire, 2010; Reshef et al., 2013; Rugg, Paterson, Britten, Bridges, & Griffiths, 2011; Smith, Ussher, Perz, Carmady, & de Lacey, 2011). These findings in addition, align with the previously referred to quantitative mood score assessments in perinatal populations (da Silva, 2007; Manber, Schnyer, Allen, Rush, & Blasey, 2004; Manber et al., 2010), as well as systematic reviews of RCTs of acupuncture for depression (Stub, Alræk, & Liu, 2011; Wang et al., 2008; Wu, Yeung, Schnyer, Wang, & Mischoulon, 2012).

An additional aim was to provide as much as possible, an ecologically valid treatment approach that enabled individualised treatment tailoring, and thus an enhancement of the possibility of demonstrating findings that more closely align to those reported by acupuncturists in routine clinical settings (MacPherson, Hammerschlag, Lewith, & Schnyer, 2008). It was encouraging therefore, to receive feedback that recipients felt specifically attended to, and also that, treatment appeared to be tailored to their specific needs. As well as this approach providing the potential for more targeted treatment effect, it also increases the possibility for improved provider satisfaction; as depressed perinatal populations reportedly desire more empathic patient centredness (Berger, Braehler, & Ernst, 2012; Mancini et al., 2005; Rugg et al., 2011), longer consultation times, and opportunities to be heard (Berger et al., 2012; Kadam, Croft, McLeod, & Hutchinson, 2001). In one recent study, depressed pregnant women reported feeling obstetricians were too busy to ‘talk’ to, and focused
only on the pregnancy (Bennett et al., 2007). Whilst no comments were made in this regard in this study, midwives did confirm that in their view, busy doctors did push mental health concerns onto midwives, with the perceived attitude that, ‘this is not an obstetric problem’.

One final benefit to emerge was that acupuncture had provided these women with a sense of hope for their futures. Having accessed a clearly acceptable therapy, that provided an unexpected way out of the severity of their antenatal mental health concerns, these women now felt like they had an additional option in times of need. Much like the placebo effect, hope is believed to contribute towards therapeutic effect, and therefore has the potential to provide an important component in symptom relief and recovery (De Craen, Kaptchuk, Tijssen, & Kleijnen, 1999; Miller, Colloca, & Kaptchuk, 2009). Hope has also been described as a utilisable self-empowerment resource that can assist with coping, as well as buffering the impact of significant stress (Betts, Dahlen, & Smith, 2014), hence in higher risk populations such as these, hope may be of particular importance.

It was also notable that the acupuncture performed in this study was well tolerated, with no adverse events being reported. In addition, 100% of recipients indicated they would seek acupuncture out again for mental health concerns, as well as recommend it to their family and friends.

### 9.2 Strengths of this Study

Even though ‘pilot’ or ‘feasibility studies’ can be criticised as retrospective justifications for underpowered unethical small clinical trials (Arain, Campbell, Cooper, & Lancaster, 2010; Thabane et al., 2010), valid applications also include the testing of various study components prior to the design of larger powered studies (Arain et al., 2010). As several previously untested components were to be incorporated into this study, including the depression specific acupuncture protocol, biomarker assessments, PMR attention comparator, and qualitative evaluations, the ‘feasibility’ approach was considered to be the most appropriate course to take.
In reference to the depression specific acupuncture protocol, it was a particular aim of this study, to maintain as much as possible within the confines of an RCT, the ecological validity of acupuncture. Such a position was chosen in light of frequently reported ambiguous findings regarding acupuncture effect (MacPherson et al., 2008); which have been suggested to be due in part to limitations with RCT designs (Grossman & Mackenzie, 2005) and implementation (Witt et al., 2012), as well as minimalistic treatment protocols (Ahn & Kaptchuk, 2005; Birch, 2004a). The comparative effectiveness research (CER) approach that has more recently been recommended for establishing effectiveness evidence was therefore taken, as in this method, pragmatically designed semi-standardised treatment protocols are able to be evaluated as adjuncts to conventional therapies (Witt et al., 2012). An additional consideration however is that when benefits are demonstrated above those provided by conventional treatments, suggestions are made that these arise as a product of non-specific placebo-type effects (Moffet, 2008). Consequently, an equivalent attention control that enabled adjustments for this possibility, was also incorporated (the PMR group).

An additional incorporated strength to this overall study design, was the qualitative inclusions, as they provided both rich detail, and valuable insight into women’s actual experienced dissatisfaction with conventional options, reasons for being willing to try acupuncture, and perceptions of benefits gained. Feedback obtained from midwives in addition, provided verifications of these views. Strengthening of the reliability of these findings was also provided by assurances of anonymity.

Further overall rigour was incorporated (Lilford & Stevens, 2002) by utilising computer generated randomisation schedules sealed in opaque envelopes by an independent researcher; de-identifying participants with codes, so as to enable both blinded data entry and analysis; and utilising a database that was subject to random audits, as well as digital recording of alterations made.
9.3 Limitations with this Study

Whilst the primary intention of incorporating the PMR attention comparator was to provide a measure of the effects of interacting with the practitioner, and being involved in the intervention, it was possible that like ‘sham’ acupuncture, PMR may also not be ‘inert’. An analysis of the literature yielded mixed findings in regard to the effectiveness of PMR (see chapter 9), however, some evidence was suggestive that the technique provided benefits to antenatal stress, disturbed mood and perinatal outcomes (Beddoe & Lee, 2008), as well as depression in general populations (Fung & White, 2012). With possible mechanisms of action being listed as enhanced production of endorphins, as well as improvements to calmness, coping, and the sense of self-control (Fung & White, 2012), one could see the potential for PMR to have impacted upon study outcomes, and thus, possibly reduce the measured effectiveness of acupuncture.

Feedback provided from PMR participants in this study did verify these findings, as in some cases, benefits were stated to have been obtained. However, for the majority, effects were reportedly modest, and experienced for very brief intervals. The high attrition rate from this group similarly supports this latter feedback, as participants indicated the level of commitment required was much greater than the benefits obtained.

It has been reported that ideally, attrition rates for control treatments should remain under 20%, so that the effectiveness of comparisons are not reduced, and data loss is not extensive (Birch, 2004a). End of intervention losses in this group were however much higher at 42%, and therefore this may have impacted upon the interpretation of findings regarding this group. Consequently, an alternative attention comparator could be considered, yet, if also minimally effective, the same issues are likely to arise. Another way to address this issue is by incorporating larger attrition estimates into power calculations, so as to provide a buffer not only for the study overall, but more specifically, from loss from attention comparator controls. As attrition as a consequence of depression was reportedly as high as 30% (Elkin et al., 1989), this additional recruitment target had been incorporated into this study.
However, as the loss to follow-up in the PMR comparator was more than anticipated, much larger attrition estimates may be required in order to achieve sufficient end of intervention numbers in each group.

As is typically reported, recruitment into this RCT was slow (Motzer, Moseley & Lewis, 1997; Smith & Coyle, 2006; Pastore & Dalal, 2009), and consequently resulted in a small sample size. Whilst the sample size was suitable for feasibility considerations, in regard to statistical analyses, it may have resulted in the incorporation of type 2 errors (Jones, Carley, & Harrison, 2003). In addition, it also made it impossible to stratify for the effects of the model of care regarding obstetric outcomes (Sandall, Soltani, Gates, Shennan, & Devane, 2016), and levels of satisfaction (Forster et al., 2016).

Several other factors may have influenced findings. Firstly, the number of interviewed women represented just under half of the total group, hence it is possible that, despite the saturation of emergent themes, views expressed may not have been representative, and in addition, more positive, as a reflection of the willingness to be interviewed. What was encouraging however, was that the opinions provided did closely mirror those expressed by all of the acupuncture recipients in the semi-structured interviews, and in addition, reflected the observations of midwives, and mood questionnaire findings. Nonetheless, it may be an additional aim of a larger study to recruit a more diverse range of depressed pregnant women, as views may differ in other populations.

Secondly, whilst data sets were provided to the author in a de-identified format, over time, the author became unblinded due to group characteristics being discernible. Analysis was however under the guidance of supervisors and independent school statisticians.

Thirdly, the utilisation of self-report measures may have created the potential for the inclusion of response bias, as a consequence of: 1) participants wishing to be ‘good’ and facilitate the investigation; 2) modifying responses due to being concerned that the investigator would be reviewing the answers; 3) adapting responses to subsequent questioning due to previous answering; and 4) automated responses, as a product of repeated exposure to the same questions.
(practice effect) (Villar, 2008). Measures were nonetheless taken to minimise such possibilities, including utilising multiple forms on several different occasions, so it was less likely that participants would have taken the time to consider their responses in this way; and also, by informing participants that questionnaire data would be entered by independent researchers.

It was also reassuring to observe, that when cross-referencing group means across all questionnaires, similar trends in change were observed by group allocation. Findings from related studies in addition, added further support to these self-reported outcomes. For example, in the Manber studies (2004; 2010), whilst response rates were demonstrated using the clinician rated HRSD$_{17}$, they also correlated well with findings from the self-reported BDI scale. Similarly, in the study by da Silva (2007), even though outcomes were demonstrated via the self-reported numerical rating scale (NRS), participants also remained under the care of an obstetrician, and no discrepancy between NRS scores and clinician's observations were reported.

Fourthly, the women who enrolled in the study were made aware that the principal researcher was to perform both the acupuncture and PMR interventions. The level of experience the principal investigator had in regard to the delivery of either intervention was however not reported to participants. Whilst participant expectations regarding possible benefits may influence outcomes (Paterson & Dieppe, 2005), expectations in this regard were not collected. What was noted from interviews with acupuncture recipients however was that the women were generally sceptical of the effectiveness of acupuncture, or hopeful but overly optimistic of beneficial outcomes.

Fifthly, as oxytocin receptor density evaluations were unable to yield informative outcomes, it would appear pertinent to use alternative RNA stabilisation methods in a larger scaled trial, that enable the collection of a larger volumes of blood.

Sixthly, it is possible that the women enrolled in this study are not representative of other women experiencing depression during pregnancy, as the majority were Caucasian, married and employed. Nevertheless, part of the
region sampled belonged to a lower socioeconomic area, that also had higher than state average indigenous Australian population density.

Lastly, whilst every attempt was made to interpret findings in an objective manner, which included thorough review from the supervisory panel in this regard, it is possible that unconscious biases resulting from the principal researcher’s positive beliefs in acupuncture, may have been inadvertently incorporated.

9.4 Future Research Directions

In light of the findings presented, as well as patient preferences for non-pharmacological options (Battle et al., 2013; Frawley et al., 2013; Matthews, Huberty, Leiferman, McClain, & Larkey, 2016), as well as more satisfying and respectful relationships with providers (Megnin-Viggars, Symington, Howard, & Pilling, 2015), future research into the effectiveness of acupuncture for the management of perinatal mental concerns, appears warranted.

The timing for this additional research may in addition, be ripe, as a recent investigation conducted by this author and colleagues, identified that on the whole, doctors, midwives, and service providers were receptive to the possible use of acupuncture for antenatal depression (Ormsby et al., 2018). Further support for this possibility has also been provided in a recent USA nation-wide survey of 128 obstetricians, in which 62% of respondents reported having recommended CM to pregnant patients, as well as utilised it themselves in 45% of cases, 9% of which was during pregnancy (Babbar, Williams, & Maulik, 2016). Similar positive views were also expressed in another survey of physicians, in which increasingly improved attitudes towards CM were reported (Waehner-Roedler et al., 2014).

It may be that the recent emphasis on robust CM research (MacPherson et al., 2010), in combination with scientific investigations into mechanistic effects, have “improved the understanding of the benefits gained from these various therapies and modalities” (Frass et al., 2012, p 45). Provisos specified before mainstream incorporation however, include further assurances of safety,
quality and effectiveness (Ormsby et al., 2018). Recommendations in this regard include rigorously conducted, and adequately powered RCTs, that when possible, also include evidence of physiological mechanisms (Wahner-Roedler et al., 2014). Nonetheless, comparative effectiveness, cost-benefit (Witt et al., 2012), and qualitative evaluations (Bryman, 2006; Johnson & Onwuegbuzie, 2004; Verhoef, Casebeer, & Hilsden, 2002) are also suggested for inclusion, due to: 1) RCTs oversimplifying “the complex and interpersonal nature of clinical care” (Williams & Garner, 2002); 2) non-inert ‘sham’ controls resulting in an underestimation of effects (Birch, 2004b; Langevin et al., 2010; Walach, 2009); and 3) important perspectives from patients regarding symptoms, consultations and treatments (Williams & Garner, 2002), as well their expectations and beliefs (Verhoef et al., 2002), not normally being assessed (Rugg et al., 2011; Russinova et al., 2002). Indeed, a more recent emphasis has been placed upon ‘evidence-based decision-making’ that integrates the best of research evidence, along with clinical expertise and patient values (Haynes, Devereaux, & Guyatt, 2002).

Certainly, the benefits of mixed-methods evaluations have been highlighted in this study, as being able to compare the findings from each component has enabled, not only a more comprehensive analysis of outcomes, but also in this case, the reinforcement of positive findings.

The more recent recommendation for the conduction of comparative effectiveness acupuncture research has also stressed the importance of treatment individualisation, as well as appropriate dosing, in order to maintain ecological validity. Consequently, this approach was intentionally incorporated. In the interests of reproducibility and generalisability however, the protocol was limited to needling and the placement of ear seeds, as well as a defined number of possible treatment options. These were however designed to be both numerous and broad in range, so as to enable the principle researcher sufficient flexibility to be able to address the presenting symptomologies contributing to mental health concerns. From the perspective of the delivery of the acupuncture intervention, as well as in regard to the results obtained, this approach appears to have been successful. Hence, it would appear that this approach could again
be utilised in a future larger scaled trial. If necessary, specific protocol training could be provided to participating acupuncturists.

Whilst recruitment was problematic, referrals from the antenatal mental health list appeared to be the most effective recruitment method, hence this approach would again be recommended for a larger scaled study design. In addition, as the incorporation of study information in antenatal information packs prior to the first antenatal visit resulted in more women being informed of the study prior to 24 weeks gestation, this strategy would again be recommended. Furthermore, as a number of women indicated child minding difficulties had influenced their decision not to enrol, as well as to drop-out after enrolment, an on-site child-minding service if possible, may boost both recruitment and retention. Lastly, the absence of adverse events resulting from the acupuncture intervention may be due to the avoidance of strong needling techniques, as well as the shallow insertions of very fine gauge needles, hence this approach may be worthy of further consideration in a larger study, especially in light of the mental health morbidity of this population.

9.5 Implications for Practice

Due to the short nature of the intervention period, the semi-standardised acupuncture protocol, and the omission from use of typically incorporated TEAM clinical tools such as moxibustion, cupping, herbs, and dietary and lifestyle, it is difficult to draw firm conclusions regarding the implications for clinical practice gained from this study. Nonetheless, a number of observations were made that are of interest. Firstly, findings in this study were in alignment with literature that suggests that a minimum of six treatments is likely to be required in order to obtain sufficient effect in clinical research (White, Filshie, & Cummings, 2001), as significant changes to the K6 were observed by this time point. Likewise, significant differences to the EPDS and stress component of the DASS-21 were not visible until after the mid-point assessment, hence occurred sometime between the fourth and eighth session. Consequently, it seems
justifiable for clinicians to recommend minimum treatment regime of six weekly sessions, prior to re-assessment, on a case-by-case basis.

Secondly, recommendations that maintenance treatments may be required for continued symptom alleviation in more complex and chronic conditions was affirmed, as significant differences between groups were not be able to be maintained over the long-time frame from the end of the intervention, to the six-weeks postnatal follow-up assessment. In contrast, when antenatal acupuncture treatments were maintained into the postnatal period, significant postnatal differences were able to be sustained amongst verum acupuncture recipients (Kent, 2011).

Lastly, despite the omission of diet and lifestyle advice, the answering of participants questions in relation to TEAM and the treatment they were receiving was clearly valued, as feedback provided from in-depth interviews demonstrated that participants found this information helpful for their understanding of their symptomologies; re-assuring that the treatment had been ‘tailored’ to them; and important for the building of rapport. Qualitative explorations of participants’ perceptions of the benefits gained from bi-directional and patient-centred discussions frequently encountered during acupuncture sessions, have similarly reported congruent findings (Paterson & Britten, 2004; Paterson et al., 2012).

**9.6 Conclusion**

This study comprehensively explored the feasibility of utilising acupuncture as an adjunct therapy for the management of depression during pregnancy. Findings confirmed that both participants and midwives felt depressed women faced extra difficulty regarding the use of conventional therapies whilst pregnant, due to treatments frequently being ineffective, and undesirable. Women however demonstrated a willingness to try acupuncture. Overwhelmingly, acupuncture recipients provided positive feedback regarding the benefits they received from treatment. Confirmations of effects were likewise provided by ward midwives, as they also observed these positive
changes to participants’ mood. Significant reductions to depression and stress symptomologies resulting from the acupuncture intervention, were in addition demonstrated, that were also supported by objective biomarker assessments, in which significant changes to the cortisol: DHEA ratio amongst acupuncture recipients was observed, when compared to the treatment as usual control.

These findings thus add further support to previously reported clinical studies that demonstrate the benefits of acupuncture for antenatal mood concerns. Additional research is however required to further verify these findings, especially in larger and more diverse populations.

9.7 Presentations and Publications Arising from This Dissertation

The author has provided several PhD related oral and poster presentations at the NICM Health and Research Institute; the school of science and health at Western Sydney University; and South West Sydney Local Health District, as part of the ongoing requirements of candidature and running of the RCT. In addition the following presentations were also conducted:

Presentations

1. 2016 - As part of the NICM, Western Sydney University ‘Women’s Health’ seminar, an oral presentation titled ‘between a rock and a hard place – the experiences of women participating in an RCT of acupuncture for antenatal depression’.

2. 2016 & 2017 - As part of the Western Sydney University Masters of Traditional Chinese Medicine ‘Women’s Health’ programme, a two-hour lecture entitled ‘Acupuncture for Antenatal Depression’.
3. 2016 - As part of the Western Sydney University ‘Three-Minute Thesis’ competition, an oral presentation titled - ‘Acupuncture for Antenatal Depression’.

4. 2016 - As part of the New Zealand School of Acupuncture and TCM Journal Club for Masters students, details regarding the published RCT protocol were provided (see later).

5. 2017 – As part of the South Western Sydney Local Health District Midwifery conference, an oral presentation of the PhD qualitative findings was presented, titled – “Between a Rock and a Hard Place”.

6. 2017 – As part of the Australasian Marcé society for Perinatal Mental Health conference in Brisbane, presented PhD qualitative research findings in the format of a poster.

7. 2018 – As part of the Western Sydney University, School of Midwifery ‘Mockingbird’ conference, presented main PhD RCT research findings, titled ‘Acupuncture for Antenatal Depression’.

8. 2019 – As part of the ‘Society of Acupuncture Research’ conference in Vermont USA, presented the main PhD research findings, for which an ‘Outstanding Junior Researcher Award In Clinical Research’ was received.

Publications

antenatal depression (AcuAnteDep): study protocol for a pragmatic randomised controlled trial. *Trials, 17*(1), 93.


References


270


301


Glossary of Terms

AGPAR scoring is a system to assess the health of a newborn at 1 and 5 minutes after birth, so as to determine whether emergency care is required.

Chong Mai or the ‘sea of blood’ is one of the eight extra meridians, thought to play a role in menstruation and reproduction, respiration and digestion, and ‘spiritual’ disorders, such as depression.

Conception Vessel or the ‘sea of yin’ is the main meridian located in the midline of the front of the body. The functions of this channel include ‘yin’, ‘essence’, fluids, female cycles, menstruation, reproduction, and gastrointestinal issues.

Deqi is a term used to describe a sensation generated at acupuncture points as a result of a specialised needling technique.

‘Even’ technique is a needling style in Chinese medicine in which the needle is gently inserted without the intention to ‘tonify’ or ‘sedate’ the energy at the point.

Five element theory in Chinese philosophy and medicine relate to observations of the seasons, which have in turn been applied to the body. Each element is thought to be in a continuous circle of transformation (the generating cycle), as well as inter-influencing motion (the controlling cycle). Each is related to a yin and yang paired meridian, as well as organ system. Each relates the qualities of the seasons, for example, heat in summer, and cold in winter.

Governor Vessel of the ‘Sea of Yang’ is a main meridian located in the midline of the back of the body. The functions of this channel include aspects relating to ‘yang’ in particular pertaining to pain, heaviness, tiredness, the brain and spinal cord, and psychological issues.

Huatuo Jia Ji are a group of 34 acupoints located lateral to the lower border of the spinous processes of the vertebrae from T1 to L5.
'Live' point is a concept in Chinese medicine needling in which the 'live' or most physiologically active part of the acupuncture point is targeted for needling, so as to generate the greatest impact.

**MicroRNA** are a class of small noncoding RNA molecules that have a role in the regulation of protein expression.

Pre-heaven essence is a concept in Chinese philosophy and medicine that describes energy obtained from the 'heavens' before birth. In modern thinking, the concept could be translated as representing genetic and epigenetic inheritance.

'Qi' in Chinese medical terminology represents 'life energy', the energy that is required to create warmth, growth, development, movement, bodily functions etc.

'Root and branch' in Chinese Medicine describes a treatment approach in which the 'root' cause of the problem is addressed through treating the fundamental issue, as well as the 'branch', or presenting symptoms that arise as a consequence of the 'root' issue.

'Shen' in Chinese medical terminology encompasses both a material aspect of the body, as well as the 'spirit' or 'mind'. It relates to concepts such as consciousness, the emotions and personality, the ability to think and discriminate, and the capacity to relate to others, and form meaningful relationships.

**T'ai chi ch'uan** is a Chinese martial art practiced for both defense training and health benefits.

'Tonify' is a concept in Chinese medicine in which the intention of treatment is to boost the under-functioning of the body, as well as invigorate the body's resistance. The idea is also applied to needling, in which techniques are utilised to boost functioning.
‘Sedate’ is a concept in Chinese medicine in which the intention of treatment is to reduce the over-functioning of the body, and eliminate pathogens. The idea is also applied to needling, in which techniques are utilised to lessen excess functioning.

‘Yin and Yang’ are concepts in Chinese philosophy and medicine that describe the opposite forces in nature, and all that exists. ‘Yin’ represents aspects such as female, cool, quiet, rest, night, structure, fluid, blood and form. ‘Yang’ represents opposites such as male, warmth, activities, daytime, ‘qi’ or ‘life energy’ and bodily processes.
Appendices

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Appendix B: AcuAnteDep – South-Western Sydney Local Health District Approval (SWSLHDD) RCT Site-specific Authorisation
Appendix C: Western Sydney University Reciprocal Ethics Approval Letter
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AC Table 2 Participant PRE, POST Cortisol and DHEA Concentrations / Cortisol: DHEA Ratios, Group Allocation and Time of Sample Collection
Appendix A
AcuAnteDep – South-Western Sydney Local Health District

Ms Simone Ormsby
University of Western Sydney
The National Institute of Complementary Medicine
Building 5, Campelltown Campus
Locked Bag 1797
PENRITH NSW 1797

Dear Ms Ormsby,

***THIS LETTER CONSTITUTES ETHICAL APPROVAL ONLY. THIS RESEARCH PROJECT MUST NOT COMMENCE AT A SITE UNTIL SEPARATE AUTHORISATION FROM THE CHIEF EXECUTIVE OR DELEGATE OF THAT SITE HAS BEEN OBTAINED. ***

Project Title: Acupuncture for Antenatal Depression
HREC Reference: HREC/14/LPOOL/400
SSA Reference: SSA/14/LPOOL/437
Local Project Number: 14/228

Thank you for your response received 9 October 2014 to our request for further information dated 15 September 2014. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans and the CPMP/ICH Note for Guidance on Good Clinical Practice.

I am pleased to advise that the Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved:

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<td>Pragmatic Randomized Controlled Trial Treatment Flow Chart</td>
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Please ensure for all future documents submitted for review include a document version number, document date and page numbering.
Appendix B

AcuAnteDep – South-Western Sydney Local Health District (SWSLHD)

Ms Simone Ormsby
University of Western Sydney
The National Institute of Complementary Medicine
Building 5, Campbelltown Campus
Locked Bag 1797
PENRITH DC NSW 1797

Dear Ms Ormsby,

Project Title: Acupuncture for Antenatal Depression
HREC Reference: HREC/14/LPOOL/400
SSA Reference: SSA/14/LPOOL/437
Local Project Number: 14/228

***SITE SPECIFIC AUTHORISATION***

Thank you for your correspondence received 2 February 2015 in response to our request for further information dated 19 September 2014.

I am pleased to inform you that the Chief Executive has granted authorisation for this study to take place at the following site(s):

- Campbelltown and Camden Hospital

The following are authorised for use at the Campbelltown and Camden Hospital site:

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Enclosed documentation signed by the CE:
- 1 x Material Transfer Agreement (copy)

Note: CV’s for Mrs Ormsby and associated investigators are not required to be submitted for future 2015 projects as there is now one on file.

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to this office.
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to this office.
3. Please note that you are responsible for making the necessary arrangements (e.g. identity pass and vaccine compliance as per NSW Health Policy Directive PD2011_005) for any researcher who is not employed by the South Western Sydney Local Health District and is conducting the research on-site.

Yours sincerely,

Annamarie D’Souza
Manager, Research and Ethics Office
South Western Sydney Local Health District (SWSLHD)
Appendix C

Western Sydney University Reciprocal Ethics Approval Letter

Locked Bag 1797
Penrith NSW 2751 Australia
Office of Research Services
ORS Reference: H10993
HUMAN RESEARCH ETHICS COMMITTEE
19 February 2015
Professor Caroline Smith
The National Institute of Complementary Medicine
Dear Caroline,

I wish to formally advise you that the Human Research Ethics Committee has approved your research proposal H10993 “Acupuncture for Antenatal Depression”, until 28 March 2016 with the provision of a progress report annually if over 12 months and a final report on completion.

Conditions of Approval

1. A progress report will be due annually on the anniversary of the approval date.
2. A final report will be due at the expiration of the approval period.
3. Any amendments to the project must be approved by the Human Research Ethics Committee prior to being implemented. Amendments must be requested using the HREC Amendment Request Form: http://www.uws.edu.au/__data/assets/pdf_file/0018/491130/HREC_Amendment_Request_Form.pdf
4. Any serious or unexpected adverse events on participants must be reported to the Human Ethics Committee via the Human Ethics Officer as a matter of priority.
5. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the Committee as a matter of priority
6. Consent forms are to be retained within the archives of the School or Research Institute and made available to the Committee upon request.

Please quote the registration number and title as indicated above in the subject line on all future correspondence related to this project. All correspondence should be sent to the email address humanethics@uws.edu.au.

This protocol covers the following researchers:
Christine Chiu, Sharon Ellis, Caroline Smith, Joanne Lind, Hannah Dahlen, Phillipa Hay, Simone Ormsby

Yours sincerely

Professor Elizabeth Deane
Presiding Member,
Human Researcher Ethics Committee
Have you been feeling flat, sad, overwhelmed, stressed, anxious, irritable or lacking in motivation? If so, you may be interested in a study being run at Campbelltown and Camden Hospitals by the NSW Department of Health and the National Institute for Complementary Medicine (NICM) at Western Sydney University (WSU). We are exploring if acupuncture as an additional therapy to standard care, helps to lessen emotional upsets in pregnancy.

We are running the study from the 24th week of pregnancy. If you choose to join the study, you will be randomly assigned to one of three groups - acupuncture, progressive muscle relaxation or non-treatment. We need these three groups to make comparisons. If you are in either of the treatment groups, you will receive a one-hour treatment each week for eight weeks, up until the 32nd week of your pregnancy. If you are in the non-treatment group, you can have 4 acupuncture treatments from six weeks after your baby is born. To test how the study is going, we will be giving you some questionnaires to fill out and also collecting 3 saliva and 2 blood samples. There is no cost to participation.

If you are interested, please contact Simone Ormsby on 0414 476 711 or simone.ormsby@westernsydney.edu.au before your 24th week of pregnancy. Thank you.

This study has been approved by the SWSLHD Human Ethics Committee.
Appendix E

AcuAnteDep Trial Poster Advertisement

Depression in Pregnancy?

Did you know that depression in pregnancy is actually quite common? Approximately 10 – 15% of pregnant women experience depression & this may continue post-birth.

The National Institute for Complementary Medicine at Western Sydney University is conducting a randomised controlled trial examining the effectiveness of acupuncture as an additional therapy to standard care for the treatment of depression in pregnancy.

Three different groups are needed to make comparisons. These groups will be - acupuncture, progressive muscle relaxation and non-treatment. Weekly treatments over an 8-week period from pregnancy week 24 - 32 will be performed either at Camden Hospital or at NICM on Western Sydney University Campbelltown Campus.

All participants, including the non-treatment group will be required to fill out several questionnaires, provide 3 saliva samples and 2 blood samples. Interested? Please contact Simone Ormsby on 0414 476 711, 4620 3284, simone.ormsby@westernsydney.edu.au or let the antenatal staff know.

This study has been approved by the SWSLHD Human Ethics Committee.
Appendix F

Edinburgh Postnatal Depression Scale (EPDS)

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt in the past 7 days, not just how you feel today.

Here is an example, already completed.

I have felt happy:
- Yes, all the time
- Yes, most of the time - This would mean: "I have felt happy most of the time" during the past week.
- No, not very often
- No, not at all

Please complete the other questions in the same way.

In the past 7 days:

1. I have been able to laugh and see the funny side of things
   - As much as I always could
   - Not quite so much now
   - Definitely not so much now
   - Not at all

2. I have looked forward with enjoyment to things
   - As much as I ever did
   - Rather less than I used to
   - Definitely less than I used to
   - Hardly at all

*3. I have blamed myself unnecessarily when things went wrong
   - Yes, most of the time
   - Yes, some of the time
   - Not very often
   - No, never

4. I have been anxious or worried for no good reason
   - No, not at all
   - Hardly ever
   - Yes, sometimes
   - Yes, very often

*5. I have felt scared or panicky for no very good reason
   - Yes, quite a lot
   - Yes, sometimes
   - No, not much
   - No, not at all
*6. Things have been getting on top of me
   □ Yes, most of the time I haven’t been able to cope at all
   □ Yes, sometimes I haven’t been coping as well as usual
   □ No, most of the time I have coped quite well
   □ No, I have been coping as well as ever

*7. I have been so unhappy that I have had difficulty sleeping
   □ Yes, most of the time
   □ Yes, sometimes
   □ Not very often
   □ No, not at all

*8. I have felt sad or miserable
   □ Yes, most of the time
   □ Yes, quite often
   □ Not very often
   □ No, not at all

*9. I have been so unhappy that I have been crying
   □ Yes, most of the time
   □ Yes, quite often
   □ Only occasionally
   □ No, never

*10. The thought of harming myself has occurred to me
   □ Yes, quite often
   □ Sometimes
   □ Hardly ever
   □ Never
Appendix G

AcuAnteDep - Participant Information Sheet

Participant Information Sheet

Interventional Study - Adult providing own consent

Camden & Campbelltown Hospitals

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<td>Coordinating Principal Investigator/Principal Investigator</td>
<td>Simone Ormsby</td>
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<tr>
<td>Associate Investigator(s)</td>
<td>Professors' Smith, Dahlen &amp; Hay &amp; Associate Professor Lind</td>
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Part 1  What does my participation involve?

Introduction

You are invited to take part in this study involving a new treatment, acupuncture for antenatal depression. This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

What is the purpose of this research?
The purposes of this research are to investigate whether acupuncture can reduce the severity of depressive symptoms in pregnancy and improve overall quality of life and, in
addition, whether this effect continues into the post-birth period. Recent research has suggested that acupuncture may be helpful in the treatment of antenatal depression however there are still questions to be answered and a need for a well-designed study to see whether acupuncture really does help with reducing the severity of depression in pregnancy.

The results of this research will be used by the study investigator Simone Ormsby, to obtain a Higher Degree by Research, Doctorate of Philosophy. This study is under the principal supervision of Professor Caroline Smith as well as the co-supervisory team, Professor’s Hannah Dahlen and Phillipa Hay and Associate Professor Joanne Lind, from Western Sydney University.

**What does participation in this research involve?**

This study is open to pregnant women aged 18 years or older identified as mild to moderately depressed by the Edinburgh Postnatal Depression Scale (EPDS) at their first antenatal hospital visit. In this study, we are unable to recruit women who: have been suffering from a major depressive episode of greater than 2 years duration; have phobias to acupuncture needles or have major obstetric complications such as bleeding, pre-eclampsia, gestational diabetes or premature rupture of membranes.

This is a ‘randomized controlled trial’: This means that study participants will be randomly placed into groups and given different treatments in order for the results from each to be compared, to see if one is better than another. You will be randomly allocated to one of three study groups. Neither the clinician Ms Ormsby, nor you will be able to decide which treatment you receive. Regardless of the group to which you are assigned, you will continue to receive normal antenatal hospital care as well as your regular depression treatment.

In this study, the 3 groups are acupuncture plus treatment as usual for the treatment of depression, progressive muscle relaxation (PMR) plus treatment for depression and treatment as usual only for the treatment of depression.

The treatments will commence during the 24\textsuperscript{th} week of pregnancy and will be completed at the end of the 31\textsuperscript{st} week of pregnancy. Data will be collected at the commencement of the study, midway through and at the end but also at birth, and at a 6-week post-birth follow up. The specific details of what will occur at each stage of the study are provided below in a table.

The requirements of all the participants in this study will be:

1. 3 questionnaires will need to be filled out 4 times assessing levels of depression, stress and anxiety as well as quality of life at the commencement of the study, 4 and 8 weeks later, and 6 weeks following delivery. Another questionnaire assessing your early mothering experiences also needs to be completed 6 weeks following delivery.
2. All participants will be required to answer some questions about their sleep at 4 weeks and at the end of the study at 8 weeks. Those participants receiving either treatment will also be required to answer questions about the treatments at these same 2 times.

3. 3 saliva samples are to be collected and used to assess levels of hormones that may indicate stress such as cortisol as well as oxytocin, which is altered in depression and important for bonding with your baby. These will be collected at commencement of the study and 4 and 8 weeks later.

4. 2 blood samples will also be collected, one at commencement of the study and the other at the end, 8 weeks later. These will be used to measure oxytocin receptor levels, as these are also altered in depression.

5. Those participants randomised to receive a treatment will need to attend the clinic at either Campbelltown or Camden Hospitals or the National Institute of Complementary Medicine (NICM), to receive weekly treatments for 8 weeks.

6. Every week from commencement to the end of the study a form assessing depression levels will also need to be completed.

7. If you are randomly assigned to the acupuncture group, once you have completed all 8 treatments, you may be asked to be interviewed in regard to your experiences of receiving the intervention. The interview is likely to take approximately 1 – 1.5 hours and will be conducted by an associate researcher and recorded.

The questions and questionnaires will either be provided to you directly by Ms Ormsby or via mail or the internet.

If you are assigned to the acupuncture group, Ms Ormsby or an additional acupuncturist will also take your pulse and insert acupuncture needles into points located on your lower legs, arms, back and head. Needles will stay in for approximately 10-15 minutes. At the end of the session, 1-2 very small stainless-steel balls will be taped to the outer aspects of your ears, to remain in place as long as possible until the next session.

If you are assigned to the progressive muscle relaxation group, each week you will be required to lie in a comfortable position while you are guided through a specific muscle relaxation technique. In the first session, the overall technique will be taught and in the following sessions, a different area of the body will be focused on. The aim each time will be to achieve overall body relaxation.

If you are assigned to the treatment as usual only group, you will not receive any treatments during the study period however you will be offered 4 acupuncture treatments after the study is completed.

**How will the research be monitored?**

Every week the principle researcher's supervisory panel at scheduled meetings will monitor the conduct of the research. In addition, staff involved in facilitating the smooth running of the project in the obstetric departments of Campbelltown or Camden
Hospitals will be in regular communication with the principle researcher regarding the conduct and progress of the research.

**Will taking part in this study cost me anything, and will I be paid?**

There are no additional costs associated with participating in this research project, nor will you be paid.

**What do I have to do?**

If you decide to participate, you will be required to continue with your normal depression treatments as well as regular pregnancy care provided by your obstetric antenatal team.

**Do I have to take part in this research project?**

If you do not wish to take part, you do not have to. Your relationship with those assisting you will not be affected in any way whatsoever if you decide not to take part. If you do decide to take part, you will be given a Consent Form to sign and you will be given a copy of this sheet to keep.

**What are the alternatives to participation?**

Other options are available if you are not already receiving help such as antidepressant medications and psychotherapy. Your obstetric antenatal care team will discuss these and possibly other options with you before you decide whether to take part in this study. You can also discuss your options with your local doctor.

**What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a reduction in the severity and duration of depressive symptoms both in pregnancy and after your baby is born. You may also experience an overall improvement to the quality of your life.

This is an important study because acupuncture is unlikely to be offered to women until we have a better understanding of the advantages or any problems that may arise when acupuncture is used for antenatal depression. The study aims to further knowledge however; it may not directly benefit you.

**What are the possible risks and or disadvantages of taking part?**

All medical procedures involve some risk of injury. In addition, there may be risks that are currently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

When receiving acupuncture, sometimes people report discomfort when a needle is inserted such as a sharp sensation, which may last for a second or two. Some people do not feel anything while the needles are in. Possible side effects may include nausea,
dizziness, fainting, increased pain or bruising. The risk of minor side effects is small (a rate of 1.3 per 1000 treatments).

Acupuncture needles are sterile prior to insertion, and are used only once. All needles are disposed of into a sharps-container. The area of needle insertion is also sterilised with an alcohol swab prior to insertion.

There are minimal possible risks of receiving progressive muscle relaxation, which may include slight discomfort whilst lying in the same position for lengthy periods of time and dizziness when getting up too quickly after lying down for long periods.

It is not expected that any of the possible mild and or infrequent side effects will require treatment but in the unlikely event that they do, they will be treated directly by the clinician or you will be referred to your obstetric antenatal care team.

In this study, 2 blood samples are required and having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If you become upset or distressed because of your participation in the research, or independently of the study, the clinician will arrange a prompt referral to your antenatal care team for appropriate support, which may involve medication and or counselling. Any counselling or support will be provided by your antenatal care team free of charge.

What will happen to my samples?

You will be asked to provide additional consent for the collection of your blood and saliva for this study. Blood samples will be collected by Douglass Hanly Moir Pathology Service at Camden or Campbeltown Hospital Pathology service in Campbeltown before being transported directly to Western Sydney University by the principal investigator Ms Simone Ormsby. Saliva samples will be collected at Western Sydney University or at either Campbeltown or Camden Hospitals by Ms Ormsby before being directly transported to Western Sydney University. All samples collected will be coded but re-identifiable if required. Privacy/confidentiality of stored tissue samples will be maintained. Any sample remaining after completion of the study will be securely stored in a freezer; however, as these samples may also be useful in future research, we would like to ask you for unspecified consent, which would allow for the possibility of these samples being used again. If this is to occur, separate ethics approval will be sort for the new study. After a certain time, samples will begin to degrade and need to be destroyed and appropriately disposed of.

Confidentiality / Privacy

Under Australian privacy law, all information collected about you must be kept confidential, unless you agree to it being released. If you consent to take part in this study, your medical records and the data collected for the study will be looked at by the research team. They may also be looked at by authorised people from Western Sydney University to check that the study is being carried out correctly. All of these
people will have a duty of confidentiality to you as a research participant and no information that could identify you will be given to anyone else. The only exception that may apply is if a serious worsening of your depression occurs and the clinician deems it necessary to share information with either your obstetric antenatal health care team or the acute mental health service team CoMHET at Campbelltown or Camden Hospitals or both.

Table 1 Study Events, Times and Requirements

<table>
<thead>
<tr>
<th>Study Stages</th>
<th>Location</th>
<th>What you need to do / what will happen</th>
<th>Time needed</th>
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</table>
| **Visit 1: Sign up & Questionnaire Collection: Pregnancy Week 24.** | Campbelltown or Camden Obstetrics Department | If after reading the study details & considering your options you decide to sign up, the following will be required:  
- Filling out of the consent form  
- Filling out the Trial Entry Form  
- Filling out of 4 questionnaires  
- Filling out of a medical case history  
Ms Ormsby will check that these have been fully completed. | 2 min 5 -10 min 10 - 15 min 10 – 15 min |
| **Visit 1: Sample Collection: Pregnancy Week 24.** | Douglass Hanly Moir Camden or Campbelltown Hospital Pathology Service | Collection of 1st blood & saliva sample | 20 – 25 min |
| **Visit 1: Randomisation Pregnancy Week 24** | Campbelltown or Camden Obstetrics Department | You will open the envelope revealing your group allocation. If you are in either treatment group, you will be given your treatment schedule. 1st treatment is this week. | 2 min |
| **Visit 1 or 2: 1st session: Pregnancy Week 24. Acupuncture & PMR.** | Campbelltown or Camden Obstetrics Department or NICM, WSU. | Attend your first acupuncture or PMR session at pregnancy week 24. | 60 min |
| **Session 2 - 3: Pregnancy week 25 - 26. Acupuncture & PMR** | Campbelltown or Camden Obstetrics Department or NICM, WSU. | The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR. | 60 min |
| **Session 4: Pregnancy week 27. Acupuncture & PMR.** | Campbelltown or Camden Obstetrics Department or NICM, WSU. | The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR. Collection of 2nd saliva sample. Collection of 4 questionnaires, sleep & study questions. | 60 min |
| **Visit 2 or 3: Pregnancy week 27. Treatment as usual only.** | Campbelltown or Camden Obstetrics Department or NICM, WSU. | Collection of 2nd treatment as usual saliva sample, 4 questionnaires & sleep question. | 20 min |
| **Sessions 5-7 : Pregnancy Week 28 - 30. Acupuncture & PMR** | Campbelltown or Camden Obstetrics Department or NICM, WSU. | The first fifteen minutes will be spent discussing how you are & your signs and symptoms prior to you receiving either acupuncture or PMR. | 60 min |
### Confidentiality / Privacy Continued.

The results of this study will be published, for example in scientific journals, you will not be identified by name and a summary of findings will be provided to you by letter.

Any information regarding genetic disease predisposition will not obtained nor will any samples be used to create tissue banks or for any commercial purposes. In addition, any genetic material and information, where potentially identifiable, will not be released for other uses without the participant’s prior consent, unless required by law.

**What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your clinician will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your clinician will arrange for your regular health care to continue. If you

<table>
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<tr>
<th>Session 8a: Pregnancy week 31</th>
<th>acupuncture &amp; PMR</th>
<th>Campbelltown or Camden Obstetrics Department or NICM, WSU.</th>
<th>The first fifteen minutes will be spent discussing how you are &amp; your signs and symptoms prior to you receiving either acupuncture or PMR. Collection of the final saliva sample. Collection of 4 questionnaires &amp; sleep &amp; study questions.</th>
<th>60 min</th>
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<tr>
<th>Session 8b: Pregnancy week 31</th>
<th>acupuncture &amp; PMR</th>
<th>Douglass Hanly Moir Camden or Campbelltown Hospital Pathology Service</th>
<th>Final blood collection.</th>
<th>60 min</th>
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<tbody>
<tr>
<td>Visit 3 or 4a: Pregnancy week 31</td>
<td>Treatment as usual only.</td>
<td>Campbelltown or Camden Obstetrics Department or NICM, WSU.</td>
<td>Collection of final treatment as usual saliva sample, 4 questionnaires &amp; sleep question.</td>
<td>20 – 25 min</td>
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<tr>
<td></td>
<td>Douglass Hanly Moir</td>
<td>Camden or Campbelltown Hospital Pathology Service</td>
<td>Final blood collection</td>
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<td>By phone or sms</td>
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<td>20-25 min</td>
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| Post Birth | By phone or post | Once your baby is born, please let Ms Ormsby know, then she will arrange the 6-week post-birth follow up. | | 1 min |

| 6 weeks post-birth follow-up | 6 questionnaires will be either posted to you or filled out over the phone. Ms Ormsby will contact you to facilitate the return of the filled out questionnaires. | | 20 – 25 min |
If you decide to continue in the research project, you will be asked to sign an updated consent form.

In addition, on receiving new information, your clinician might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

**Can I have other treatments during this research project?**

During the entire duration of the study, that is from signing up to participate at pregnancy week 24 right up until 6 weeks past the birth of your baby, you will not be able to receive either acupuncture or progressive muscle relaxation during the study other than that provided by the clinician.

**What if I withdraw from this research project?**

If you wish to withdraw from the study after it has started, you can do so at any time without having to give a reason. There will be no consequences to you for withdrawing from the study and it will not affect the type of care you receive from either the clinician or any of the obstetric antenatal care team, now or at any time into the future. Personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should also be aware that data collected up to the time you withdraw will form part of the research project results and it may not be possible to return to you your samples and or withdraw your data from the study results if these have already had your identifying details removed.

If you do decide to withdraw from the project, please notify the clinician before you withdraw. This notice will allow the clinician or research supervisors’ time to discuss any special requirements linked to withdrawing.

**Complaints and compensation**

If you suffer any injuries or complications because of this study, you should contact the Ms Ormsby as soon as possible, who will then assist you in arranging appropriate medical treatment. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe equipment, or by the negligence of one of the parties involved in the study (for example, the phlebotomist, the hospital, or the clinician). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for
your injury or complication free of charge as a public patient in any Australian public hospital.

**Who is organising and funding the research?**

This research is being conducted as part of a Higher Degree by Research at Western Sydney University. No external sponsorship is involved and no member of the research team will receive any personal financial benefit from your involvement in this research project.

**Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the South-Western Sydney Local Health District (SWSLHD).

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact the HREC of the South-Western Sydney Local Health District (SWSLHD) directly. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**Further information and who to contact**

When you have read this information, the researcher will discuss with you any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the clinician Simone Ormsby at NICM, Western Sydney University. If you have any problems during the study, please contact Simone Ormsby on +61 2 4620 3290 or 0414 476 711 or by email on simone.ormsby@westernsydney.edu.au or Professor Caroline Smith on +61 2 4620 3777 or by email on caroline.smith@westernsydney.edu.au.

If you feel you require urgent medical attention, please either call an ambulance or attend the emergency department of your local hospital. The contact phone number for Campbelltown and Camden Hospital is 02 4634 3000.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Reviewing HREC approving this research and HREC Executive Officer details**

This study has been approved by the South-Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the
conducted of this study should contact the Ethics and Research Governance Office, Locked Bag 7279, LIVERPOOL BC, NSW, 1871 on 02 8738 8304, fax 02 8738 8310, email research.support@sswahs.nsw.gov.au, website: http://www.sswahs.nsw.gov.au/swsld/about/ethics/default.html and quote HREC/14/LPOOL/400, SSA-14/228.

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.
Appendix H
AcuAnteDep - Participant Informed Consent Form

Consent Form - Adult providing own consent

Title
Acupuncture for Antenatal Depression

Short Title
AcuAnteDep

Protocol Number
1.0

Project Sponsor
Western Sydney University

Coordinating Principal/Investigator/
Simone Ormsby

Associate Investigator(s)
Professors’ Smith, Dahlen & Hay & Associate Professor Lind

Location
Campbelltown & Camden Hospitals

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the principal investigator Ms Ormsby or the associate investigators involved in this study at Western Sydney University, in relation to my depression and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

<table>
<thead>
<tr>
<th>Name of Participant (please print)</th>
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<th>Signature</th>
<th>Date</th>
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Name of Witness* to
Participant’s Signature (please print)

Signature ___________________________ Date ________________________

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print)

Signature ___________________________ Date ________________________

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the collection of two blood samples by Douglass Hanly Moir Camden or Campbelltown Hospital Pathology services and three saliva samples by Ms Ormsby to be taken from me and transported to NICM, Western Sydney University for the use, as described in the relevant section of the Participant Information Sheet, for:

☐ This specific research project
☐ Other research that is closely related to this research project
☐ Any future research.

Name of Participant (please print)

Signature ___________________________ Date ________________________
Name of Witness* to Participant’s
Signature (please print) ___________________________________________
Signature ________________________ Date ____________________________

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Doctor/
Senior Researcher† (please print) ______________________________________
Signature ________________________ Date ____________________________

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.

The conduct of this study at Campbelltown & Camden Hospitals has been authorised by the South-Western Sydney Local Health District, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: research.support@sswahs.nsw.gov.au and quote project number HREC/14/LPOOL/400 – SSA/14/228

MASTER Consent Form Version 3.0 – 21/09/2015

Campbelltown & Camden Hospitals’ Consent Form Version 4.0 – 21/09/2015
Appendix I

Acupuncture Protocol – Eight Extraordinary Vessel Charts, Auricular Maps and Point Prescription Possibilities

1. Governing vessel or Du Mai meridian trajectory and diagnostic indicators
2. Directing vessel or Ren Mai meridian trajectory and diagnostic indicators
3. Penetrating vessel or Chong Mai meridian trajectory and diagnostic indicators
4. Penetrating vessel or Chong Mai meridian trajectory and diagnostic indicators
5. Yin heel vessel or Yin Qiao Mai meridian trajectory and diagnostic indicators
6. Yang heel vessel or Yang Qiao Mai meridian trajectory and diagnostic indicators
7. Yin linking vessel or Yin Wei Mai meridian trajectory and diagnostic indicators
8. Yang linking vessel or Yang Wei Mai meridian trajectory and diagnostic indicators
9. Auricular chart A
10. Auricular chart B
11. Auricular chart C
12. Auricular chart D
13. Auricular chart E
14. Auricular chart F
15. Auricular chart G
16. Table T1
17. Table T2
1. Governing vessel or Du Mai meridian trajectory and diagnostic indicators

GOVERNING VESSEL

Opening point: Houxia S.I.3
Coupled point: Shenmai BL-62
Starting point: Changqiang Du-1
Area of body influenced: back, spine, back of neck and head.

The Governing vessel is called the “Sea of Yang channels” as it exerts an influence on all the Yang channels and it can be used to strengthen the Yang of the body. It can strengthen the spine and tonify Kidney-Yang.

The Governing vessel also nourishes the spine and brain as the inner pathway of the vessel enters the brain. In this sense, it can be used to strengthen the Kidney function of nourishing Marrow and Brain, for such symptoms as dizziness and poor memory. To summarize, the opening and coupled points can be used for the following cases:

1) To tonify Kidney-Yang and strengthen the back. The Governing vessel is extremely useful in all cases of chronic lower back ache due to Kidney deficiency, especially (but not exclusively) when the pain is on the midline of the back. The use of the opening and coupled points can strengthen the back and actually straighten the spine. In men the Governing Vessel can be used on its own, and in women it is best combined with the Directing Vessel, crossing over the opening and coupled points. Thus in a woman, one would use Houxia S.I.3 on the right, Shenmai BL-62 on the left, Lieque LU-7 on the left and Zhaohai KI-6 on the right, the needles being inserted in this order and taken out in the reverse order.

When used for lower back ache, the Governing Vessel opening and coupled points are used first and left in about 10-15 minutes. This has the effect of opening the Governing Vessel, making it more receptive to further treatment with local points. It also has the effect of actually straightening the spine. After withdrawal of the opening and coupled point needles, local points can be used, particularly Yaoyangguan Du-3 or the extra point Shiqizhuixia situated on the midline below the tip of L5 lumbar vertebra.

2) To expel Wind: this can be either internal or external Wind. In exterior attacks, the Governing vessel can be used to release the Exterior and expel Wind at the Greater Yang stage of the 6 Stages (see App. 1). It is therefore used for such symptoms as fever, runny nose, headache, stiff neck and a Floating pulse.

In interior conditions, the Governing Vessel can be used to subdue interior Wind, for such symptoms as dizziness, tremors, convulsions, epilepsy, or for the sequelae of Wind-stroke.

3) To nourish the spine and the brain. Using the opening and coupled points of the Governing Vessel can strengthen the Kidney function of nourishing Marrow and Brain, for such symptoms as dizziness, tinnitus and poor memory.
2. Directing vessel or Ren Mai meridian trajectory and diagnostic indicators

Case history
A man suffered from chronic back ache on the midline in the lumbar area. This was caused by a Kidney deficiency and the Governing Vessel opening and coupled points (Houxi SI-3 and Shenmai BL-62) were used, together with Taiji KI-3 and Shenshu BL-23, producing an immediate marked improvement.

DIRECTING VESSEL

Opening point: Lieque LU-7
Coupled point: Zhohai KI-6
Starting point: Huiyin Ren-1
Area of body influenced: abdomen, thorax, lungs, throat, face.
The Directing vessel is called the “Sea of the Yin channels” as it exerts an influence on all the Yin channels of the body. It originates from the Kidneys and flows through the uterus down to Huiyin Ren-1 where the superficial pathway starts. The Directing Vessel is of paramount importance for the reproductive system of both men and women, but particularly women, as it regulates menstruation, fertility, conception, pregnancy, childbirth and menopause. Its functions and clinical use can be summarized as follows:
1) It can be used to nourish the Yin energy of the body. In this context, it is particularly useful to nourish Yin in women after menopause as the Directing channel controls the uterus and determines the 7-year life cycles of women. It can therefore regulate the energy of the reproductive system and, after the menopause, tonify Blood and Yin to reduce the effects of Empty-Heat symptoms deriving from Yin deficiency.
   It can therefore be used for such symptoms as night sweating, hot flushes, feeling of heat, mental irritability, anxiety, dry mouth at night, dizziness, tinnitus or insomnia, all symptoms of Kidney-Yin deficiency and Heart Empty-Heat. When used in this way, the opening and coupled points are best combined with Guanyuan Ren-4.
2) It regulates the uterus and Blood in women, so that it is responsible for menstruation, fertility, conception, pregnancy, childbirth and menopause.
   It can be used for infertility to promote the supply of Blood to the uterus and in many menstrual disorders such as dysmenorrhea, amenorrhoea, menorrhagia and metrorrhagia.
3) It moves Qi in the Lower Burner and uterus, so that it can be used for lumps, fibroids and carcinoma of the uterus. In men, it is used for hernia.
4) The sphere of action of the Directing Vessel extends not only to the Lower Burner, but also the Middle and Upper Burner. It can in fact be used also to stimulate the Lung descending function and the Kidney function of reception of Qi. For this reason, it is used for chronic asthma, for which it is excellent.

Case history
A man of 37 suffered from chronic asthma characterized by difficulty in inhalation. There was no sputum and he felt very tired generally. His voice was
3. Penetrating vessel or Chong Mai meridian trajectory and diagnostic indicators

low and his complexion Pale. He also had a lower back ache and felt cold. His pulse was Deep and Weak and his tongue was Pale. These manifestations clearly point to deficient Kidney-Yang unable to hold Qi resulting in asthma. Besides this there was also a Lung-Qi deficiency as evidenced by the low voice and pale complexion.

The opening and coupled points of the Directing Vessel (Lieque LU-7 on the left and Zhaohai KI-6 on the right) were used to tonify the Lungs, stimulate the descending of Lung-Qi and stimulate the Kidney function of reception of Qi.

Case history

A woman of 41 had a large fibroid in the uterus for several years. Her periods were very heavy and painful and the menstrual blood was dark. Her lower abdomen was extremely hard and the fibroid was clearly felt on palpation.

She was treated several times using the opening and coupled points of the Directing Vessel producing a complete normalization of her periods and a very marked softening of her lower abdomen. The size of the abdominal swelling was also markedly reduced. Obviously a fibroid of that size cannot be dissolved but the use of the Directing Vessel at least normalized her periods, took the menstrual pain away and made her lower abdomen much more comfortable.

Penetrating Vessel

Opening point: Gongsun SP-4
Coupled point: Neiguan P-6
Starting point: Huiyin Ren-1
Area of body influenced: abdomen, uterus, chest, heart.

The Penetrating Vessel is very complex as it has many different functions at different levels. In a way, it could be considered to be the origin of the other extraordinary vessels (excluding Governing and Directing Vessels) as it originates in the Kidneys and spreads its Qi all over the body at the Defensive Qi level. When this energy arrives at the relevant starting points, it gives rise to the Yin and Yang Linking Vessels, the Yin and Yang Heel Vessels and the Girdle Vessel.

The Penetrating Vessel is described as the “Sea of the 5 Yin and 6 Yang organs” and also as the “Sea of the 12 channels.” It is described as the Sea of the 5 Yin and 6 Yang organs as it is a fundamental vessel which connects the Pre-Heaven and the Post-Heaven Qi, due to its connection with Kidneys and Stomach. It is connected to the Kidneys as it originates in them and it distributes Essence all over the body, and it is connected to the Stomach as it passes through the point Qichong ST-30 which is a point for the Sea of Food. Furthermore, the Penetrating Vessel is connected to the Spleen channel along which it flows on the inner aspect of the thigh, down to the big toe.

It is called the “Sea of the 12 channels” because it branches out in many small capillary-like vessels that circulate Defensive Qi over the abdomen and chest.

The functions and clinical use of the Penetrating vessel can be summarized as follows:
1) The Penetrating Vessel is excellent in cases of rebellious Qi and is therefore often used to move Qi and Blood when they stagnate in the abdomen and chest, for such cases as dysmenorrhea, flatulence, borborygmi, abdominal distension or abdominal masses. In this respect, it is used mostly for Excess patterns chara-
4. Girdle vessel or Dai Mai meridian trajectory and diagnostic indicators

characterized by stagnation and obstruction with a characteristic feeling of fullness of the chest or epigastrium.

2) The Penetrating Vessel, together with the Directing vessel, regulates the uterus and menstruation and it nourishes Blood. It can be used for such conditions as dysmenorrhea, amenorrhea and menorrhagia. The main difference between the Directing vessel and the Penetrating vessel in relation to menstruation is that the former controls Qi and can be used to tonify and nourish, whereas the latter controls Blood and is mostly used to move Qi and Blood and remove obstructions.

3) Since the Penetrating vessel provides the link between the Pre-Heaven and Post-Heaven Qi, it can be used in all cases of weak constitution with digestive symptoms, such as poor appetite, abdominal distension and poor assimilation of food.

4) The Penetrating Vessel exerts an influence on the heart, as it flows through it, and it can be used to move the Blood of the Heart in cases of pain in the chest, feeling of stuffiness of the chest and palpitations.

Case history

A man of 45 suffered from chronic indigestion with a sensation of fullness of the epigastrium, belching and nausea. His pulse was Full and Tense especially in the Middle position, and his tongue had a thick white coating. The clinical manifestations point to retention of food in the Middle Burner. The opening and coupled points of the Penetrating Vessel (Gongsun SP-4 and Neiguan P-6) were used producing a complete recovery after several treatments.

GIRDLE VESSEL

Opening point: Zulinqi G.B.-41
Coupled point: Waiguan T.B.-5
Starting point: Daimai G.B.-26

Area of body influenced: genitals, waist, hips. The Girdle Vessel is the only horizontal vessel of the body. It divides the body in two halves and flows through Zhangmen LIV-13, Daimai G.B.-26, Wushu G.B.-27 and Weidao G.B.-28. It is closely related to the Liver and Gall-Bladder and it connects with the Kidney divergent channel.

The functions and clinical use of the Girdle Vessel can be summarized as follows:

1) It can be used to harmonize the Liver and Gall-Bladder, particularly in Excess patterns of the Liver, when the Gall-Bladder pulse is Full and Wiry, for such symptoms as temporal headaches.

2) The Girdle Vessel can be used to disperse Damp-Heat in the genitals, causing such symptoms as burning; on urination and difficulty in urination.

3) The Girdle Vessel encircles the leg channels and it affects their circulation. Disorders of this channel can therefore impair the circulation of Qi in the leg channels, resulting in such symptoms as cold legs and feet, purple feet or tense outer leg muscles (due to Liver-Blood not moistening the sinews).

4) The Girdle Vessel particularly affects the circulation of Qi in the Stomach channel and can cause weakness of the leg muscles, and in severe cases, atrophy. In these cases the opening and coupled point of the Girdle Vessel can be used to ease the vessel and tonify the Stomach and Spleen channels.

5) The Girdle Vessel flows through the waist and
influences the hip. It can therefore be used for hip pain, particularly when there is a condition of deficiency of Liver-Blood and excess of Liver-Yang, with Liver-Blood deficiency leading to malnourishment of sinews and joints.

Case history

A woman of 45 suffered from chronic migraine headaches characterized by a severe throbbing ache on the temple. Her pulse was Wiry and Full and her tongue was Red with a yellow coating. The headaches were clearly due to the rising of Liver-Yang and the Girdle Vessel opening and coupled points (Zuling G.B.41 and Waiguan T.B.3) were used several times in successive treatments producing a complete cure.

Case history

A woman of 72 suffered from chronic cystitis characterized by severe burning on urination and dark-scanty urine. She also experienced a severe distending sensation in the hypogastrum. Her pulse was Full, Rapid and very Wiry particularly in the Middle position. Her tongue was Deep-Red and had a yellow coating which was thicker on the root. The root of the tongue also had red spots. This problem was caused by the downward infusion of Liver-Fire affecting the Bladder. The opening and coupled points of the Girdle Vessel were used several times in succession, together with other points to clear Liver and Bladder Heat, producing a nearly complete cure.

YIN HEEL VESSEL

Opening point: Zhaohai KI-6
Coupled point: Lianque LU-7
Starting point: Zhaohai KI-6
Accumulation point: Jiuxin KI-8
Area of body influenced: inner side of legs, abdomen, eyes.

The Yin and Yang Heel Vessels are closely related, especially in their relation with the eyes. They both flow up to the eyes, the Yin Heel Vessel bringing Yin energy to them, the Yang Heel Vessel bringing Yang energy to them. When the Yin Heel Vessel is diseased, the eyes cannot stay open and tend to close all the time, i.e. the person feels always sleepy. When the Yang Heel Vessel is diseased, the eyes cannot close and tend to stay open all the time, i.e. the person cannot sleep.

The Yin and Yang Heel Vessels also exert an influence on the tone of the leg muscles. When the Yin Heel Vessel is in Excess the inner leg muscles are tight, and the outer leg muscles loose; when the Yang Heel Vessel is in Excess, the inner leg muscles are loose and the outer ones tight.

The Yin Heel Vessel is an offshoot of the Kidney channel, while the Yang Heel Vessel is an offshoot of the Bladder channel.

The clinical uses of the Yin Heel Vessel can be summarized as follows:

1) Because of its relation with the eyes, it can be used in disturbances of sleep, either insomnia or somnolence. In this context, it is often used in conjunction with the Yang Heel Vessel. In case of insomnia, the Yin Heel Vessel is tonified (by tonifying Zhaohai KI-6) and the Yang Heel Vessel sedated (by reducing Shenmai BL-62). In case of somnolence, the Yin Heel Vessel is
seded (by reducing KI-6) and the Yang Heel Vessel tonified (by reinforcing BL-62). In both cases, the point Jingming BL-1 can be added to establish a connection between the Yin and Yang Heel Vessels, so that Yin and Yang energy in the eyes can be balanced.

2) The Yin Heel Vessel can be used in certain cases of Atrophy Syndrome, when the muscles of the inner aspect of the legs are loose and the foot turns inwards, partly pulled by the tight outer leg muscles; this makes walking very difficult and a person prone to tripping. The Yin Heel Vessel opening and coupled points can be used to balance the tension of the inner and outer leg muscles.

3) The Yin Heel Vessel extends its range of action to the abdomen, and can be used in Excess patterns of the Lower Burner in women, for such symptoms as abdominal distension, abdominal masses, lumps, fibroids, difficult delivery or retention of placenta.

4) Finally, the Yin and Yang Heel Vessels can harmonize left and right, and can therefore be used in structural imbalances between left and right side of the body.

Case history

A man of 28 suffered from continuous somnolence. This followed a car accident during which he suffered a fracture of the skull. He came for treatment as he was studying hard for an exam and could not keep awake.

The point Shenmai BL-62 on the left side was reinforced to stimulate the Yang Heel Vessel, Zhaohai KI-6 on the right side was reduced to sedate the Yin Heel Vessel, and the point Jingming BL-1 was used bilaterally with even method. After only one treatment the somnolence completely disappeared and he could not actually sleep for two days!

YANG HEEL VESSEL.

Opening point: Shenmai BL-62
Coupled point: Houxi SI-3
Starting point: Shenmai BL-62
Accumulation point: Fuyang BL-59
Area of body influenced: lateral aspect of leg, back, neck, head, eyes.

The Yang Heel Vessel is an offshoot of the Bladder channel and it brings Yang energy up to the eyes. Its influence on the eyes and the muscle tone of the lateral side of the legs, has already been mentioned in the discussion of the Yin Heel vessel.

Although the Yin and Yang Heel Vessels are somewhat symmetrical in their functions, there are some differences in their practical use.

Whilst the Yin Heel Vessel’s sphere of influence is mostly in the lower abdomen and genitals (apart from its action on the eyes), the Yang Heel Vessel’s sphere of action is mostly in the head, absorbing excess Yang energy or stagnation in the head area. For this reason, it is used for Wind-stroke, hemiplegia, aphasia and facial paralysis.

The functions and clinical use of the Yang Heel Vessel can be summarized as follows:
1) It absorbs excess Yang energy from the head, and it is therefore used to subdue internal or external wind from the head (Wind is a Yang pathogenic factor), in such conditions as facial
paralysis (exterior Wind), Wind-stroke, severe dizziness and aphasia (interior Wind).
2) It is used to expel exterior Wind and release the Exterior in invasions of exterior Wind-Heat or Wind-Cold, causing such symptoms as sneezing, headache, stiff neck, runny nose and Floating pulse. It is particularly indicated if the exterior attack is accompanied by severe headache and stiff neck.
3) It is extremely effective for lower back ache with pain along the Bladder channel of the leg, but only if this pain is of Excess nature, i.e. acute in character and due to sprain or invasion of Cold. It is only used if the pain is unilateral.
4) The Yang Heel Vessel is also very useful in cases of extreme nervous tension, particularly in young men, when the pulse is very Wiry and the face is red (showing excess Yang energy in the head).
5) As the Yang Heel Vessel flows through the point Juliao G.B.-29, its opening and coupled points can be used as distal points for the treatment of pain in the hip.

Case history
A man of 43 suffered from giddiness and an ache on the lateral side of the legs. His blood pressure was high. His face was red and the muscles on the lateral side of the legs were very tight. He appeared very tense. His pulse was Full, Rapid and Wiry and his tongue was Red.

The Yang Heel Vessel was chosen to calm the Yang, relax the muscles on the lateral side of the legs, subdue interior Wind (manifested by the giddiness) and calm the Mind. The successive use of its opening and coupled points (Shenmai BL-62 on the left and Houxi SL-3 on the right) produced a marked improvement.

YIN LINKING VESSEL

Opening point: Neiguan P-6
Coupled point: Gongxu SP-4
Starting point: Zhubin KI-9
Accumulation point: Zhubin KI-9
Area of body influenced: chest, heart.

The Yin Linking vessel connects all the Yin channels. This is partly due to the fact that its opening point is P-6 pertaining to the Terminal Yin which is the “hinge” of the Yin channels.

Its functions and clinical use can be summarized as follows:
1) Since it connects all the Yin channels, it can be used for deficiency of Blood and/or Yin, especially if accompanied by psychological symptoms such as insomnia, anxiety and mental restlessness. In this context, it has a remarkable effect in calming the mind, especially in women.
2) Since it tonifies Blood, it has a tonifying action on the Heart and can be used for such symptoms as chest pain or a feeling of stuffiness of the chest, a feeling of oppression or tightness of the chest, anxiety, apprehension, depression or nightmares.
3) The Yin Linking Vessel is effective in treating headaches from deficiency of Blood, especially if they are at the back of the neck. This is due to the fact that it nourishes Blood and its opening.
8. Yang linking vessel or Yang Wei Mai meridian trajectory and diagnostic indicators

Point P-6, being also the Connecting point of the Pernardium channel, affects the Triple Burner channel area on the neck.

Case history

A woman of 54 suffered from severe anxiety and claustrophobia. She was afraid to go to the theatre, church or in the underground. She was anxious when alone at home and felt a tight, gripping sensation in the chest. Her pulse was Chophy and her tongue Pale, but with a red tip. The clinical manifestations are due to deficiency of Blood, depriving the Mind of its residence resulting in severe anxiety.

Due to the deficiency of Blood and the typical sensation of tightness of the chest, the Yin Linking Vessel was used (Neiguan P-6 on the right and Gongsun SP-4 on the left) producing excellent results.

YANG LINKING VESSEL

Opening point: Waiguan T.B.-5
Coupled point: Zulinqi G.B.-41
Starting point: Jinmen BL-63
Accumulation point: Yangjiao G.B.-35
Area of body influenced: lateral aspect of leg, sides of body, lateral aspect of neck and head, ears.

The Yang Linking Vessel connects all the Yang channels. Its functions and clinical use can be summarized as follows:

1) It is used for intermittent fevers and alteration of chills and fever. These are symptoms of affection of the Lesser Yang stage in the 6-Stage patterns of penetration of exterior pathogenic factor (see App. 1). The chief symptom at this stage is alternation of chills and fever because the pathogenic factor is lodged half in theterior and half in the Exterior.

2) The Yang Linking Vessel exerts its influence on the sides of the body and is used for such symptoms as hypochondriac pain, pain in the lateral aspect of the leg (such as sciatica along the Gall Bladder channel) and pain in the lateral side of the neck.

3) The Yang Linking Vessel affects the ears and can be used for ear problems due to the rising of Liver-Fire, such as tinnitus and deafness. It can also be used in any ear diseases manifesting caused by a Gall-Bladder disharmony.

Case history

A boy of 12 had a middle-ear infection and the Yang Linking Vessel was used (Waiguan T.B.-5 on the left and Zulinqi G.B.-41 on the right), producing a complete cure.
<table>
<thead>
<tr>
<th>Point(s)</th>
<th>Indications / Symptom alleviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST 40</td>
<td>Spleen deficiency, damp &amp; phlegm misting – Heaviness, confusion, metal disturbance</td>
</tr>
<tr>
<td>ST 23</td>
<td>Transforms phlegm &amp; calms the spirit – mania depression, agitation</td>
</tr>
<tr>
<td>ST 24</td>
<td>Transforms phlegm &amp; calms the spirit – mania depression</td>
</tr>
<tr>
<td>LR 3</td>
<td>LR Qi stagnation, irritability, feeling of oppression</td>
</tr>
<tr>
<td>BL 42</td>
<td>Breathing difficulties, grief, worry, sadness</td>
</tr>
<tr>
<td>BL 44</td>
<td>Calming &amp; mental clarity</td>
</tr>
<tr>
<td>BL 47</td>
<td>Enables clear &amp; positive life planning and decision making</td>
</tr>
<tr>
<td>BL 47 &amp; BL 52</td>
<td>Together adds stability to plans and decisions. Also for LR Qi stasis attack on lungs</td>
</tr>
<tr>
<td>BL 49</td>
<td>Obsessive thinking, improved memory and concentration</td>
</tr>
<tr>
<td>BL 52</td>
<td>Will power, determination, initiation</td>
</tr>
<tr>
<td>BL 52 &amp; BL 42</td>
<td>Will power &amp; emotional release</td>
</tr>
<tr>
<td>BL 52 &amp; BL 44</td>
<td>Will power, calming, anxiety, depression, mental restlessness &amp; insomnia</td>
</tr>
<tr>
<td>BL 52 &amp; BL 47</td>
<td>Will power &amp; life direction, chronic depression with mental exhaustion, apathy &amp; despondency</td>
</tr>
<tr>
<td>BL 52 &amp; BL 49</td>
<td>Will power, obsessive thoughts, worry &amp; confusion</td>
</tr>
<tr>
<td>BL 10</td>
<td>Calms the spirit</td>
</tr>
<tr>
<td>BL 17</td>
<td>Mania, depression</td>
</tr>
<tr>
<td>GV 18</td>
<td>Liver blood deficiency, calming, mental restlessness, agitation, confusion, obsessive thinking</td>
</tr>
<tr>
<td>GV 19</td>
<td>Will power, calming, anxiety, mental restlessness, kidney yin deficiency heat</td>
</tr>
<tr>
<td>GV 19 &amp; CV 15</td>
<td>Calming, insomnia, mental restlessness</td>
</tr>
<tr>
<td>GV 20</td>
<td>Lifts mood, aids memory &amp; concentration</td>
</tr>
<tr>
<td>GV 21</td>
<td>Anxiety, insomnia, depression</td>
</tr>
<tr>
<td>GV 24</td>
<td>Clears the mind</td>
</tr>
<tr>
<td>GV 24 &amp; GB 13</td>
<td>Calming, anxiety, mental restlessness due to LR causes</td>
</tr>
<tr>
<td>CV 14</td>
<td>Transforms phlegm and calms the spirit</td>
</tr>
<tr>
<td>CV 15</td>
<td>Calming, chest oppression</td>
</tr>
<tr>
<td>GB 9</td>
<td>Calms the spirit and pacifies fright</td>
</tr>
<tr>
<td>GB 12</td>
<td>Mania, agitation of the heart &amp; insomnia</td>
</tr>
<tr>
<td>GB 13</td>
<td>Calming, mental clarity, severe anxiety &amp; mental restlessness resulting from LR disharmony</td>
</tr>
<tr>
<td>GB 13 &amp; GV 24</td>
<td>As for GB 13 with enhanced calming effect</td>
</tr>
<tr>
<td>GB 13 &amp; HT 7</td>
<td>Calming, severe anxiety due to heart disharmony</td>
</tr>
<tr>
<td>GB 15</td>
<td>Calms the spirit, reduces emotional fluctuations and obsessive thinking</td>
</tr>
<tr>
<td>GB 17</td>
<td>Calms the spirit, aids memory &amp; concentration</td>
</tr>
<tr>
<td>Acupuncture Point</td>
<td>Function</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>GB 18</td>
<td>Stops obsessive thoughts, strengthens the function of the Lungs and clears the nose</td>
</tr>
<tr>
<td>GB 40</td>
<td>Willpower, difficulty making decisions</td>
</tr>
<tr>
<td>HT 7</td>
<td>Calms the spirit, heart blood and yin deficiency</td>
</tr>
<tr>
<td>HT 6</td>
<td>Calms the spirit, repletion patterns with vacuity heat</td>
</tr>
<tr>
<td>HT 8</td>
<td>Calms the spirit – agitation, fright palpitations, depleted sadness and worry</td>
</tr>
<tr>
<td>HT 9</td>
<td>Calms the spirit – mania-depression, severe mental restlessness, anxiety, insomnia</td>
</tr>
<tr>
<td>HT 5</td>
<td>Calms the spirit – depressive disorder</td>
</tr>
<tr>
<td>PC 4</td>
<td>Calms the spirit – agitation, insomnia, melancholy, spirit qi deficiency</td>
</tr>
<tr>
<td>HT 7 &amp; PC 6</td>
<td>Calms the spirit - Shen disturbance, anxiety, mental restlessness</td>
</tr>
<tr>
<td>KD 6 &amp; HT 6</td>
<td>Calms the spirit - Heart &amp; Kidney not communicating, agitation, insomnia, anxiety</td>
</tr>
<tr>
<td>PC 5</td>
<td>Settles and calms the spirit – mania &amp; agitation</td>
</tr>
<tr>
<td>PC 7</td>
<td>Calms the spirit – depressive disorder</td>
</tr>
<tr>
<td>PC 6</td>
<td>Calms the spirit, lifts mood - qi stagnation emotional problems, anger, resentment &amp; frustration</td>
</tr>
<tr>
<td>PC 6 &amp; SP 4</td>
<td>Opens yin wei mai, nourishes blood, relaxes the chest, calms the spirit</td>
</tr>
<tr>
<td>PC 6 &amp; LR 3</td>
<td>Resolves qi stasis from repressed anger</td>
</tr>
<tr>
<td>PC 6 &amp; GV 20</td>
<td>Lifts the mood, relieves depression</td>
</tr>
<tr>
<td>PC 6 &amp; GV 26</td>
<td>Lifts the mood, opens heart orifices, relieves depression</td>
</tr>
<tr>
<td>SI 7</td>
<td>Calms the spirit – mania-depression, anxiety, sadness, fear &amp; fright</td>
</tr>
<tr>
<td>KD 9</td>
<td>Clears the heart &amp; transforms phlegm - madness, mania, madness depression disorder</td>
</tr>
<tr>
<td>SI 7 &amp; HT 3</td>
<td>Chronic anxiety, depression, fear or emotional distress</td>
</tr>
<tr>
<td>LI 5</td>
<td>Calms the spirit – mania-depression</td>
</tr>
</tbody>
</table>
Table T.2 – Auricular Point Possibilities: Name and Function*

<table>
<thead>
<tr>
<th>Point</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point zero</td>
<td>Homeostasis, will power</td>
</tr>
<tr>
<td>Shen men</td>
<td>Pain, tension, anxiety &amp; depression</td>
</tr>
<tr>
<td>Sympathetic tone</td>
<td>Sympathetic nervous system balance</td>
</tr>
<tr>
<td>Cheerfulness</td>
<td>Relieves depression</td>
</tr>
<tr>
<td>Excitement</td>
<td>Relieves hyperomnia &amp; depression</td>
</tr>
<tr>
<td>Master cerebral point</td>
<td>Anxiety, worry, obsessive compulsive disorders, psychosomatic disorders &amp; chronic pain</td>
</tr>
<tr>
<td>Master oscillation point</td>
<td>Balances left and right cerebral hemispheres</td>
</tr>
<tr>
<td>Sleep disorders 1</td>
<td>Relieves insomnia, nervousness</td>
</tr>
<tr>
<td>Sleep disorders 2</td>
<td>Relieves insomnia, sleep difficulties, nervous dreams</td>
</tr>
<tr>
<td>Depression</td>
<td>Relieves depression</td>
</tr>
<tr>
<td>Endocrine</td>
<td>Hormonal Imbalance</td>
</tr>
<tr>
<td>Nervousness</td>
<td>Relieves nervousness</td>
</tr>
<tr>
<td>Adrenal</td>
<td>Adrenal fatigue / disturbance</td>
</tr>
<tr>
<td>Thyroid 1-4</td>
<td>Thyroid function disturbance</td>
</tr>
<tr>
<td>Marvellous / Wonderful</td>
<td>Lifts mood</td>
</tr>
<tr>
<td>Aggression</td>
<td>Alleviates aggression / irritability</td>
</tr>
<tr>
<td>Mania</td>
<td>Relieves manic symptomology</td>
</tr>
<tr>
<td>Insomnia</td>
<td>For sleep disturbance</td>
</tr>
<tr>
<td>Vitality</td>
<td>For lethargy &amp; despondency</td>
</tr>
<tr>
<td>Stress control</td>
<td>Relieves stress</td>
</tr>
<tr>
<td>Tranquilizer</td>
<td>Calms the spirit</td>
</tr>
<tr>
<td>Guilt</td>
<td>Alleviates feeling of guilt</td>
</tr>
<tr>
<td>Overwhelmed</td>
<td>Stress, emotional paralysis, despondency</td>
</tr>
<tr>
<td>Burdened</td>
<td>Emotional paralysis, despondency, overwhelm</td>
</tr>
</tbody>
</table>
11. Auricular Chart C
13. Auricular Chart E

- Shen Men
- Sympathetic
- Point Zero
- Master Oscillation
- Stress Control
- Thalamus
- Tranquilizer
- Endocrine
- Master Sensorial
- Master Cerebral

14. Auricular Chart F

- Sympathy & Guilt
- Self-Pity
- Depression
- Overwhelmed
- Bearing the Burden of the World
- Rejection
- Anger & Hate
- Self-Expression
- Fear
- Vision
- Heart
- Open
15. Auricular Chart G
Appendix J

PMR Protocol

As the hospital rooms were very bright, participants were instructed to keep their eyes closed in all sessions. The treatment room at NICM had a light that could be dimmed, however, for consistency, these participants were also instructed to keep their eyes closed.

Session 1 – introductory class

Welcome to your first progressive muscle relaxation session.

Progressive muscle relaxation is simple and easy to learn and involves progressive tensing and relaxing of the muscles of the body

Progressive muscle relaxation can help you release tension and let go of stress and achieve a sustained relaxation as you work through the exercises in each of the other sessions

In this first session, the aim is to achieve overall body relaxation

After this week, each session will help you to focus on different parts of your body to help you identify areas where you hold your stress

Start this first session by finding a comfortable position to lie in on the bed. At this stage of pregnancy, you may be able to comfortably lie on your back for extended periods of time, however if you are unable to do this, lie on whichever side feels most comfortable. If you are on your back and during the session you start to feel uncomfortable, nauseated or dizzy, gently adjust yourself to lying on your side, whichever way feels best. If after lying on your side for some time, you start to feel uncomfortable, feel free to swap sides as you need.

[After the participant has decided which position to be in, choose which one to say]

If you are lying on your back, stretch your legs out in front of you, with your arms by your sides, and find a comfortable position to rest your head
If you are lying on your side, have both legs slightly bent at the knees, with one in front of the other and find a comfortable position to rest your head.

Once you are comfortable, take several deep breaths to let yourself relax a little - gently close your eyes and try to keep them closed, as this will help to keep you focused.

Now begin by making a conscious effort to remove all thoughts from your mind.

Take 3 long deep sighs and begin to let your body relax, allow yourself to become more and more relaxed with each breath.

As you breathe out, let go of all thoughts from your mind - leave the day's activities behind, allow your mind become free and empty.

Take 3 more long deep breaths and really let your body relax.

Take your mind to your toes and feet and tighten and contract them as much as you can, holding for as long as you can.

Now let your toes and feet relax and feel the release as you do so.

We will repeat 2 more times.

Tighten and contract your toes and feet, hold for as long as you can and when you release feel the warmth and heaviness spread through the area.

Tighten and contract your toes and feet, hold for as long as you can and when you release feel the warmth and heaviness spread through the area, allowing them to sink into the bed.

Take your mind to your lower legs, knees and your calf muscles, and tighten and contract them as much as you can, holding for as long as you can.

Now let your lower legs and calf muscles relax and feel the release as you do so.

We will repeat 2 more times.
Tighten and contract your lower legs, knees and your calf muscles, hold for as long as you can and when you release feel the warmth and heaviness spread through the area.

Tighten and contract your lower legs, knees and your calf muscles, hold for as long as you can and when you release feel the warmth and heaviness spread through the area, allowing them to sink into the bed.

Take your mind to your upper legs and thighs and tighten and contract them as much as you can, holding for as long as you can.

Now let your upper legs and thighs relax and feel the release as you do so.

We will repeat 2 more times.

Tighten and contract your upper legs and thighs, hold for as long as you can and when you release feel the warmth and heaviness spread through the area.

Tighten and contract your upper legs and thighs, hold for as long as you can and when you release feel the warmth and heaviness spread through the area, allowing them to sink into the bed.

You might like to have a gentle stretch now.

While you are stretching and relaxing, bring your attention to your breathing, check that you are breathing slowly in and slowly out and not holding on to your breath. Take another long deep sigh as you remove all thoughts from your mind again.

Now take your mind to your abdomen and bottom and tighten and contract them both as much as you can, holding for as long as you can.

Now let your abdomen and bottom relax and feel the release as you do so.

We will repeat 2 more times.

Tighten and contract your abdomen and bottom, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area.
Tighten and contract your abdomen and bottom, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area, allowing them to sink into the bed…….

Take your mind to your chest and back, fill your chest full of air, expanding into the back as well, holding for as long as is comfortable ……

Now slowly release the air from your lungs, let your back sink back into the bed, releasing the tension as you do so

We will repeat 2 more times

Fill your chest full of air, expanding into the back as well, hold for as long as is comfortable and when you release feel the warmth and heaviness spread through the area……

Fill your chest full of air, expanding into the back as well, hold for as long as is comfortable and when you release feel the warmth and heaviness spread through the area, allowing them to sink into the bed……

Now take your mind to your fingers and hands and tighten and contract them as much as you can for as long as you can………..

Let your fingers and hands relax and feel the release as you do so
We will repeat 2 more times

Tighten and contract your fingers and hands, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area……

Tighten and contract your fingers and hands, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area, allowing them to sink into the bed……

Bring your attention to your breathing again, check that you are breathing slowly in and out, not holding on to your breath as you allow yourself to really relax now. Take another long deep sigh and remove all thoughts from your mind again
Take your mind to your shoulders and neck and tighten and contract them, bringing your shoulders up to your ears in a heavy shrug, holding for as long as you can…….

Now let your neck and shoulders relax and sink your shoulders into the bed, and feel the tension in your neck release as you do so

We will repeat 2 more times

Tighten and contract your shoulders and neck, bringing your shoulders up to your ears in a heavy shrug, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area…….

Tighten and contract your shoulders and neck, bringing your shoulders up to your ears in a heavy shrug, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area, allowing them to sink into the bed…….

Take your mind to your face and head and screw your face up as tightly as you can and push your head hard into the pillow, holding for as long as you can…….

Now let your face relax and neck fully relax

We will repeat 2 more times

Tighten and contract your face and head and screw your face up tightly and push your head hard into the pillow, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area…….

Tighten and contract your face and head and screw your face up tightly and push your head hard into the pillow, hold for as long as you can and when you release, feel the warmth and heaviness spread through the area, allowing them to sink into the bed…….

Make sure now that your mouth is relaxed, your tongue is on the floor of your mouth, and take another long deep heavy sigh…….

Bring your attention to your breathing again, concentrate on slowly breathing in and slowly breathing out, let yourself relax completely, sink into the bed as your body feels heavier and more relaxed……
Next, we are going have an extended relaxation time of about 15 minutes. I want you to take yourself to a special place of peace and calm in your mind. In this place you feel safe, warm and relaxed. I want you to feel like you are really in this place. Feel the breeze on your face, smell the scents in the air, hear the sounds around you and the surface beneath your body. Allow yourself to feel peaceful and tranquil in this safe place, as you quietly breathe in and out, feeling calm and relaxed as your mind is free of all other thoughts...

Do not read ..............................................lapse of time 15 minutes

Slowly bring your mind back to focus on yourself again, bring yourself back into the room, as you take a long deep heavy sigh

Slowly and gently stretch yourself from your toes to your shoulders
If you were on your back, slowly and gently move to your side. Once you are on your side or if you already were, slowly and gently, when you feel ready, come up to sitting. After that, when you are ready, slowly come up to standing

Take some time to gently move around the room to make quite sure that you are well roused and awake. If you did drive here today, make sure you are fully awake before you get into your car.

Once you feel ready, please take a seat again as I will ask a few questions about how you are feeling.

Session 2 – lower legs and knees

Welcome back to your 2nd progressive muscle relaxation session

Having spent the last session focusing on overall body relaxation, this session will continue on with this theme with a particular focus on your lower legs and knees

Start this session by finding a comfortable position to lie in on the bed. Remember that if you are on your back and you start to feel uncomfortable, nauseated or dizzy, feel free to gently adjust yourself to lying on your side, whichever side feels best. If after lying on your side for some time, you start to feel uncomfortable, feel free to swap sides.
Gently bring your attention to your breathing, take 3 long deep sighs as you start to allow yourself to relax and leave the day’s activities behind….

With even deep and relaxed breathing begin now by tensing tightly your calf muscles, hold for as long as you can and then let them release them, letting them, feeling the warmth and relaxation spread through the area

--- we will repeat this long tensing and relaxing 5 times ...

tense your calf muscles, hold for as long as you can ..........release when you are ready
and again, tense, hold for as long as you can........ and release
and again, tense, hold for as long as you can........ and release
and again, tense, hold for as long as you can........ and release
and again, tense, hold for as long as you can........ and release

Now gently move and stretch your calf muscles, let go of any remaining tension and then let them fully relax, feel heavy and sink into the bed

Now with even breathing focus on your knees and knee caps, tense and tighten your knees as tightly as you can for as long as you can, and when you can't hold it any longer, let them relax, feeling the warmth and heaviness spread through the area

--- we will repeat this long tensing and relaxing 5 times ...

tense your knees, hold for as long as you can ......and release
and again, tense, hold for as long as you can........ and release
and again, tense, hold for as long as you can........ and release
and again, tense, hold for as long as you can........ and release
and again, tense, hold for as long as you can........ and release

Now gently shake your lower legs and knees to let go of all remaining tension and let them relax, feel heavy and sink into the bed

Now take your mind now to your toes and feet, tighten and contract them and hold them like this for as long as you can.....
When you can't hold it anymore, let your toes and feet relax and feel the release as you do so. Let your feet feel very heavy, warm and relaxed and let them sink into the bed.

Take your mind now to your lower legs, knees and your calf muscles, tighten and contract them as much as you can, holding for as long as you can.

Once you can't hold it any longer, let your lower legs and calf muscles relax and feel the release as you do so.

Take your mind to your upper legs and thighs and tighten and contract them as much as you can, holding for as long as you can.

When you release, let your upper legs and thighs relax and feel the release as you do so. Your whole legs should feel very warm and heavy now.

If you feel like having a gentle stretch, do this now, checking that you are still breathing slowly in and out, and not holding on to your breath. Once settled again, take another long deep sigh and remove all thoughts from your mind again.

Take your mind now to your abdomen and bottom and tighten and contract them both as much as you can, holding for as long as you can.

When you can't hold it any longer, let your abdomen and bottom relax and feel the release as you do so, let this area feel heavy, warm and sink into the bed.

Take your mind to your chest and back, fill your chest full of air, expanding the back of your lungs as well, hold like this for as long as is comfortable.

When you release, let your back sink back into the bed, releasing any tension, feeling warm and heavy.

Now take your mind to your fingers and hands and tighten and contract them as much as you can for as long as you can.

When you can't hold it any longer, let your fingers and hands relax, feel the release as you do so, let this area feel heavy, warm and sink into the bed.
Check again that your breathing is slowly in and out, you are not holding on to your
breath as you take another long deep sigh as you remove all thoughts from your mind
again

Take your mind to your shoulders and neck and tighten and contract them, bringing your
shoulders up to your ears in a heavy shrug, hold like this for as long as you can........

When you release, let your neck and shoulders relax and sink into the bed, and feel the
tension in the area release as you do so

Take your mind to your face and head and screw your face up tightly and push your head
back into the pillow, holding for as long as you can........

When you release, let your face and neck completely relax, letting go of all of the tension
in the area

Now make sure your mouth is relaxed and your tongue is on the floor of your mouth,
take another long deep heavy sigh......

Take your mind back to your breathing, concentrate on slowly breathing in and slowly
breathing out, as you let yourself relax completely, sinking into the bed as your body
feels heavier and more relaxed....... 

We are going to now have an extended relaxation time of about 12 minutes, to do this, I
want you to take yourself to a special place of peace and calm in your mind. In this place
you feel safe, warm and relaxed. I want you to feel like you are really in this place. Feel
the breeze on your face, smell the scents in the air, hear the sounds around you and the
surface beneath your body. Allow yourself to feel peaceful and tranquil in this safe place,
as you quietly breathe in and out, feeling calm and relaxed as your mind is free of all
other thoughts...

Not to be read..............................lapse of time 12 minutes

Slowly bring your mind back to focus on yourself again, bring yourself back into the
room, as you take a long deep heavy sigh

Slowly and gently stretch yourself from your toes to your shoulders
If you were on your back, slowly and gently move to your side. Once you are on your side or if you already were, slowly and gently, when you feel ready, come up to sitting. After that, when you are ready, slowly come up to standing.

Take some time to gently move around the room to make quite sure that you are well roused and awake. If you did drive here today, make sure you are fully awake before you get into your car.

Once you feel ready, please take a seat again as I will ask a few questions about how you are feeling.

**Session 3 – upper legs and buttocks**

The area substituted was as follows:

Gently start by wriggling and shaking your upper legs and buttocks as you take 3 long deep breaths

Now with even and deep relaxed breathing begin now by tensing tightly your thighs and hip muscles, holding like this for as long as you can and when you can’t hold it any longer, release, allowing warmth, heaviness and relaxation to spread through the area.

--- we will repeat this long tensing and relaxing 5 times...
  tense your thigh and hip muscles, hold for as long as you can ..........and release
  and again, tense, hold for as long as you can........ and release
  and again, tense, hold for as long as you can........ and release
  and again, tense, hold for as long as you can........ and release
  and again, tense, hold for as long as you can........ and release

Now gently shake your thigh and hip muscles, letting go of any remaining tension, allow this area to feel totally relaxed and heavy and sink into the bed.

Now take your mind to your buttocks and with even breathing, gently begin to tense your buttocks as tightly as you can, hold for as long as you can, when you release, feel the tension leave and the area feel warm and heavy.

--- we will repeat this long tensing and relaxing 5 times...
tense your buttocks, hold for as long as you can …… and release
and again, tense, hold for as long as you can…….. and release
and again, tense, hold for as long as you can…….. and release
and again, tense, hold for as long as you can…….. and release
and again, tense, hold for as long as you can…….. and release

Session 4 – lower back and pelvic floor

The area substituted was as follows:

Start by gently wriggling your lower back as you take 3 long deep breaths

Now with even breathing, slowly and gently arch your lower back, holding for as long as you can without straining and when you can’t hold it any longer, release the area, allowing it to feel warm, relaxed and heavy
--- we will repeat this gentle slow arching without straining and relaxing 5 times …

Slowly and gently arch your lower back without straining, hold for as long as you can ………..and release
and again, slowly and gently arch, hold for as long as you can without straining……..and release
and again, slowly and gently arch, hold for as long as you can without straining
……..and release
and again, slowly and gently arch, hold for as long as you can without straining
……..and release
and again, slowly and gently arch, hold for as long as you can without straining
……..and release

Now gently wriggle your lower back to let go of any tension and relax

Now take your mind to your pelvic floor and gently squeeze these muscles with even breathing. If you are squeezing your pelvic floor properly your buttocks will not move at all – if you find that you are squeezing your buttocks, move your focus forward to the flat area that supports you when sitting and squeeze that area instead –

Now with even deep and relaxed breathing, focus on your pelvic floor and begin to gently tighten these muscles as much as you can for as long as you can, and then let them release, feeling warm and heavy
--- we will repeat this tightening and relaxing 5 times...
Tighten your pelvic floor, hold for as long as you can …..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release
and again, tighten, hold for as long as you can……..and release

Session 5 – upper back and chest

The area substituted was as follows:

Take your mind to your upper back and your chest - think about how much you rely upon your upper back and chest for activity and strength every day – think about how important it is to relax this area completely so as to release stress and strain

Start by gently wriggling your upper back as you take 3 long deep breaths

Now with even breathing, slowly and gently arch your upper back, holding for as long as you can without straining and then relax --- we will repeat this gentle slow arching without straining and relaxing 5 times ...

Slowly and gently arch your upper back and without straining, hold for as long as you can ............and then release

and again, slowly and gently arch, hold for as long as you can without straining...........and then release

and again, slowly and gently arch, hold for as long as you can without straining

...........and then release

and again, slowly and gently arch, hold for as long as you can without straining

...........and then release

Now gently wriggle your upper back and let go of any tension and allow the warmth and relaxation to spread throughout this area

Now take your mind to your chest and the energy you demand of it every day
Take in a long slow deep breath to fully expand your lungs and then slowly let the air go and release --- we will repeat this slow deep breathing and relaxing 5 times...

- take a long slow deep breath to fully expand your lungs and then slowly let the air go .......and release
- and again, long slow deep breath, slowly let it go ........and release
- and again, long slow deep breath, slowly let it go ........and release
- and again, long slow deep breath, slowly let it go ........and release
- and again, long slow deep breath, slowly let it go ........and release

Now gently wriggle your chest to let go of all of the tension, take a sigh and allow this area to fully relax, feel warm and heavy

**Session 6 – arms and shoulders**

The area substituted was as follows:

Take your mind to your arms and shoulders - think about how much effort you expect of your arms and shoulders every day and how much tension they hold – think about how important it is to completely relax your arms and shoulders and give them relief

Start by gently shaking your arms as you take 3 long deep breaths

Now with even breathing, stretch your arms out tightly, holding for as long as you can and then release---we will repeat this stretching and relaxing 5 times ...

- Stretch your arms out tightly, hold for as long as you can ...........and release
- and again, stretch out tightly..........and release
- and again, stretch out tightly..........and release
- and again, stretch out tightly..........and release
- and again, stretch out tightly..........and release

Gently shake your arms again to let go of tension and relax, allowing your arms to feel heavy and warm

Now take your mind to your shoulders
Shrug your shoulders tightly for as long as you can and then relax them --- we will repeat this shrugging and relaxing 5 times...

Shrug your shoulders tightly for as long as you can ......and relax
and again, shrug tightly.......and relax
and again, shrug tightly.......and relax
and again, shrug tightly.......and relax
and again, shrug tightly.......and relax

Gently shake your shoulders, to let go of all tension and then let them relax completely, feeling both heavy and warm

**Session 7 – head, face and neck**

The area substituted was as follows:

Now take your mind to your head, face and neck - think about how much work and activity your head, face and neck engages in every day and how much strain they take - think about how important it is to relax your head, face and neck completely, to relieve them of this pressure and strain, as you take 3 long deep breaths

Now with even breathing, screw your face up tightly, holding for as long as you can and then relax ---we will repeat this screwing up tightly and relaxing 5 times ...

Screw your face up tightly, hold for as long as you can ...........and relax
and again, screw up tightly.........and relax
and again, screw up tightly........and relax
and again, screw up tightly.........and relax
and again, screw up tightly........and relax

Very slowly and gently move your head forward and back and side to side, as much as you can in the position you are in, without straining, as you breathe slowly in and out

We will repeat this gentle head movement with deep breathing 5 times ...

Slowly and gently move your head forward and back and from side to side as you breathe deeply in and out

and again, slowly and gently move your head forward and back and from side to side as you breathe deeply in and out
and again, slowly and gently move your head forward and back and from side to side as you breathe deeply in and out

and again, slowly and gently move your head forward and back and from side to side as you breathe deeply in and out

and again, slowly and gently move your head forward and back and from side to side as you breathe deeply in and out

Let your head gently find a comfortable position again and let it completely relax and feel heavy.

**Session 8 – final session - integration**

Welcome back to your 8th and final progressive muscle relaxation session.

Having spent the last session focusing on your head, face and neck, this session will bring together all of the previous classes to achieve an overall deep releasing relaxation.

Start this session by finding a comfortable position to lie in on the bed. Remember that if you are on your back and you start to feel uncomfortable, nauseated or dizzy, feel free to gently adjust yourself to lying on your side, whichever side feels best. If after lying on your side for some time, you start to feel uncomfortable, feel free to swap sides.

Gently bring your attention to your breathing, take 3 long deep sighs as you start to allow yourself to relax and leave the day's activities behind.

As you relax take your mind to each part of your body, starting with your toes and feet and progressively move up to your face, head and neck – remember how hard each area works for you and where you hold tension as you focus on each area in turn – gently remind yourself to remove all other thoughts from your mind and just focus on recognising your body’s tensions.

As you move through the progressive muscle relaxation this final time, remember how you were able to remove tension from each area previously, and how that enabled you to deeply relax.

So start now by taking your mind to your toes and feet, tighten your feet and toes together and then contract them holding for as long as you can…..when you can’t hold it any longer, relax the area completely.
We will repeat 2 more times...

When you are ready, tighten and contract and hold for as long as you can...

Release when you can't hold it any longer, feel the relaxation spread through the area

Last time, tighten and contract and hold for as long as you can...

Release when you can't hold it any longer and let your toes and feet completely relax - let your feet feel very heavy, warm and relaxed - let them sink into the bed, so that you are not aware of them at all.....

Take your mind now to your lower legs, knees and your calf muscles, tighten and contract them as much as you can holding for as long as you can.........when you can't hold it any longer, relax the area completely.

We will repeat 2 more times...

When you are ready, tighten and contract and hold for as long as you can...

Release when you can't hold it any longer, feel the relaxation spread through the area

Last time, tighten and contract and hold for as long as you can...

Release when you can't hold it any longer and let your lower legs, calf muscles and knees relax completely - let them feel very heavy, warm and relaxed, as they sink into the bed, so that you are not aware of them at all.....

Take your mind to your upper legs and thighs and tighten and contract them as much as you can, holding for as long as you can.......when you can't hold it any longer, relax the area completely.

We will repeat 2 more times...

When you are ready, tighten and contract and hold for as long as you can...

Release when you can't hold it any longer, feel the relaxation spread through the area
Last time, tighten and contract and hold for as long as you can...

Release when you can’t hold it any longer let your upper legs and thighs relax completely - let them feel very heavy, warm and relaxed, as they sink into the bed so that you are not aware of them at all....

Now take your mind back to your breathing to check that you are breathing slowly in and out, and not holding on to your breath take a long deep sigh as you remove all thoughts from your mind again

Take your mind now to your abdomen and bottom and tighten and contract them both as much as you can, holding for as long as you can......when you can't hold it any longer, relax the area completely.

We will repeat 2 mores times

When you are ready, tighten and contract and hold for as long as you can...

Release when you can’t hold it any longer, feel the relaxation spread through the area

Last time, tighten and contract and hold for as long as you can...

Release when you can’t hold it any longer let your abdomen and bottom relax completely, feeling heavy and sinking into the bed, so that you are not aware of them anymore

Take your mind to your chest and back and tighten and contract them both, holding for as long as you can with your chest expanded and full of air........ when you can't hold it any longer, relax the area completely.

We will repeat 2 mores times

When you are ready, expand your chest full of air, hold for as long as you can...

Release when you can’t hold it any longer, feel the relaxation spread through the area
Last time, expand your chest full of air, hold for as long as you can...

Release when you can’t hold it any longer and let your chest and back relax, releasing the air and letting both your back and chest sink heavily into the bed, letting go of all of the tension as you continue to breathe slowly and evenly and remove all thoughts from your mind again.

Now take your mind to your fingers and hands and tighten and contract them as much as you can for as long as you can........when you can’t hold it any longer, relax the area completely.

We will repeat 2 more times

When you are ready, tighten and contract and hold for as long as you can...

Release when you can’t hold it any longer, feel the relaxation spread through the area.

Last time, tighten and contract and hold for as long as you can...

Release when you can’t hold it any longer let your fingers and hands relax and sink heavily into the bed so that you are not aware of them anymore

Next take your mind to your shoulders and neck and tighten and contract them, bringing your shoulders up to your ears in a heavy shrug, holding for as long as you can....... when you can’t hold it any longer, relax the area completely.

We will repeat 2 more times

When you are ready, tighten and contract your shoulders in a shrug, hold for as long as you can...

Release when you can’t hold it any longer, feel the relaxation spread through the area.

Last time, tighten and contract your shoulders in a shrug, hold for as long as you can...
Release when you can’t hold it any longer, let your neck and shoulders relax and sink heavily into the bed, feel the tension in your neck release as you do so.

Take your mind now to your face and head and screw your face up tightly and push your head into the pillow, holding for as long as you can........ when you can’t hold it any longer, relax the area completely.

We will repeat 2 more times.

When you are ready, tighten and contract your face and push your head into the pillow, hold for as long as you can...

Release when you can’t hold it any longer, feel the relaxation spread through the area.

Last time, tighten and contract your face and push your head into the pillow, hold for as long as you can...

Release when you can’t hold it any longer, let your face relax and let your head roll find a comfortable position and feel really heavy and relaxed.

Relax your mouth, check your tongue on the floor of your mouth as you take another long deep heavy sigh.

Concentrate on slowly breathing in and slowly breathing out, as you let yourself relax completely, totally sinking into the bed as your body feels heavier and more relaxed.......

Let yourself feel deeply and completely relaxed .......

Now take your mind to a special place of peace and calm. In this place you feel safe, warm and relaxed. I want you to feel like you are really in this place of peace and calm. Feel the breeze on your face, smell the scents in the air, hear the sounds around you and the surface beneath your body. Allow yourself to feel peaceful and tranquil in this safe place, as you quietly breathe in and out, feeling calm and relaxed as your mind is free of all other thoughts...

Not to be read..........................Lapse of time 15 minutes

Slowly bring your mind back to focus on yourself again, bring yourself back into the room, as you take a long deep heavy sigh.
Slowly and gently stretch yourself from your toes to your shoulders

If you were on your back, slowly and gently move to your side. Once you are on your side or if you already were, slowly and gently, when you feel ready, come up to sitting. After that, when you are ready, slowly come up to standing.

Take some time to gently move around the room to make quite sure that you are well roused and awake. If you did drive here today, make sure you are fully awake before you get into your car.

Once you feel ready, please take a seat again as I will ask a few questions about how you are feeling.
## Appendix K

### The Kessler 6 (K6) Scale

During the past 4 weeks (28 days) how much of the time did you feel...

(please tick 1 box in each row)...

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>... so sad nothing could cheer you up?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>... nervous?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>... restless or fidgety?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>... hopeless?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>... that everything was an effort?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>... worthless?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Appendix L

The 21 item Depression and Anxiety Scale (DASS – 21)

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:
0  Did not apply to me at all - NEVER
1  Applied to me to some degree, or some of the time - SOMETIMES
2  Applied to me to a considerable degree, or a good part of time - OFTEN
3  Applied to me very much, or most of the time – ALMOST ALWAYS

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>N</th>
<th>S</th>
<th>O</th>
<th>AA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I found it hard to wind down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>I was aware of dryness of my mouth</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>I couldn’t seem to experience any positive feeling at all</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>I experienced breathing difficulty (e.g., excessively rapid breathing,</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>breathlessness in the absence of physical exertion)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>I found it difficult to work up the initiative to do things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>I tended to over-react to situations</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>I experienced trembling (e.g., in the hands)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>I felt that I was using a lot of nervous energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>I was worried about situations in which I might panic and make a fool of myself</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>I felt that I had nothing to look forward to</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>I found myself getting agitated</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>I found it difficult to relax</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13</td>
<td>I felt down-hearted and blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>I was intolerant of anything that kept me from getting on with what I was doing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>I felt I was close to panic</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>I was unable to become enthusiastic about anything</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17</td>
<td>I felt I wasn’t worth much as a person</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18</td>
<td>I felt that I was rather touchy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19</td>
<td>I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20</td>
<td>I felt scared without any good reason</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>21</td>
<td>I felt that life was meaningless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix M

The World Health Organisation (WHO) Quality of Life 26 Item Scale (WHOQOL-BREF)

The following questions ask how you feel about your quality of life, health, or other areas of your life. Please choose the answer that appears most appropriate. If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last four weeks.

<table>
<thead>
<tr>
<th></th>
<th>Very poor</th>
<th>Poor</th>
<th>Neither poor nor good</th>
<th>Good</th>
<th>Very good</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How would you rate your quality of life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
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<thead>
<tr>
<th></th>
<th>Very dissatisfied</th>
<th>Dissatisfied</th>
<th>Neither satisfied nor dissatisfied</th>
<th>Satisfied</th>
<th>Very satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. How satisfied are you with your health?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

The following questions ask about how much you have experienced certain things in the last four weeks.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little</th>
<th>A moderate amount</th>
<th>Very much</th>
<th>An extreme amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. To what extent do you feel that physical pain prevents you from doing what you need to do?</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4. How much do you need any medical treatment to function in your daily life?</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5. How much do you enjoy life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. To what extent do you feel your life to be meaningful?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little</th>
<th>A moderate amount</th>
<th>Very much</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. How well are you able to concentrate?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
8. How safe do you feel in your daily life?  

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<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</table>

9. How healthy is your physical environment? 

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>5</th>
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</thead>
</table>

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little</th>
<th>Moderately</th>
<th>Mostly</th>
<th>Completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Do you have enough energy for everyday life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Are you able to accept your bodily appearance?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. Have you enough money to meet your needs?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. How available to you is the information that you need in your day-to-day life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. To what extent do you have the opportunity for leisure activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</tbody>
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<tr>
<th></th>
<th>Very poor</th>
<th>Poor</th>
<th>Neither poor nor good</th>
<th>Good</th>
<th>Very good</th>
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</thead>
<tbody>
<tr>
<td>15. How well are you able to get around?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</tbody>
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<tr>
<th></th>
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<th>Dissatisfied</th>
<th>Neither satisfied nor dissatisfied</th>
<th>Satisfied</th>
<th>Very satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>16. How satisfied are you with your sleep?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. How satisfied are you with your ability to perform your daily living activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. How satisfied are you with your capacity for work?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>How satisfied are you with yourself?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>19.</td>
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<th></th>
<th>Very dissatisfied</th>
<th>Dissatisfied</th>
<th>Neither satisfied nor dissatisfied</th>
<th>Satisfied</th>
<th>Very satisfied</th>
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<tbody>
<tr>
<td>20. How satisfied are you</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>with your personal relationships?</td>
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<tr>
<td>21. How satisfied are you</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>with your sex life?</td>
<td></td>
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<tr>
<td>22. How satisfied are you</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<td>with the support you get</td>
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<td>from your friends?</td>
<td></td>
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<tr>
<td>23. How satisfied are you</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<td>with the conditions of your</td>
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<td>living place?</td>
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<td>24. How satisfied are you</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>5</td>
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<td>with your access to health</td>
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<td>services?</td>
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<tr>
<td>25. How satisfied are you</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td>with your transport?</td>
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</tbody>
</table>

The following question refers to how often you have felt or experienced certain things in the last four weeks.

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Seldom</th>
<th>Quite often</th>
<th>Very often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>26. How often do you have</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
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<tr>
<td>negative feelings such as</td>
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<tr>
<td>blue mood, despair, anxiety,</td>
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<tr>
<td>depression?</td>
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</tbody>
</table>
Appendix N
The Being a Mother - 13 (BaM-13) Scale

Your baby/toddler’s age: __________ (weeks or months or years?)

Do you have any other children? Yes / No (if Yes, how old are they:

-----------------------------------------------------------------------------------------------

The items below will help us understand how you are experiencing being a mother.

There are no right or wrong answers. Just answers that tell us how you have been feeling.

For each question think about how you have been feeling over the past two - three weeks.

Please tick one statement for each item.

Over the past 2 - 3 weeks

1. I have felt confident about looking after my baby/toddler
   □ Yes, most or all of the time
   □ Yes, some of the time
   □ No, not very often
   □ No, rarely or never

2. I have missed the life I had before I became pregnant with this baby/toddler (or for adoptive mothers: before I had this baby/toddler)
   □ No, rarely or never
   □ No, not very often
   □ Yes, some of the time
   □ Yes, most or all of the time

3. I have found it hard to cope when my baby/toddler cries
   □ No, rarely or never
   □ No, not very often
   □ Yes, some of the time
   □ Yes, most or all of the time

4. I have felt close to my baby/toddler
   □ Yes, most or all of the time
   □ Yes, some of the time
   □ No, not very often
   □ No, rarely or never

5. I have felt lonely or isolated
6. I have felt bored
   - No, rarely or never
   - No, not very often
   - Yes, some of the time
   - Yes, most or all of the time

7. I have felt unsupported
   - No, rarely or never
   - No, not very often
   - Yes, some of the time
   - Yes, most or all of the time

8. I have felt alright about asking people for help or advice when I needed to
   - Yes, most or all of the time
   - Yes, some of the time
   - No, not very often
   - No, rarely or never

9. I have felt nervous or uneasy around my baby/toddler
   - No, rarely or never
   - No, not very often
   - Yes, some of the time
   - Yes, most or all of the time

10. I have been worried that something would happen to my baby/toddler
    - No, rarely or never
    - No, not very often
    - Yes, some of the time
    - Yes, most or all of the time

11. I have been annoyed or irritated with my baby/toddler
    - No, rarely or never
    - No, not very often
    - Yes, some of the time
    - Yes, most or all of the time

12. I worry I am not as good as other mothers
    - No, rarely or never
    - No, not very often
    - Yes, some of the time
    - Yes, most or all of the time
13. I have felt guilty
☐ No, rarely or never
☐ No, not very often
☐ Yes, some of the time
☐ Yes, most or all of the time

- If you have found being a mother very stressful, very difficult, or unenjoyable, why do you think this is?

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

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Appendix O

AcuAnteDep – Trial entry identifiable data form

CONTACT & MEDICAL DETAIL

Last Name

____________________________

First Names

____________________________

______/______/_______

Contact Phone Number

Date of Birth

Age

____________________________

Address

____________________________________________________

____________________________

Suburb

Post Code

Email

____________________________________________________

Hospital Antenatal Clinic you are registered at?

____________________________________________________

Place you intend to give birth?

____________________________________________________

Your Local Doctor’s Name & Practice Suburb

____________________________________________________

Alternative Contact:

Last Name

____________________________

First Names

____________________________

Contact Phone Number

Relationship to you

____________________________________________________

Acupuncture for Antenatal Depression – AcuAnteDep – Version 1.0 – 14/07/2014
INCLUSION AND EXCLUSION CRITERIA

**Inclusion Criteria:** Are you over 18 years of age? 
☐ Yes  ☐ No

Are you less than 24 weeks gestation? 
☐ Yes  ☐ No

**Exclusion Criteria:** Have you been experiencing a major depressive episode that has lasted for more than two years duration? 
☐ Yes  ☐ No

Do you have a phobia to acupuncture needles? 
☐ Yes  ☐ No

Over the trial period, are you willing to abstain from having either acupuncture or Progressive Muscle Relaxation other than that provided during the trial? 
☐ Yes  ☐ No

Have you been diagnosed with any of the following?

☐ Pre-eclampsia  ☐ Gestational Diabetes  ☐ Premature Rupture of Membranes

☐ An obstetric bleeding disorder  ☐ An obstetric disorder that will require extensive bed rest

☐ Any other serious medical condition – is ‘yes’ please list: ____________________________________________

MEDICAL & PERSONAL INFORMATION – Please tick the appropriate box or answer as required.

Ethnicity

Were you born in Australia? 
☐ Yes  ☐ No
If no please tell us your country of birth____________________________________

Are you of Aboriginal or Torres Strait Islander ancestry?* optional       □ Yes   □ No

What was the date of your last menstrual period?                     __/______/  

What is your estimated date of delivery?                            __/______/  

Current stage of pregnancy?                                         __________     

Are you becoming a mum for the first time?                         □ Yes   □ No

Relationship Status?                                                  □ Married or living as married
                                                                 □ Single / Divorced / Widowed
                                                                 □ Never married

What is your highest level of education?                             □ Year 10 □ HSC □ TAFE / College
                                                                     □ Undergraduate □ Post-graduate

Are you working?

If 'yes' full-time (F/T) or part-time (P/T)                       □ F/T   □ P/T

If 'yes' what is your occupation?                                    _________________________________

If 'yes' are you planning to take maternity leave?                   □ Yes   □ No

If 'yes', for how long?                                              __________
Do you feel financially supported? □ Yes □ No

Do you feel emotionally supported? □ Yes □ No

If ‘yes’ do you have someone you can confide in? □ Yes □ No

Was this pregnancy conceived using Assisted Reproductive Technology? □ Yes □ No

If ‘yes’ how many other pregnancies have you conceived this way? __________

Do you know the sex of this baby? □ Yes □ No

If happy to tell, please tick male (M) or female (F). □ M □ F

Do you have children? □ Yes □ No

If ‘yes’, how many children do you have? ________________________________

What are their sexes? __________________________

Did you breast feed? □ Yes □ No

If ‘yes” how many times & for how long? ________________________________

Are you planning to breast feed again this time? □ Yes □ No

Have you had depression in pregnancy before? □ Yes □ No

If ‘yes’, how many times and for how long? ______________________________

If ‘yes’ how would you describe the depression? □ Mild □ Moderate □ Severe □ Mixed

If ‘yes’ how was your antenatal depression managed? □ Psychotherapy □ Antidepressants □ Other

If ‘other” please explain method used if any _________________________________

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During this pregnancy, have you used any Complementary or Alternative Therapies, including: treatments, herbs or supplements? □ Yes □ No

If ‘yes’, please list: ____________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

Have you ever had post-partum depression (within 1 year post birth)? □ Yes □ No

If ‘yes’, how many times? _______________________________________________________

If ‘yes’ how would you describe the depression? □ Mild □ Moderate □ Severe □ Mixed

If ‘yes’ how was your post-partum depression managed? □ Psychotherapy
□ Antidepressants □ Other

If ‘other” please explain method used if any _______________________________________

Have you had depression at times other than pregnancy or within the first-year post-birth? □ Yes □ No

If “yes” how old were you the first time? ____________________________

Approximately how many times have you been depressed? ______________

How long do the phases generally last? ________________________________

How would you describe the episodes? □ Mild □ Moderate □ Severe □ Mixed

How was your depression managed? □ Psychotherapy □ Antidepressants □ Other

If ‘other” please explain method used if any _______________________________________

Is there any family history of depression? □ Yes □ No

Are you currently taking medication(s)? □ Yes □ No

Name of Medication(s) _______________________________________________________
Do you drink alcohol?  
☐ Never  ☐ Quit  ☐ Current

If 'Quit' or 'Current' how many drinks per week? ________________

Smoking history  
☐ Never  ☐ Quit  ☐ Current

If 'Quit' or 'Current' how many years did/have you smoked for? ____________

If 'Quit' or 'Current' how many cigarettes did/do you smoke per day? ____________

Recreational drug use  
☐ Never  ☐ Quit  ☐ Current

If 'quit' for how many years did you use recreational drugs? ____________

If 'quit' when was the last time you used recreational drugs? ____________

If 'current' what is your current use? ____________________________

Have you ever had acupuncture before?  
☐ Yes  ☐ No

If 'yes' please list what you had it for ____________________________

If 'yes' approximately how many sessions have you have? ____________

Do you think it was helpful?  
☐ Yes  ☐ No

What was your expectation prior to having it the first time? ____________

If 'no' had you heard of it?  
☐ Yes  ☐ No

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Model of antenatal care:
1. Obstetrician
2. Standard Antenatal care
3. Caseload Midwifery

Group Allocation:
1. Acupuncture Group
2. Progressive Muscle Relaxation Group
3. Treatment as usual Group

Randomised Participant Number
Appendix Q

AcuAnteDep – Trial Entry Participant History and Chinese Medicine Diagnosis Form

Please list any current medical conditions

________________________________________________________

Current Western & complementary or over the counter medication:

________________________________________________________

Past History

List any major past illness & age of occurrence

________________________________________________________

________________________________________________________

List any broken bones & age of occurrence

________________________________________________________

List any surgery, age of occurrence & location of scars

________________________________________________________

List the frequency and types of exercise you currently do

________________________________________________________

Please indicate as follows:

✓ any condition experienced occasionally

✓✓ any condition experienced commonly

✓✓✓ any condition of major concern

☐ otherwise, leave blank

General

Chills ☐ ☐ ☐ Fever ☐ ☐ ☐ Night sweats ☐ ☐ ☐
Insomnia ☐ ☐ Fatigue ☐ ☐ Cold hands & Feet ☐ ☐
Hot/sweaty palms & feet ☐ ☐ ☐ ☐ Facial flushing ☐ ☐
Heavy Sleep ☐ ☐ ☐ Sweating Easily ☐ ☐ ☐ Waking tired ☐ ☐
Heavy limbs ☐ ☐ ☐ Fluid retention ☐ ☐ ☐ Where?
How often do you catch colds / flus? _____________________________
Do you smoke? (Cigarettes / Marijuana) ☐ How much p.w.? _________________
Do you drink alcohol? ☐ What type? ☐ ☐ ☐ How much p.w.? _________________
How many hours sleep do you get on average each night? _________________
Disturbed sleep? ☐ ☐ ☐ ☐ Dreaming / nightmares? ☐ ☐ ☐ ☐
How much coffee / tea do you drink per day? _________________
**Musculoskeletal**

Do you experience pain or stiffness or weakness in your:

Muscles  
Joints  
Bones  

If so, describe where


**Digestive**

Poor appetite  
Excessive appetite  
Indigestion  
Heartburn  
Bloating after eating  
Thirst  
Food &/or acid reflux  
Food sitting in the stomach  
Nausea  
Vomiting  
Flatulence  
Hunger  
Pain under the rib cage  
Stomach pain  
Cramps  
Sore gums  
Dry mouth  
Bad breath  
Rapid weight gain  
Rapid weight loss  
Can’t gain weight  
Ulcer  
Hernia  
Gallstones  
Constipation  
Difficulty and / or pain passing stools  
Burning anus  
Blood in stools  
Diarrhoea  
Soft unformed stools  
Watery stools  
Urgency upon passing  
Alternating diarrhoea & constipation  
Haemorrhoids  
Irritable Bowel Syndrome  
Food allergies  

**Average Daily Diet**

B’fast  
Lunch  
Dinner  


**Urinary**

Is urination?  -  
Frequent  
Dribbling  
Stress incontinent  
Prolapse Bladder  
Blood in urine  
Kidney stones  
Wake to urinate?  -  
If so how many times?

Approximately how many times do you urinate per day?

How much water do you drink per day?

**Head, Eyes, Ears, Nose & Throat**

Eye strain  
Eye Pain  
Eye Redness  
Dry eyes  
Blurred vision  
Spots in vision  
Conjunctivitis  
Ear aches  
Ringing in the ears  
Loss of hearing  
Mouth and or tongue ulcers  

Sinus pain & congestion
Post nasal drip
Tonsillitis
Teeth grinding
Hair thinning
Headaches

Nasal congestion / mucus
Dry throat
Swollen glands
Toothache
Hair loss

Sore throat
Lump in throat
Loose teeth
Dry hair & scalp

Post nasal drip
Toothache
Loose teeth

Dry throat
Swollen glands
Lump in throat

Sore throat
Lump in throat

Nasal congestion / mucus
Dry hair & scalp

Sinus pain & congestion

Post nasal drip

Tonsillitis

Teeth grinding

Hair thinning

Headaches

Respiratory

Dry cough
Productive cough
Asthma

Wheezing
Shortness of breath
Tight Chest

Bronchitis
Difficulty breathing
Catarrh

Allergies

Cardiovascular

High BP
Low BP
High cholesterol

Irregular heartbeat
Chest Pain
Fainting

Dizziness
Palpitation
Anaemia

Skin

Rashes
Eczema
Psoriasis
Acne

Shingles
Herpes
Warts
Itching

Emotions

Irritability
Frustration
Depression
Worry

Melancholy
Sadness
Fear
Anxiety

Easily startled
Shyness
Nervousness
Stressed

Inability to let go
Excessive / obsessive thinking

Are you quiet & reserved? or more outgoing and extroverted?

Do you have difficulty speaking up for yourself / being assertive?

Difficulty making decisions?

Difficulty making plans?

Difficulty expressing your emotions?

Female Reproduction Related:

Menstruation commenced age?
Normal Cycle time & duration?

Previously did you experience:

Absence of periods
Irregular
Painful
Clots

Heavy flow
Light flow

Colour of flow
PMT - irritability  ☑  Sore breasts  ☑  Swollen abdomen  ☑
Pelvic Inflammatory Disease  ☑  Endometriosis  ☑  Thrush  ☑
Positive PAP  ☑  Ovarian Cysts  ☑  Breast lumps  ☑
Infertility  ☑  Prolapse Uterus  ☑  Fibroids  ☑  Cystitis  ☑

Current Gestation Age: ____________________________

Anything else you would like to add? ______________________________________

________________________________________________________________________

________________________________________________________________________

Practitioner Area: ___________________
Meridian: _______________________
Tongue: _________________________
Pulse: __________________________
Observations: ____________________
TCM Diagnosis: __________________
8 Extra Vessel Disharmony: ________
Other Chinese Medical Diagnosis: __________
Treatment: _______________________

Session Completion Follow Up: __________________________
How are you feeling after the session?
________________________________________________________________________
### MEDICAL HISTORY FROM PATIENT FILE

**Booking in date:**

___/___/_______

**Gestation age:**

___________

**Booking in EPDS score:**

___________

- If 'yes' management was?
  - Psychotherapy
  - Antidepressants
  - ECT/EST
  - Other

- If 'other' please specify:

________________________________________________________________________

- Medication prescribed?

_____________________________

- Was there risk of self-harm?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- How was depression managed during pregnancy?

<table>
<thead>
<tr>
<th>Psychotherapy</th>
<th>Antidepressants</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECT/EST</td>
<td>Other</td>
</tr>
</tbody>
</table>

- If 'other' please specify:

________________________________________________________________________

- Was a referral made to a mental health team?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- Was there risk of self-harm risk?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- If 'yes' management was?

________________________________________________________________________

- Did the woman develop any obstetric complications?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
If ‘yes’ please tick?  
☐ Gestational Hypertension  ☐ Pre-eclampsia

☐ Gestational Diabetes  ☐ PROM

☐ Obstetric Bleeding Disorder  ☐ Preterm Birth  ☐ Other

If ‘other’ please specify: ______________________________

**Labouring & Post Natal Results**

At what gestation age did labour commence?  ____________________

How long was the labour?  ____________________

How was the baby born?

☐ Normal vaginal delivery  ☐ Assisted vaginal delivery  ☐ C–section

If ‘assisted vaginal delivery’ what else was required?

☐ Ventouse  ☐ Episiotomy  ☐ Forceps

Was induction required?  ☐ Yes  ☐ No

If ‘yes’ which methods were used?

☐ A.R.M  ☐ Gel  ☐ Foleys catheter  ☐ Drip

Was pain relief administered?  ☐ Yes  ☐ No

If ‘yes’ what was used?  ☐ Gas  ☐ Pethidine/Morphine

☐ Epidural  ☐ Other

If ‘other’ please specify: __________________________________________

Did the women experience a post-partum haemorrhage?  ☐ Yes  ☐ No
| If 'yes' estimated blood loss (ml)? | ☐ ☐ ☐ |
| Infant sex | ☐ M ☐ F |
| Infant Weight (grams) | ☐ ☐ ☐ |
| Agpar Scores | ☐ 1 min ☐ 5 min |
| Need for NICU? | ☐ Yes ☐ No |
| If 'yes' length of stay and why? | __________________________________________ |
| | __________________________________________ |
| Breast Feeding: | Initiated ☐ Yes ☐ No |
| At discharge | ☐ Yes ☐ No |
| Breast milk exclusive | ☐ Yes ☐ No |
| Formula Only | ☐ Yes ☐ No |
| Breast & Formula | ☐ Yes ☐ No |
| Date of discharge | _____/_____/_______ |

Acupuncture for Antenatal Depression – AcuAnteDep – Version 1.0 – 14/07/2014
Appendix S

AcuAnteDep – Week 4 and 8 Intervention Feedback Form

Acupuncture for Antenatal Depression  Participant Code
Collection By
Date
Time

INTERVENTION FEEDBACK (Session 4 and 8 – intervention groups only)

The following questions relate to the interventions used in the study, please answer as applicable.

**Question 1:** If you were randomized to receive acupuncture or Progressive Muscle Relaxation, could you please describe your experience of receiving the intervention so far / overall?

**Question 2:** Has your experience differed from your expectation? If so, in what way?

**Question 3:** Have you found acupuncture of Progressive Muscle Relaxation helpful and if so, in what way?

**Question 4:** Would you consider having the therapy again and if so, why?

**Question 5:** Would you recommend the therapy to your friends and if so, why?
Appendix T

AcuAnteDep – Week 4 and 8 Sleep Feedback Form

Acupuncture for Antenatal Depression          Participant Code
Collection By
Date
Time

SLEEP QUALITY FEEDBACK

Overall, have you noticed any change in your overall quality of sleep and if so, can you please describe in what way?
Appendix U

AcuAnteDep – Six-Week Postnatal Follow Up Form

Since having your baby, have you breastfed? ☐ Yes ☐ No

If ‘yes’ are you still breastfeeding? ☐ Yes ☐ No

If ‘no’, on what date did you stop breastfeeding? __________

If ‘yes’, at present are you? ☐ Exclusive breastfeeding ☐ Yes ☐ No
☐ Mixed with formula ☐ Yes ☐ No

How many feeds per day on average? __________

How would you describe the depression you experienced during pregnancy?
☐ Mild ☐ Moderate
☐ Severe ☐ Mixed

How was your depression managed? ☐ Psychotherapy
☐ Antidepressants
☐ Other

If ‘other’ please explain method used if any ____________________________

Have you been feeling depressed since giving birth? ☐ Yes ☐ No

If ‘yes’ for how long? ____________________________

If ‘yes’ are you still experiencing it? ☐ Yes ☐ No

If ‘yes’ how would you describe the depression? ☐ Mild ☐ Moderate
If 'yes' how is it being managed?  ☐ Psychotherapy

☐ Antidepressants

☐ Other

If 'other' please explain method used if any ________________________
Appendix V
Per-protocol, ACM and LVCF ITT Between Group Analyses of Intervention Changes to EPDS Scores

Table 6.13 Per-Protocol and ‘Average Closet Match’ and ‘Last Value Carried Forward’ ITT Comparative Analysis of the Primary Intervention Outcome EPDS Scores per Group Allocation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Progressive Muscle Relaxation</th>
<th>Acupuncture</th>
<th>Standard Care</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1 – Baseline</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17.84 ± 3.88</td>
<td>17.05 ± 3.24</td>
<td>17.74 ± 3.48</td>
<td>0.758</td>
</tr>
<tr>
<td>Session 4 – Mid intervention</td>
<td>(n=15)</td>
<td>(n=17)</td>
<td>(n=19)</td>
<td></td>
</tr>
<tr>
<td>Per-protocol</td>
<td>13.73 ± 5.12</td>
<td>13.71 ± 4.47</td>
<td>16.21 ± 4.76</td>
<td>0.208</td>
</tr>
<tr>
<td>ACM Imputed ITT</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13.63 ± 4.61</td>
<td>13.58 ± 4.26</td>
<td>16.21 ± 4.76</td>
<td>0.135</td>
</tr>
<tr>
<td>LVCF Imputed ITT</td>
<td>14.74 ± 5.31</td>
<td>13.90 ± 4.28</td>
<td>16.21 ± 4.76</td>
<td>0.330</td>
</tr>
<tr>
<td>Session 8 – End of intervention</td>
<td>(n=11)</td>
<td>(n=17)</td>
<td>(n=18)</td>
<td></td>
</tr>
<tr>
<td>Per-protocol</td>
<td>12.46 ± 4.55</td>
<td>9.18 ± 4.53</td>
<td>14.78 ± 4.20</td>
<td>0.002*</td>
</tr>
<tr>
<td>ACM Imputed ITT</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12.37 ± 3.40</td>
<td>8.95 ± 4.34</td>
<td>14.79 ± 4.08</td>
<td>0.000**</td>
</tr>
<tr>
<td>LVCF Imputed ITT</td>
<td>13.63 ± 4.73</td>
<td>9.84 ± 4.74</td>
<td>14.90 ± 4.11</td>
<td>0.003***</td>
</tr>
<tr>
<td>Six weeks postnatal</td>
<td>(n=11)</td>
<td>(n=15)</td>
<td>(n=18)</td>
<td></td>
</tr>
<tr>
<td>Per-protocol</td>
<td>11.18 ± 5.85</td>
<td>9.33 ± 6.36</td>
<td>10.67 ± 6.40</td>
<td>0.729</td>
</tr>
<tr>
<td>ACM Imputed ITT</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td>(n=19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.16 ± 4.39</td>
<td>9.21 ± 5.76</td>
<td>10.58 ± 6.23</td>
<td>0.539</td>
</tr>
<tr>
<td>LVCF Imputed ITT</td>
<td>12.84 ± 5.67</td>
<td>10.11 ± 6.45</td>
<td>11.00 ± 6.39</td>
<td>0.386</td>
</tr>
<tr>
<td>Linear mixed model repeated measures analysis for between group difference over the 3 antenatal collection points - subject variance</td>
<td>7.75 ± 2.27</td>
<td>0.017*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACM imputed linear mixed model repeated measures analysis for between group difference over the 3 antenatal collection points - subject variance</td>
<td>7.25 ± 2.06</td>
<td>0.023*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVCF imputed linear mixed model repeated measures analysis for between group difference over the 3 antenatal collection points - subject variance</td>
<td>8.74 ± 2.34</td>
<td>0.061</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per protocol linear mixed model repeated measures analysis for between group difference over the 4 collection points (incl. 6 weeks postnatal - subject variance</td>
<td>7.59 ± 2.30</td>
<td>0.113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACM imputed linear mixed model repeated measures analysis for between group difference over the 4 collection points (incl. 6 weeks postnatal - subject variance</td>
<td>7.17 ± 2.08</td>
<td>0.170</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVCF imputed linear mixed model repeated measures analysis for between group difference over the 4 collection points (incl. 6 weeks postnatal - subject variance</td>
<td>9.04 ± 2.43</td>
<td>0.365</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are mean ± SD; alpha values are set at p=0.05; ACM – ‘average closet match’; 1 session 4 data was missing for one individual in the PMR group, other week 4 forms were provided by this individual; * group 4 vs group 1, p = 0.002; ** group 4 vs group 1, p = 0.000; *** group 4 vs group 1, p = 0.003, group 4 vs group 6, p=0.038; * significant group difference.
Appendix W

**Background**

In developed countries, including Australia, depression in pregnancy occurs at rates similar to those seen in non-pregnant women [1, 2], with prevalence reportedly ranging from 7.4% [3] to 25% [5] or higher [1] in vulnerable at-risk groups [1, 4]. Whilst areas of lower socioeconomic status (SES) have not been identified as a risk factor in all studies [5], they have been shown to contribute to the presence of a greater number of individual psychosocial risk factors [6] and consequently may result in increased vulnerability. Modest consequences include a significantly increased risk of obstetric complications [1, 4, 7–11] and postnatal depression in mothers [2, 12], as well as alterations in growth, development [11, 13], autonomic neuroendocrine function [4, 14–18] and mental health [4, 14, 17] in offspring. Treatment recommendations range from psychotherapy or antidepressants for moderate cases to electroconvulsive therapy or a tricyclic combined with an anti-psychotic for depression with psychosis [18]. Providing medical opinion advocates that the consequences of leaving maternal depression pharmacologically untreated is comparable to or greater than the risks associated with anti-depressant side effects and toxicity [11, 19, 20]. Yet, the efficacy of anti-depressants in pregnancy remains untested in large randomised controlled trials (RCTs), and, whilst expected to be comparable to those observed in non-pregnant populations [21], pregnancy-related pharmacokinetic changes may necessitate a need for increased dosage [21, 22]. Clinicians often reduce prescriptions in an attempt to limit fetal exposure, and resultant levels may therefore be subtherapeutic [22]. Recent evaluations of anti-depressant response rates in non-pregnant populations report modest improvements ranging from 14% [23] to 32% overall [24, 25], and more than 50% of cases failing to achieve remission [25]. Treatment adherence is also an issue, with 45% partially [26] and 42% completely discontinuing medication within the first 3 months [27, 28], due in part to unwanted adverse effects [27, 28]. This is especially the case in intentionally conceiving or pregnant women, in whom cessation of medication is particularly common [9, 29], resulting in relapse rates of 68% compared to 36% in those who continue medication [30]. Combined pharmacologic treatments and psychotherapies, although considered to be more efficacious, also appear to be limited in regard to depression severity and chronicity [31].

Studies indicate that depressed, pregnant women are reluctant to take anti-depressant medication [9, 32] and are significantly more likely to voice a preference for non-pharmacologic options [33, 34]. Preliminary research into acupuncture for the management of antenatal depression, although limited to three clinical studies, appears promising and reflective of similar findings in systematic reviews of acupuncture as a treatment for depression [35–37]. In the first antenatal depression RCT, published in 2004, Munber and co-workers [38] compared 12 sessions of depression-specific, manualised acupuncture with sham acupuncture and a massage control in 61 pregnant women with major depression. Significantly higher response rates were reported for depression-specific acupuncture (69%) compared with massage (23%) (p = 0.003) and a non-significant intermediate response rate in comparison to sham (47%). The depression-specific acupuncture group also demonstrated a significantly higher average rate of reduction in depression scores within the first month of treatment compared with the massage control (p = 0.007). In 2005, Munber et al. [39] conducted a larger RCT of 150 pregnant women and demonstrated significantly decreased symptom severity in the acupuncture group (p < 0.05) compared with combined control (sham alone, as well as significantly greater response rates (63.6%) compared with combined controls (p = 0.05) or sham alone (p < 0.05). In 2007, Basco Guerreiro da Silva [40] similarly investigated emotional complaints in pregnancy by quasi-randomising 51 women to a pre-programmed acupuncture protocol with four optional points or a non-treatment control. Symptom severity reportedly reduced by up to 50% in 15 (60%) of 25 subjects in the acupuncture group compared with 5 (26%) of 19 in the control group (p = 0.003). In addition, significant reductions in the impact of distress in 3 of 5 life disturbance categories were also reported (p < 0.05). Whilst the findings of these three trials appear encouraging, the overall methodological quality is limited by small sample sizes [38, 40], quasi-randomisation and lack of an equivalent attention control [40], unclear randomisation generation and concealment [38, 39], unclear assessor blinding [38, 39, 40], and incomplete baseline and outcome data [9, 34]. Participant and practitioner blinding was performed in the two RCTs [38, 39], as was outcome assessor blinding in one [9, 35]. In all three studies, emotional distress was clinically evaluated.

How acupuncture may reduce depressive symptomatology remains uncertain, however, one mechanism by which it may exert an effect is via the oxytocergicergic system. This system, regulated by both oxytocin (OT) hormone levels and oxytocin receptor (OT receptor) activity [41], is responsible for stress response and is associated with a number of positive effects at the physiological, psychological and social level [42]. The resultant anti-anxiety, anti-depressant and stress reducing effects [41, 43] appear to mask from adjustments to the hypothalamic-pituitary axis, autonomic nervous system activity [44] and reward centres in the brain [45]. A multitude of physical [42], psychosocial, emotional and cognitive functions [44–48], including mental health and parental-infant bonding [49], have been attributed to this system, and, not surprisingly, disruptions within it are also implicated in a plethora of negative emotional and psychological conditions.
social phenotypic traits [50]. Studies of the relationship between mental health and the oxytocinergic system are suggestive of dysregulation [51], as lowered [52–56] and elevated OT and OTR levels [51, 61–66], as well as deregulated patterns of peripheral OT release [66], are seen in participants with depression in a variety of different observational and experimental conditions. The influence of acupuncture upon this system has also been assessed in 12 rodent studies and 1 human study in which significant positive regulatory effects were reported, directly via radioimmunoassay and/or enzyme-immunoassay or quantitatively real-time polymerase chain reaction (qR-PCR) analysis [67–74], as well as indirectly via assessment of behaviour [75–79]. Further indirect evidence has been provided by 11 human studies examining acupuncture for the prevention, induction or enhancement of labour. Among these studies, significantly reduced requirements for syntocinon augmentation were reported in the acupuncture groups of nine studies [80–88], as was a trend toward less need in the acupuncture group of another [89]. In the remaining study, acupuncture was performed in addition to intravenous syntocinon, and labour effectiveness rates were also significantly improved [90]. Marginal non-significant elevations in syntocinon use were reported in two similar studies [91, 92]; however, methodological issues in both cases may have compromised the results.

As preliminary evidence is suggestive that acupuncture may be beneficial in reducing the severity of antenatal depression and may exert a regulatory effect upon the oxytocinergic system, additional research is warranted to determine whether acupuncture is a viable alternative therapeutic option. The aim of this study is to conduct an RCT to examine the hypotheses that acupuncture compared with an attention comparator or usual care, reduces the severity and duration of antenatal depression, anxiety and stress; decreases adverse maternal and infant outcomes; improves maternal quality of life and infant bonding; and positively regulates OT and OTR expression.

Methods/design

Overview

A pragmatic, parallel-group RCT will be conducted to compare individually tailored, semi-standardised, depression-specific acupuncture with an equivalent attention progressive muscle relaxation (PMR) comparator and usual care. The feasibility of this population is sufficient to sustain existing treatment and evaluate the interventions as adjunctive therapies [93]. The trial design incorporates individualised treatment flexibility [94], typical of a "whole systems" approach [95, 96], within the framework of a semi-standardised protocol [97–100] and is thereby reflective of the recent emphasis on effectiveness studies of acupuncture interventions to maintain ecological validity [101] as well as generalisability and interpretability [98, 99]. The non-specific, placebo-like effects resulting from intervention participation [102, 103] will be estimated via the attention comparator, whereas antenatal depression progression or remission and compliance to standard therapy will be monitored via the non-treatment control [100].

Ethical approval for this study was granted in February 2015 by the Research and Ethics Office of the New South Wales Department of Health, South West Sydney Local Health District (SWLHDOHRFC/14/POCI/400) and the Western Sydney University Human Research Ethics Committee (USUHREC/14/WSY/1011). The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615002653388). The protocol (version 1.0) has been designed in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines for interventional trials [104, 105] (see Additional file 1) and will be conducted in accordance with the Declaration of Helsinki (1964) and the International Conference on Harmonization Good Clinical Practice (1996). Any changes that need to be made to the trial protocol will be communicated to all investigators, the ethics committees and the trial registry.

Eligibility criteria

Women will be eligible if they are at 34 weeks of gestation, ≥ 21 years of age, have mood disorders and score ≥ 13 on the Edinburgh Postnatal Depression Scale (EPDS [106] (indicative of a high probability of current depression) [106, 107]. Women will be excluded if they are experiencing a medically diagnosed major depressive episode ≥ 2 years in duration and/or have psychotic or manic features rendering them incapable of consent, post-traumatic stress disorder with needle phobia, a current psychiatric assessment of suicidal risk, a condition necessitating bed rest, and/or other major obstetric risks. Participants must also agree not to receive acupuncture or PMR other than that provided within the study.

Recruitment, setting and informed consent

The study is being conducted at two hospital sites in South Western Sydney, Australia. Both sites provide antenatal outpatient services and are under the governance of the same health authority; however, birthing services are available only in the larger of the two. The region serviced includes suburbs considered to be of disadvantaged SES [108], high ethnic diversity and greater than state average indigenous population density [108, 109]. Pregnant women will be introduced to the study via flyers included in antenatal information packs. Antenatal staff will additionally supply a study poster to all women identified with elevated EPDS scores during routine antenatal screening. Details of these women will be provided to the researcher, who, upon
contact, will forward participant information sheets to all interested potential recruits. Once agreeing to join the study, all women will be further screened and, if eligible, randomised after signed informed consent forms containing separate provisions for the collection and use of biological specimens have been obtained in every case (Additional file 2).

Randomisation and blinding
Participants and practitioners are not blinded to the study; however data entry and analysis will be blinded. The randomisation schedule was computer-generated to contain three groups of random numbers, enabling stratification for the three different models of antenatal care (obstetrician, standard and caseload midwifery) as well as to randomly contain 'blocks of three' within each group, acupuncture, PMR or usual antenatal hospital care (1:1:1). The schedule was generated by the school statistician (Paul Fahey) and concealed in opaque envelopes by an independent researcher from the National Institute of Complementary Medicine (NICM) (Anthony Good).

Treatment and assessment schedules
The study period will run for 8 consecutive weeks from gestation week 24 to the end of week 31 (Fig. 1). At baseline, age, gestational age, number of previous pregnancies and/or births, relationship status and/or quality, education, employment status and country of birth will be collected, along with depression-related clinical data, including medical diagnoses, entry EPDS score, age of onset and length of index episodes, number and severity of past depressive episodes, length and severity of current episode, family history of depression and current medication and/or psychotherapy use. Collected data will be de-identified and securely stored at the NICM.

Safety monitoring
Owing to the morbidity of this population, women will undergo a weekly psychological assessment with the Kessler 6 (K6) instrument [110], either during the weekly session (intervention groups) or by telephone (usual care). If notable worsening or a 'cut-off' score is reached, immediate referral will be made to hospital antenatal mental health services. Any adverse events arising from the acupuncture intervention will be documented and reported to Westmead Sydney University and the South West Sydney Local Health District, and prevalence will be calculated. Such events are reportedly rare (occurring approximately 1.3 times every 1000 treatments) and generally of a mild [111, 112] to moderate nature [112]. However, if such
Interventions

In the first session, a full case history will be taken and a traditional Chinese medicine (TCM) and meridian therapy diagnosis will be made. This will also occur for the usual care group upon trial entry. The intervention groups will then receive weekly 1-h treatments over the 8-week period. At the end of each session, 5 minutes will be spent gaining feedback regarding the session. Treatments will be conducted in the maternal clinics of either hospital or at the NICM.

The acupuncture protocol drawn upon TCM theoretical foundations and treatment strategies as well as some generalisable traditional East Asian medicine approaches. The three-stage semi-standardised flexible process (Fig. 2) incorporates a ‘root’ and ‘branch-style’ treatment [113, 114] as well as auricular acupuncture. The ‘root’ treatment (step 1) aims to provide a fundamental harmonization via the extraordinary meridian system while the ‘branch’ treatment (step 2) focuses on remaining disruptions in a more symptomatic way [114–116]. Use of the extraordinary meridian system as a root-style approach has been suggested to facilitate a longer-lasting, more penetrating effect [114, 116] by virtue of the system’s ability to regulate the ‘qi’ of all of the yin-and-yang channels [117], access and distribute ‘pre-existing essence’ throughout the entire body [116, 118], and affect a person at a constitutional level, due to its embryological roots [115, 118, 119]. Specific functions relevant to depression include influences to the marrow (116), brain, spinal chord, hypothalamic-pituitary-gonadal axis [120], circulatory, hepatic, biliary [121] and endocrine [118] systems. Pathology within this system is thought to manifest in the mind or ‘Shen’ [118], and such treatment is recommended for mental and/or emotional problems [110, 120] as well as cases of mixed pattern complexity involving multiple meridians [118]. In step 1, diagnosis of the most dis harmonious extraordinary meridian pair will be made on the basis of the presence of relevant mood disturbance symptomology [116] in combination with disease indicating palpation findings along involved channel trajectories [117–119]. If uncertainty remains regarding which of the 2 points of the meridian pair will be the master point (MP), each point will be tested with a tap to see which one provides the greatest meridian improvement. After identification, the gender-appropriate MP and coupled point (CP) (Table 1) will be unilaterally needled with a meridian flow to ensure that the areas traversed by both vessels are influenced [118]. This method was recommended by Maciocia in 2006 [118] for problems of the head and internal organs, weakened body condition and anxiety. It is also suitable for pregnant women in side-lying position. Japanese-style practitioners typically apply polarity devices to the MP and CP to remedy detected pathologies in the extraordinary vessel system [119, 122]. However, for the purposes of generalisability, polarity in this case will be achieved by use of unidirectional unilateral needling and reverse-order withdrawal [116]. Whilst needles are retained for 10–15 minutes, further diagnosis will be performed by palpation and questioning. As many of the symptoms of depression correspond to TCM ‘yang deficiency’ such as lethargy, reduced libido and lack of motivation [116], it has been theorised that disruption to the major yang channel, the extraordinary meridian governor vessel (GV) that traverses the middle of the back and head, is implicated in depression [123]. Treatment recommended by Wang and Zheng in 2010 [123] is the needling of the most painful or obstructed points along this channel or on the slightly adjacent (ST 41) points, serving a dual main channel and extraordinary vessel function [118]. Fig. 2 illustrates the key points of the two points located in this way, in combination with either GV 20 (Gai hu) [124] + GV 16 (feng fu) [124], the Sea of Marrow, indicated for mania, suicidal tendencies and calming the spirit; or Shi Shen Cong 4–4 Alert points, indicated for mania, depression, insomnia and calming of the spirit [117]. Selection in either case will be based upon palpation, tenderness and/or symptom differentiation. Whilst these needles are retained, step 2a will involve the needling of two to six additional tender points, if required, according to numerous theoretical possibilities (see Tables 2 and 3).
such as the ability to clear reflex areas, for a combined total time of 15–20 minutes. A step 2b example is the association between depression and inflammation [125] viewed as ‘heat’ in TCM; hence, if detected at a ‘fire’ point on a meridian trajectory, a remedying treatment involving the needling of ‘water’ and ‘metal’ points [116] to extinguish the ‘fire’ may be selected. Step 3 will then comprise two stainless steel pellets (Helio Supply Co., San Jose, CA, USA) being placed on appropriate points in the ear (Table 4) to extend the treatment effect [122] for an additional 5 days. Lifestyle and dietary advice, contraindicated labour augs

Table 1: Master and coupled point pairings of the eight extra vessels

<table>
<thead>
<tr>
<th>Master (right)</th>
<th>Couple (left)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung (LU 7)</td>
<td>Bladder (BL 69)</td>
</tr>
<tr>
<td>Kidney (KI 6)</td>
<td>Lung (LU 7)</td>
</tr>
<tr>
<td>Small intestine (SI 4)</td>
<td>Small intestine (SI 3)</td>
</tr>
</tbody>
</table>

The eight extra vessels are described by Marocca [114].

Table 2: Step 3: Additional relevant point possibilities

<table>
<thead>
<tr>
<th>Symptom and theoretical foundation</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Yang deficiency*</td>
<td>GR 4 (ming men) and GB 14 (da shu) or GR 4 and TB 4 (ying xin)</td>
</tr>
<tr>
<td>Anxiety + pressure/pain at CV 8 (sao yong) or SP 2 (da di) – pneumatum or spleen meridian and water points*</td>
<td>PC 3 (yuan wu) and 5 (ke shu) or SP 5 (shang gu) and 9 (yin ling quan)</td>
</tr>
<tr>
<td>Depression due to mental exhaustion – ‘blood stagnation in the head’</td>
<td>GB 13 (ben shen)</td>
</tr>
<tr>
<td>Depression due to mental exhaustion – ‘blood stagnation in the head’</td>
<td>GB 13 (ben shen)</td>
</tr>
<tr>
<td>Depression and splenic bone disturbance – pressure points at GB 6 and GB 8</td>
<td>KD 9 (shu san) and KD 17 (qi feng) and TMF</td>
</tr>
<tr>
<td>Depression and pituitary disturbance*</td>
<td>KD 9 (shu san) and KD 17 (qi feng) and TMF</td>
</tr>
<tr>
<td>Meandric depression* – if positive for pressure/pain at CV 9 (shu feng)</td>
<td>ST 24 (hao rou men) RIS, LJ 9 (bai yin)</td>
</tr>
<tr>
<td>Depression – LR 2 (ting jian) pressure/pain – water and metal points*</td>
<td>LR 4 (zhong feng) and 8 (guan quan)</td>
</tr>
<tr>
<td>Depression – pressure points LR 5 (zhong ci) and LR 14 (yi men)</td>
<td>LR 5 (zhong ci) and LR 14 (yi men)</td>
</tr>
</tbody>
</table>

*Marocca [114].
<table>
<thead>
<tr>
<th>Points</th>
<th>Indications/symptom alleviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST 40 (teng luo)</td>
<td>Spleen deficiency, damp and phlegm stagnation – heaviness, confusion, mental disturbance</td>
</tr>
<tr>
<td>ST 23 (bi ye)</td>
<td>Transforms phlegm and calms the spirit – mania, depression, agitation</td>
</tr>
<tr>
<td>ST 24 (hun rou men)</td>
<td>Transforms phlegm and calms the spirit – mania, depression</td>
</tr>
<tr>
<td>LR 3 (qu chong)</td>
<td>LR Qi stagnation, irritability, feeling of oppression</td>
</tr>
<tr>
<td>BL 40 (pu huo)</td>
<td>Breathing difficulties, grief, worry, sadness</td>
</tr>
<tr>
<td>BL 43</td>
<td>Increases spleen yang and lung function, calms the spirit, resolves phlegm</td>
</tr>
<tr>
<td>BL 44</td>
<td>Calming and mental clarity</td>
</tr>
<tr>
<td>BL 47 (zun men)</td>
<td>Enables clear and positive life planning and decision making; together adds stability to plans and decisions, also for LR Qi stagnation on lungs</td>
</tr>
<tr>
<td>BL 49</td>
<td>Obsessive thinking, improved memory and concentration</td>
</tr>
<tr>
<td>BL 52</td>
<td>Willpower, determination, initiative</td>
</tr>
<tr>
<td>BL 52 and BL 42</td>
<td>Willpower and emotional release</td>
</tr>
<tr>
<td>BL 52 and BL 44</td>
<td>Willpower, calming anxiety, depression, mental restlessness and insomnia</td>
</tr>
<tr>
<td>BL 52 and BL 47</td>
<td>Willpower and life direction, chronic depression with mental exhaustion, apathy and despondency</td>
</tr>
<tr>
<td>BL 52 and BL 49</td>
<td>Willpower, obsessive thoughts, worry and confusion</td>
</tr>
<tr>
<td>BL 13 (tian zhu)</td>
<td>Calms the spirit</td>
</tr>
<tr>
<td>BL 17 (ge shu)</td>
<td>Mania, depression</td>
</tr>
<tr>
<td>GV 16 (sheng jian)</td>
<td>Liver blood deficiency, calming, mental restlessness, agitation, confusion, obsessive thinking</td>
</tr>
<tr>
<td>GV 18 (niu ding)</td>
<td>Willpower, calming anxiety, mental restlessness, kidney yin deficiency heat</td>
</tr>
<tr>
<td>GV 19 and CV 15 (ju wei)</td>
<td>Calming, insomnia, mental restlessness</td>
</tr>
<tr>
<td>GV 20 (bai hui)</td>
<td>Lifts mood, aids memory and concentration</td>
</tr>
<tr>
<td>GV 21 (pin ding)</td>
<td>Anxiety, insomnia, depression</td>
</tr>
<tr>
<td>GV 24 (shen bing)</td>
<td>Clears the mind</td>
</tr>
<tr>
<td>GV 24 and GB 13</td>
<td>Calming, anxiety, mental restlessness due to LR causes</td>
</tr>
<tr>
<td>CV 14 (gu qiao)</td>
<td>Transforms phlegm and calms the spirit</td>
</tr>
<tr>
<td>CV 15</td>
<td>Calming, chest oppression</td>
</tr>
<tr>
<td>GB 9 (tian chang)</td>
<td>Calms the spirit and pacifies fright</td>
</tr>
<tr>
<td>GB 12 (wang gui)</td>
<td>Mania, agitation of the heart and insomnia</td>
</tr>
<tr>
<td>GB 13</td>
<td>Calming, mental clarity, severe anxiety and mental restlessness resulting from LR disharmony</td>
</tr>
<tr>
<td>GB 13 and GV 24</td>
<td>Same as for GB 13 with enhanced calming effect</td>
</tr>
<tr>
<td>GB 13 and HT 7 (shen men)</td>
<td>Calming, severe anxiety due to heart disharmony</td>
</tr>
<tr>
<td>GB 15 (zhao lin)</td>
<td>Calms the spirit; reduces emotional fluctuations and obsessive thinking</td>
</tr>
<tr>
<td>GB 17 (zheng ying)</td>
<td>Calms the spirit, aids memory and concentration</td>
</tr>
<tr>
<td>GB 18 (sheng ling)</td>
<td>Stops obsessive thoughts, strengthens the function of the lungs and clears the nose</td>
</tr>
<tr>
<td>GB 40 (gu xi)</td>
<td>Willpower, difficulty making decisions</td>
</tr>
<tr>
<td>HT 3</td>
<td>Calms the spirit, heart blood and yin deficiency</td>
</tr>
<tr>
<td>HT 6 (tang li)</td>
<td>Calms the spirit, replenishment patterns with vacuity heat</td>
</tr>
<tr>
<td>HT 8 (xue bao)</td>
<td>Calms the spirit – agitation, fright palpitations, depressed sadness and worry</td>
</tr>
<tr>
<td>HT 6 (shao chang)</td>
<td>Calms the spirit – mania, depression, severe mental restlessness, anxiety, insomnia</td>
</tr>
<tr>
<td>HT 5 (tang li)</td>
<td>Calms the spirit – depressive disorder</td>
</tr>
<tr>
<td>PC 4 (xi men)</td>
<td>Calms the spirit – agitation, insomnia, melancholy, spirit qi deficiency</td>
</tr>
<tr>
<td>HT 7 and PC 6</td>
<td>Calms the spirit – shen disturbance, anxiety, mental restlessness</td>
</tr>
<tr>
<td>KD 7 (fu lu) and HT 6 (yin xiao)</td>
<td>Calms the spirit – heart and kidney not communicating, agitation, insomnia, anxiety</td>
</tr>
<tr>
<td>PC 5</td>
<td>settles and calms the spirit – mania and agitation</td>
</tr>
</tbody>
</table>
Table 3: Possible points and point combinations useful for the treatment of antenatal depression (Continued)

| PC 7 (Hae ling) | Calms the spirit—depressive disorder |
| PC 6 | Calms the spirit; lifts mood—reduces depression, anxiety, restlessness, and frustration |
| PC 6 and SP 4 | Opens yin well, nourishes blood, releases chest, calms the spirit |
| PC 6 and LR 3 | Releases qi stagnation, reduces anger |
| PC 6 and SP 20 | Lifts the mood, relieves depression |
| PC 6 and SP 20 (blu gua) | Lifts the mood, opens heart orifice, relieves depression |
| SI 7 (zhun cong) | Calms the spirit—manifests depression, anxiety, sadness, fear, and hepatic |
| KD 9 (shu bei) | Clears the heart and transforms phlegm—mental disturbances, mania, depression disorders |
| SI 7 and HT 3 (zhao hai) | Chronic anxiety, depression, fear or emotional distress |
| LI 5 (yang xi) | Calms the spirit—manifests depression |

R. Kidney meridian; G. Stomach meridian; SI. Small intestine meridian; BL. Bladder meridian; GB. Gallbladder meridian; PC. Pericardium meridian; SP. Splenic meridian; LR. Large intestine meridian; ST. Stomach meridian; BL. Bladder meridian; SI. Small intestine meridian. Information is from Madhmoun and Schriner [48]; Schryer and Allen [29]; Deardorff et al. [117]; Matsunoto and Sato [131]; and Roger and Roger [147].

In our examination of recent reviews of acupuncture as a treatment for depression [55, 56, 138–139], we identified three main treatment approaches previously used: (1) fixed points for mood disturbance alleviation, (2) fixed points of this function in combination with additional points selected

Table 4: Auricular point possibilities

<table>
<thead>
<tr>
<th>Name</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point Zero</td>
<td>Homeostasis, will power</td>
</tr>
<tr>
<td>Shen men</td>
<td>Pain, tension, anxiety and depression</td>
</tr>
<tr>
<td>Sympathetic tone</td>
<td>Sympathetic nervous system balance</td>
</tr>
<tr>
<td>Cheek point</td>
<td>Relieves depression</td>
</tr>
<tr>
<td>Front point</td>
<td>Relieves headache, insomnia and depression</td>
</tr>
<tr>
<td>Nerve point</td>
<td>Anxiety, worry, obsessive compulsive disorders, psychosomatic disorders and chronic pain</td>
</tr>
<tr>
<td>Master electrode</td>
<td>Balance, left and right cerebral hemispheres</td>
</tr>
<tr>
<td>Sleep disorders 1</td>
<td>Relieves insomnia, nervousness</td>
</tr>
<tr>
<td>Sleep disorders 2</td>
<td>Relieves insomnia, sleep difficulties, nervous dreams</td>
</tr>
<tr>
<td>Depression</td>
<td>Relieves depression</td>
</tr>
<tr>
<td>Endocrine</td>
<td>Hormone imbalance</td>
</tr>
<tr>
<td>Nervousness</td>
<td>Relieves nervousness</td>
</tr>
<tr>
<td>Adrenal</td>
<td>Adrenal fatigue/disturbance</td>
</tr>
<tr>
<td>Thyroid 1–4</td>
<td>Thyroid function disturbance</td>
</tr>
<tr>
<td>Marvelous/wonderful</td>
<td>Lifting mood</td>
</tr>
<tr>
<td>Aggression</td>
<td>Aggression/intimacy</td>
</tr>
<tr>
<td>Mania</td>
<td>Somatic symptomatology</td>
</tr>
<tr>
<td>Insomnia</td>
<td>For sleep disturbance</td>
</tr>
<tr>
<td>Vitality</td>
<td>For fertility and dependancy</td>
</tr>
<tr>
<td>Stress control</td>
<td>Relieves stress</td>
</tr>
<tr>
<td>Tranquility</td>
<td>Calms spirit</td>
</tr>
<tr>
<td>Guilt</td>
<td>Allases feeling of guilt</td>
</tr>
<tr>
<td>Cough</td>
<td>Stress, emotional paralysis, dependancy</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Emotional paralysis, dependancy, overemotional</td>
</tr>
</tbody>
</table>

Adapted from several different Chinese medicine-based auricular maps obtained from the internet: https://www.google.com/search?q=chinese+auriculaur+acupuncture+chart&tbm=isch&sa=X&ved=0ahUKEwiZ36sni6vUAhWAG4jLHYjPQMQgIAIhAc.44.
according to TCM pattern differentiation and (3) flexible point selection based entirely upon TCM pattern discrimination. Variations included diagnosis of disrupted extraordinary vessel Chong and Ren in one study [131], an abdominal points focus in another [132] and scalp acupuncture in a third [133]. Many studies included auricular acupuncture as well as multiple points along the extraordinary GV meridian. Two research groups developed flexible manualised protocols based on pattern differentiation [98, 99], one of which also provided modifications for pregnancy [99]. Both have been drawn upon for therapeutic possibilities presented in Tables 2 and 3. In combination with those suggested by Matsumoto and Ide [134] and 2006 [135], such as for the alleviation of commonly observed LR Qi stagnation [98]. It is theorised that the approach of extraordinary meridian treatment in combination with mental disturbance–oriented pattern differentiation and symptom alleviation may provide additional therapeutic outcomes. In 2009, Finstrom [136] used a similar strategy in patients with severe mental disorders and reported significant reduction or alleviation of psychotic symptoms [136].

The PAM comparator has been adapted from previous research [137] to achieve overall body relaxation in all sessions with an additional weekly focus as follows: introduction (week 1); lower leg and knees (week 2); upper legs and buttocks (week 3); lower back and pelvic floor (week 4); upper back and chest (week 5); arms and shoulders (week 6); head, face and neck (week 7); and integration (week 8). Participants, whilst lying in a comfortable position, will be guided through the PAM in a one-to-one format. A participant who is unable to attend will be offered either a recording- or telephone-based session for home administration.

All groups will continue standard antenatal care, which may include medication and or counselling as well as maternal dunes. In compensation for not receiving treatment, the usual care group will be offered four acupuncture sessions after collection of final data at 6 weeks post-natally.

The principal investigator of this trial (SMC) has 14 years of full-time clinical experience and will conduct all acupuncture sessions, unless unable, in which case a backup acupuncturist with 14 years of part-time clinical experience will be employed. Both practitioners have bachelor’s degrees in acupuncture and are registered with the Chinese Medicine Board of Australia and the Australian Acupuncture and Chinese Medicine Association. The principal investigator will also conduct all PAM sessions, unless unable, in which case a backup assistant researcher will be employed.

Outcome measures
Data and samples will be collected at various time points, including baseline, mid-intervention (week 4), end of intervention (week 8), birthing and hospital discharge (medical records) and 6 weeks post-natally. All questionnaires will be self-administered and collected by the principal investigator. The primary outcome endpoint, reduction in depression severity, will be assessed at baseline, at 4 and 8 weeks from trial entry and at 6 weeks post-natally via the EPDS, an extensively validated, clinically sensitive [138] 10-item self-report questionnaire. Additional secondary outcome endpoints will also be examined as follows:

1. At the same time points as the EPDS, reduction in stress and anxiety will be monitored with the 21-item Depression Anxiety and Stress Scale (DASS-21) [139] and improvement in quality of life will be evaluated using the 36-item World Health Organisation Quality of Life Scale (WHO-QoL-26) [140]. The DASS-21 is a short-form of the clinically validated [141] and cross-culturally reliable [142] self-report measure of emotional states of stress and anxiety. The WHO-QoL-26 [140] is also an abbreviated form of this discriminant, content valid, internally consistent and reliable self-report measure for overall quality of life.

2. Adjustment to parenting and maternal-infant bonding will be evaluated at 6 weeks post-natally via the 13-item Being a Mother Scale (BaM-13) [143]. The BaM-13 is a clinically discriminating, reliable and valid self-report tool specifically designed to enable early assessment of women’s experiences of motherhood.

3. Maternal-infant outcomes such as gestational diabetes, mode of delivery, method of pain relief, labour augmentation, post-partum hemorrhage, breastfeeding level and duration, gestational age at delivery, birth weight, 1 and 5-minute Apgar scores, neonatal intensive care unit admission and need and reason for resuscitation and or intensive care will be assessed at delivery, discharge and 6 weeks post-natally.

4. Salivary OTT levels will be determined using saliva specimens collected by the principal investigator at baseline and at 4 and 8 weeks from trial entry. Leucocyte OTT messenger RNA (mRNA) expression will be assessed using blood collected by phlebotomists at local pathology centres at baseline and 8 weeks from trial entry.

Every effort will be made to minimise missing data by ensuring weekly contact with participants during the intervention period as well as robust follow-up at later data collection points. Missing data for the primary endpoint of depression will be estimated using multiple imputation data derived from the K5 instrument. All missing data will be reported with reasons given and patterns of occurrence explored.
Sample analysis
The principal investigator will process samples as follows. 4 ml of saliva will be obtained via passive drool into sterile CELLSTAR polypropylene test tubes (15 ml, catalogue number 189271, Greiner Bio-One, Frickenhausen, Germany), transported on ice and frozen and stored at −20 °C. Thawed samples will later be batch-processed and concentrated using equilibrated Sep-Pak C18 200-μg resin cartridges (catalogue number WAT 054945; Waters Corporation, Millford, MA, USA) before re-freezing at −20 °C in 5-ml sterile Eppendorf tubes (catalogue number 0030119401, Eppendorf, Hauppauge, NY, USA). Triplicate OT concentrations will be batch-calculated using an OT enzyme-linked immunosorbent assay (ELISA) kit (catalogue number AXY-001-153A-0001; Enzo Life Sciences, Farmingdale, NY, USA) and an ELISA plate reader. Blood (2.5 ml) collected into PAXgene blood tubes (catalogue number 762165; BD Diagnostics, Huntsville, USA) will be stored at −20 °C no sooner than 2 h after collection. Batch extraction of mRNA will later be performed using PAXgene blood RNA kits (catalogue number 762174; BD Diagnostics) and stored at −20 °C before cDNA libraries are made using Trizol Advanced cDNA Synthesis kits (170-88-43 Bio-Rad Laboratories, Hercules, CA, USA) and mRNA expression is determined by qRT-PCR using human OTR primers (catalogue number VHS-6655. Applied Biosystems, Foster City, CA, USA).

Sample size
Mean antenatal EPDS scores extracted from a recent Australian study [111], as well as estimated post-intervention between-groups differences derived from a meta-analysis of two antenatal depression acupuncture studies [8], were used for a power calculation for this study. Using a power of 0.80 and two-sided testing at a 5% significance level, detecting a significant difference in end of intervention mean ± standard deviation (SD) EPDS scores of 8.9 ± 5 for the acupuncture group plus usual hospital care versus 13 ± 6.5 for usual hospital care will require a total recruitment goal of 75 participants. As a high attrition rate have been reported in this population [144], an additional recruitment of 30% has been added, resulting in a total goal of 96, or 32 participants per group.

Statistical analysis
Descriptive statistics will be used to describe characteristics of the study population. An intention-to-treat analysis will be undertaken [145], with between-groups differences explored using analysis of variance for the primary and secondary endpoints of depression, stress, anxiety, quality of life and OTR/OTR. Effect sizes will be reported with 95% confidence intervals, and results will be considered significant if p values are less than 0.05.

Discussion
In consideration of the sufficiently serious consequences of antenatal depression in combination with therapeutic difficulties, a thorough evaluation of any promising preventative and/or therapeutic techniques that may be effective in reducing antenatal distress is required. As to date no studies have been conducted to investigate an acupuncture protocol of this type in depressed pregnant women or to evaluate the effects of acupuncture on the oxytocinergic system in this regard, it is the aim of this RCT to collect such data as well as to assess the usefulness of this acupuncture treatment for the alleviation of antenatal depression. Limitations of this study include the current lack of research evidence regarding the effectiveness of the proposed acupuncture treatment strategy, the use of self-report measures for the determination of treatment effect, a practice effect that may occur due to repeated use of self-report measures and the unquantifiable possible effects of FMR that are in addition to non-specific placebo effects resulting from intervention procedures and interactions.

Trial status
Recruitment is ongoing.

Additional files

Additional file 1: SPIRIT 2013 Checklist. (DOC 124 kb)
Additional file 2: Consent form. (DOCX 43 kb)

Abbreviations

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
WAL, LC, SC, LC, HC and CM designed the RCT. WAL is responsible for running all aspects of the clinical trial including screening, recruitment, intervention, administration, sample collection, processing and analysis data, and drafting the report. In accordance with the STROCSS guidelines for clinical trials of acupuncture interventions [146] and communication of finding to stakeholders. Data will be entered, including 20% double data entry, by an independent associate investigator from the NICM and analyzed in consultation with the clinical trial statistician.
Acknowledgement

The authors acknowledge Dr. Paul Fleby for permission of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation, Dr Anthony Good for consent of the randomisation schedule and sample size calculation.


Appendix X

SWSLHD Approval Letter for In-Depth Interviews with Acupuncture Recipients Study

Ms Simone Drmsby
University of Western Sydney
The National Institute of Complementary Medicine
Building 5, Campbelltown Campus
Locked Bag 1797
PENRITH NSW 1797

Dear Ms Drmsby,

Project Title: Acupuncture for Antenatal Depression
HREC Reference: HREC/14/LPOOL/400
SBA Reference: SBA/14/LPOOL/437
Local Project Number: 14/233

Thank you for your Summary Sheet for an Amendment to an Approved Protocol dated 20 October 2015, requesting approval from the South Western Sydney Local Health District Human Research Ethics Committee. I am pleased to inform you that the following documents are approved for the above-mentioned study:

<table>
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<th>Document</th>
<th>Version</th>
<th>Date</th>
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<td>N/A</td>
<td>09/10/2016</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>4.0</td>
<td>09/10/2016</td>
</tr>
<tr>
<td>Consent form</td>
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<td>21/09/2016</td>
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Approval has been granted for the following site(s):
- Campbelltown and Camden Hospitals

The following are authorised for use at the Campbelltown and Camden Hospitals site:

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<td>09/10/2016</td>
<td></td>
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<tr>
<td>Consent form</td>
<td>3.0</td>
<td>21/09/2016</td>
<td></td>
</tr>
</tbody>
</table>

Conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
   - any serious or unexpected adverse events, and
   - unforeseen events that might affect continued ethical acceptability of the project.

2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each site so that they can notify their Research Governance Officer.
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.

4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

5. The Principal Investigator must reassure participants about confidentiality of the data.

6. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.

Yours faithfully,

Annamarie D'Souza
Manager, Research and Ethics Office
South Western Sydney Local Health District
Ms Simone Ormsby
University of Western Sydney
The National Institute of Complementary Medicine
Building 8, Campbelltown Campus
Locked Bag 1757
PENRITH NSW 1757

Dear Ms Ormsby,

Project Title: Acupuncture for Antenatal Depression
HREC Reference: HREC/14/LPOOL/400
SSA Reference: SSA/14/LPOOL/437
Local Project Number: 14/228

I refer to your correspondence of 11 February 2015 and enclosing the following documentation for the above mentioned study has been authorised for use at the Camden and Campbelltown Hospital sites:

<table>
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<th>Document</th>
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We note this version includes the addition of the hospital site and number and NICM site on pages 2 (item 5) and page 8. We apologise for this oversight.

Yours sincerely,

Annamarie D'Souza
Manager, Research and Ethics Office
South Western Sydney Local Health District
Appendix Y

SWSLHD Midwives focus groups PIS

Participant Information Sheet

Interventional Study Midwife Focus Group - Adult providing own consent

Camden & Campbelltown Hospitals

Title: Acupuncture for Antenatal Depression
Short Title: AcuAnteDep
Protocol Number: 1.0
Project Sponsor: Western Sydney University (WSU)
Coordinating Principal Investigator/Principal Investigator: Simone Ormsby
Associate Investigator(s): Professors' Smith, Dahlen & Hay & Associate Professor Lind
Location: Camden & Campbelltown Hospitals

What does my participation involve?

Introduction

You are invited to take part in a midwife focus groups assessing the study - acupuncture for antenatal depression. This Participant Information Sheet tells you about the aims of the focus groups, the topics to be discussed and how data will be collected and stored, in order for you to decide if you'd like to participate.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. If you decide you want to take part in the research, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have your responses digitally recorded, confidentially de-identified and securely stored at Western Sydney University.
You will be given a copy of this Participant Information Sheet to keep.

**What is the purpose of this research?**

The aim of the focus groups is to:

Examine both the individual and shared perspectives of standard and caseload midwives in regard to being involved in the RCT evaluating acupuncture for antenatal depression, particularly in regard to the feasibility and acceptability of the intervention to midwives, allied health professionals and antenatally depressed women.

Data collected will be provided de-identified to the principal researcher, Simone Ormsby, who will then group content into themes for Thematic Analysis, for the purpose of integrating findings with other data collected during the RCT.

The results of this research will be used by the study investigator Simone Ormsby, to obtain a Higher Degree by Research, Doctorate of Philosophy. This study is under the principal supervision of Professor Caroline Smith as well as the co-supervisory team, Professor's Hannah Dahlen and Phillipa Hay and Associate Professor Joanne Lind, from Western Sydney University.

**What does participation in this research involve?**

The format utilised will consist of facilitated semi-structured group discussions, which encourage discourse between individuals, midwives and the facilitator Professor Hannah Dahlen. Professor Dahlen will use approximately 5 open prompts to stimulate discussion amongst the midwives.

Prompts will be focused around:

a) Midwives preconceptions of the study and current views

b) Midwives perspectives in regard to the impacts of the study - on depressed pregnant women, administration staff, midwives and obstetricians

c) Any other relevant observations or reflections?

d) Suggestions for improvement.

**Do I have to take part in this research project?**

If you do not wish to take part, you do not have to. Your relationship with involved researchers will not be affected in any way whatsoever if you decide not to take part. If you do decide to take part, you will be given a Consent Form to sign and you will be given a copy of this sheet to keep.
What are the possible benefits of taking part?

The findings of this research may provide additional qualitative detail in relation to this RCT that may contribute to future research and health care policy.

Confidentiality / Privacy

Data will be digitally recorded, verbatim transcribed and provided to the principal researcher Simone Ormsby in a de-identified format, so that all identities remain confidential.

The results of this study will be published, for example in scientific journals, you will not be identified by name and a summary of findings will be provided to you by letter.

Who is organising and funding the research?

This research is being conducted as part of a Higher Degree by Research at Western Sydney University. No external sponsorship is involved and no member of the research team will receive any personal financial benefit from your involvement in this research project.

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the South Western Sydney Local Health District (SWSLHD).

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact the HREC of the South Western Sydney Local Health District (SWSLHD) directly. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact

If you would like to know more at any stage, please contact Simone Ormsby on +61 2 4620 3290 or 0414 476 711 or by email on simone.ormsby@westernsydney.edu.au or Professor Caroline Smith on + 61 2 4620 3777 or by email on caroline.smith@westernsydney.edu.au.
Reviewing HREC approving this research and HREC Executive Officer details

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Ethics and Research Governance Office, Locked Bag 7279, LIVERPOOL BC, NSW, 1871 on 02 8738 8304, fax 02 8738 8310, email research.support@sswhs.nsw.gov.au, website: http://www.sswahs.nsw.gov.au/sswhd/ethics/default.html and quote HREC/14/LPOOL/400, SSA -14/228.

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.
Appendix Z

SWSLHD Midwives Focus Groups Consent Form

Consent Form - Adult providing own consent

Title
Acupuncture for Antenatal Depression

Short Title
AcuAnteDep

Protocol Number
1.0

Project Sponsor
Western Sydney University

Coordinating Principal
Simone Ormsby

Associate Investigator(s)
Professors’ Smith, Dahlen & Hay & Associate Professor Lind

Location
Campbelltown & Camden Hospitals

Declaration by Participant

I have read the Participant Information Sheet.

I understand the purposes and procedures of the research described in the project.

I give permission for Professor Hannah Dahlen to digitally record my responses, knowing that they will be de-identified, copied verbatim and provided to the principal investigator Ms Ormsby for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)

Signature

Date

425
Name of Witness* to Participant's
Signature (please print)  

Signature  Date

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project and its procedures. I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print)  

Signature  Date

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

The conduct of this study at Campbelltown & Camden Hospitals has been authorised by the South-Western Sydney Local Health District, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: research.support@sswhs.nsw.gov.au and quote project number HREC/14/LPOOL/400 – SSA/14/228.
Appendix AA

SWSLHD Advertising Flyers for Focus Groups with Midwives

Acupuncture for Antenatal Depression?
Invitation to a midwives focus group
February 16th 11.00 am Campbelltown Hospital – Group 1 Room G0002

The Professor of Midwifery at Western Sydney University, Hannah Dahlen will be running a focus group regarding the current study being conducted by Simone Ormsby at Campbelltown and Camden Hospitals examining acupuncture as an adjunct therapy for antenatal depression.

As you may be aware, the study is a RCT comparing mood disturbance orientated acupuncture to progressive muscle relaxation and a non-treatment control. The treatment phase runs for 8 consecutive weeks from gestation weeks 24-31 and participants are required to fill out several questionnaires at multiple time points as well as provide two blood and three saliva samples.

The aim of the focus group is to explore:

1. Midwives preconceptions of the study and current views
2. Midwives perspectives in regard to the impacts of the study - on depressed pregnant women, administration staff, midwives and obstetricians
3. Any other relevant observations or reflections?
Acupuncture for Antenatal Depression?

Invitation to a caseload midwives focus group

March 23rd 10.00 am Campbelltown Hospital – Ob & Gyn Meeting Room

The Professor of Midwifery at Western Sydney University, Hannah Dahlen will be running a focus group regarding the current study being conducted by Simone Ormsby at Campbelltown and Camden Hospitals examining acupuncture as an adjunct therapy for antenatal depression.

As you may be aware, the study is a RCT comparing mood disturbance orientated acupuncture to progressive muscle relaxation and a non-treatment control. The treatment phase runs for 8 consecutive weeks from gestation weeks 24-31 and participants are required to fill out several questionnaires at multiple time points as well as provide two blood and three saliva samples.

The aim of the focus group is to explore:

1. Caseload midwives preconceptions of the study and current views
2. Caseload midwives perspectives in regard to the impacts of the study - on depressed pregnant women, administration staff, themselves and obstetricians
3. Any other relevant observations or reflections?
Appendix AB

ITT ‘Average Closest Match’ Calculations

As previously mentioned in chapter 4, the method of calculating missing values suggested by Elliott and Hawthorne (2005), the ‘average closest match’ was selected in preference to the ‘closest match’, as there were occasions in which: a) more than one individual had the same score, and consequently it was considered that an average value would provide a more balanced estimate, and b) no individual had an exactly matched score. Modification of this method was however also required for the following reasons:

1. There were a number times in which more than four individuals had identical scores and rather than randomly selecting four of these, all individuals with matched scores had their follow-up scores averaged to provide the imputed follow up value for the individual for which the datum was missing. For example, for the individual SM12 randomised to the acupuncture group with missing data beyond baseline, all individuals with the identical baseline EPDS score of 14 had their follow-up week 4 scores averaged to produce the imputed follow up value of 11 as follows: (OB11 14→14; SM04 14→11; CL03 14→14; SM09 14→10; SM18 14→16; CL06 14→9) = 10.83 ~ 11.

2. There were also occasions in which there were either zero or less than four individuals that had matching scores. In this case individuals with scores one score up as well as one score down were included in the averaging of the follow-up scores to provide the imputed follow up value for the individual for which the datum was missing. If this method provided more than four individuals, all datum points were averaged. For example, for the individual SM01 randomised to the acupuncture group with missing data beyond baseline, all individuals with the identical baseline EPDS
scores of 17 had their follow-up week 4 scores selected, however there were only two
available (OB17 and SM15). An individual with score that was one up (18) was also
included, as well as two with scores that were one down (16, SM19 and OB02) to
produce an averaged imputed follow up value of 14 as follows: (OB17 17 → 12; SM17
17 → 25; CL08 18 → 9; SM19 16 → 9; OB02 16 → 17) = 14.4 ~ 14.

3. There were additional occasions however when despite including individuals with the
same score or one score up and one down, that there were still less than four
individuals for which follow up data point scores could be averaged, hence individuals
with scores two up and or two down were also included. If this method still yielded
less than four individuals, individuals were sourced with scores three up and three
down and so on, until a minimum of four individuals were obtained. If in the process
of obtaining a minimum of four, other individuals were also able to be included, all
data points were averaged. For example, for the individual OB16 randomised to the
progressive muscle relaxation group with missing data beyond baseline, all
individuals with the identical baseline EPDS scores of 22 had their follow-up week 4
scores selected, however there were only one available (CL02). Searching for
individuals with scores that were one up provided no matches, however two had
scores one down (OB12 and OB05). As there were still less than four individuals from
which the follow-up scores could be averaged to provide the imputed value for
individual, participants with scores two up and two down were also included. There
were no individuals scoring two up or 24, however there were two scoring values that
were two down or 20 (CL09 and SM03). Consequently, the averaged imputed follow
up value of 14 was calculated as follows: (CL02 22 → 13; OB12 21 → 6; OB05 21 → 13;
CL09 20 → 25; SM03 20 → 12) = 13.6 ~ 14.
In the standard care group, imputed values were calculated for only one individual (OB04), for the timepoints end of intervention (session 8) and six weeks postnatal. Values incorporated in these calculations did not utilise any previously imputed values.

In acupuncture group, imputations were required for four individuals; two required imputation at six weeks postnatal (OB17 and SM18), whereas the remaining two (SM01 and SM12) required imputations for the timepoints mid and end of intervention, as well as at six weeks postnatal. Values incorporated in these calculations did not utilise any previously imputed values, apart from the six-week postnatal timepoint for SM12, in which one of the seven values incorporated in the imputation had been previously imputed.

In the progressive muscle relaxation group, many more imputations were required, as data was missing for seven of the nineteen randomised participants. One individual (OB07) required imputation for only the end of intervention timepoint, which was able to be calculated without the incorporation of previously imputed values, however two participants required two imputations, and the remaining four, required three. As a consequence, many imputations utilised previously imputed values. It is possible therefore that the more frequent incorporation of imputed values in this group may have resulted in the multiplication of potential errors by the final timepoint at six-weeks postnatal. Despite this potentiality however, one-way ANOVA and linear mixed model repeated measures analysis yielded very similar outcomes to those obtained from per protocol analysis, (see table 6.12). An additional observation was that the provisions of complete data sets as a consequence of amputation decreased within group standard deviations and thus also p values.
### Appendix AC

**AC Table 1** Participant PRE, POST and POST minus PRE-OT Concentrations per Group Allocation / Time of Sample Collection

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| (4.25 pm) | (12.30 pm) | (4.25 pm) | (12.30 pm) |
| SM14 (KR)  | 0.32 | 0.49 | 218.69 | 248.56 |
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| SM20 (CR)  | 0.22 | 0.23 | 119.87 | 94.44 |
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| SM30 (Z.D) | 0.27 | 0.15 | 144.28 | 64.43 |
| (12.00 pm) | (6.40 pm) | (12.00 pm) | (6.40 pm) |
| SM15 (S.H) | 0.31 | 0.55 | 48.94 | 135.80 |
| (12.15 am) | (9.30 am) | (12.15 am) | (9.30 am) |
| SM18 (K.FV) | 0.41 | 0.05 | 147.73 | 28.60 |
| (11.45 am) | (1.15 pm) | (11.45 am) | (1.15 pm) |
| SM19 (DF)  | 0.19 | 0.30 | 145.13 | 97.06 |
| (5.00 pm) | (5.25 pm) | (5.00 pm) | (5.25 pm) |

| SM22 (CS)  | 0.24 | 0.33 | 36.53 | 54.28 |

<p>| OB11 (A.B) | 0.14 | 0.19 | 35.71 | 20.65 |
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| OB17 (F.SC) | 0.19 | 0.29 | 81.07 | 132.70 |
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| SM 18 (K.FV) | 0.41 | 0.05 | 147.73 | 28.60 |
| (11.45 am) | (1.15 pm) | (11.45 am) | (1.15 pm) |
| SM 19 (DF)  | 0.19 | 0.30 | 145.13 | 97.06 |
| (5.00 pm) | (5.25 pm) | (5.00 pm) | (5.25 pm) |
| SM 22 (CS)  | 0.24 | 0.33 | 36.53 | 54.28 |</p>
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436
Appendix AD

1. Introduction

Recent estimates suggest that up to 25% of women are affected by depression during pregnancy, with pre-existing and/or family histories of mental illness, medical co-morbidities and higher levels of exposure to social adversity being greater risk factors for the development of symptoms. Reports of depression during pregnancy, however, vary widely. The symptoms of depression, which can be extremely distressing, affect up to 20% of pregnant women. Depression during pregnancy may lead to poor health outcomes for women, their partners and children, as well as for their babies. Treatment guidelines recommend non-pharmacological options such as psychotherapy and psycho-education support for milder forms of depression, and the addition of medication for more severe cases. Whilst conventional treatments provide benefit to many, it has been estimated that approximately 10% of women experiencing depression during the perinatal period obtain adequate management using these approaches. Uncertainty around the use of medication safety with respect to possible increased risks of malformations, obstetric complications, and longer-term health outcomes has also resulted in some clinicians exercising caution in prescribing medications, especially considering modest antidepressant medication response rates, as well as reluctance by some women to take pharmacological medication.

Indeed, studies reveal that both pregnant women and the general public are turning to complementary medicines (CM) and alternative medicine practices in response to mental health issues as a consequence of dissatisfaction with conventional options, as well as a desire for non-toxic, psychologically holistic approaches to health and disease. In Australia, recent data suggests that up to 70% of women used some form of CM during pregnancy. Such treatments include nutritional supplementation, herbal and homeopathic remedies, medications, yoga and massage.

Acupuncture is an individually tailored, low-risk Chinese medical treatment that involves the insertion of fine needles into specific areas of the skin. Preliminary randomized or quasi-randomized controlled clinical studies investigating acupuncture for the management of depression or emotional disturbances during pregnancy have demonstrated significant improvements in depressive or mental health symptomology amongst acupuncture recipients, that are generally reflective of findings in systematic reviews examining acupuncture for the treatment of depression; however further research is required. A randomized controlled trial (RCT) evaluating the effectiveness of acupuncture for maternal depression was recently conducted in two hospitals in Western Sydney, Australia. Alongside this, a qualitative exploration was undertaken to ascertain the views of acupuncture recipients regarding their experiences of depression during pregnancy as well as receiving the intervention (manuscript under review).

In order to further examine the possible role that acupuncture could provide as a supplementary therapeutic option for antenatal depression, we felt it was necessary to obtain the perspectives of maternal service providers who are routinely involved in the care of women experiencing depression during pregnancy. In this aim we sought to explore midwives', doctors' and maternity services managers' experiences with and opinions of acupuncture. We also aimed to understand their views of the potential barriers and facilitators to the implementation of acupuncture into mainstream maternity care. This paper presents the findings from this qualitative study.

2. Methods

2.1 Study design

As stated, this study arose from the RCT examining acupuncture as an adjunct therapeutic option for depression during pregnancy, that also incorporated in-depth interviews with women who had experienced acupuncture as part of the investigation. We considered it additionally important to gather the views of midwives working in the wards in which the RCT was run in order to also gain their perspectives regarding the issues they faced in implementing acupuncture in combination with conventional depression treatments, as well as their opinions of the possible role that acupuncture could provide as an additional therapeutic option for antenatal depression. Focus groups were chosen at the data collection method to achieve this aim, as they provide an opportunity to explore both individual and shared perspectives.

As an opinion expressed in the focus group sessions was that doctors were likely to be opposed to incorporating acupuncture in mainstream antenatal care, we additionally sought the perspectives of other antenatal health service providers including obstetricians, general practitioners and service managers in this regard. Undertaking focus groups with such a diverse range of professionals would however have been difficult to coordinate, and also likely to discourage some freely expressed opinions, consequently one to one in-depth interviews were determined to be the most suitable approach to explore the subjective and complex experiences of doctors and maternity service managers face when caring for women experiencing depression during pregnancy, as well as valuable detail regarding views of acupuncture and its possible incorporation into mainstream care for antenatal depression. The findings generated from the focus groups used in the data collection method were used to develop the open-ended questioning prompts utilised during the interviews with doctors and maternity service managers.

A qualitative methodology was chosen as it was deemed to be the most appropriate methodology to enable the detailed exploration of participants' experiences of antenatal mental health management and their views of the possible role that acupuncture could provide within the 'context-specific setting' of the hospital system. Qualitative research is appropriate for exploring and understanding experiences and attitudes of people towards issues or possible interventions in health care while quantitative research is appropriate for measuring frequency and outcomes. In this study, our questions were qualitative in nature as we wanted to understand what health providers thought about acupuncture and its use in women who are experiencing depression during pregnancy. Little is known about this issue and so focus groups and in-depth interviews were ideal for exploring understanding and attitudes. We wanted to ask 'what', 'why' and 'how' questions, for which qualitative methodology is appropriate.

The overarching aim of exploring the perspectives of different antenatal healthcare professionals from focus groups (with midwives) and individual interviews (with GPs, obstetricians, psychiatrists and maternity managers) was to obtain the opinions of all the key maternity health care providers about the role of acupuncture as an additional therapeutic option for antenatal depression, as well as the likely structural and organisational barriers to implementation into mainstream care. We were additionally interested in exploring whether attitudes and beliefs regarding acupuncture was seen to differ between midwives and doctors. It is important when testing interventions for effectiveness (reference removed to de-identify), that feasibility of upscaling for widespread implementation is undertaken.
2.2. Participants and recruitment

Midwives were invited to participate in the focus groups by emailed flyers and posters displayed in the hospital. Prior to the commencement of the scheduled sessions, attending midwives were provided with a participant information sheet to read, in which the procedures were outlined and anonymity was assured. Upon agreeing to participate, informed consent forms were freely obtained from all participants.

Obstetricians, perinatal psychiatrists and maternity service managers in the Sydney metropolitan region with expertise in their field, were purposively selected to be invited to be interviewed for this study. Of these participants, none had prior knowledge of and or familiarity with the RCT investigating acupuncture for antenatal depression, whereas others had no previous exposure to it. Individual invitations along with study information sheets were emailed to all potential participants for consideration. General practitioners with a special interest in antenatal care were also invited to participate via group notification distributed through affiliated professional associations. Upon indicating interest, individual general practitioners were then emailed the study information sheet for further consideration. The aim of this sampling strategy was to obtain a broad range of views and perspectives from the different professionals involved in the care of women experiencing depression during pregnancy, both with and without knowledge of the RCT.

All potential participants were informed that their responses would remain anonymous and that all identifying material would be removed from transcripts, apart from their professions. Prior to the commencement of the interviews, informed consent forms were freely obtained from all participants and demographic data collected where possible.

2.3. In depth interviews with doctors and maternity service managers

Telephone interviews were conducted by researchers (HD & CE), in a one-to-one format using the open-ended questioning prompts provided in Fig. 1. Nine doctors comprising of four general practitioners (GPs), two psychiatrists (PSYs) and three obstetricians (OBs) were interviewed, along with two maternity service managers (MMSs). Interviews ranged in duration from 25 to 60 min and all interviewees were remunerated with $300 gift vouchers for their time.

2.4. Focus groups with midwives

Focus groups were conducted by researcher (HD). As a practising midwife with extensive knowledge of the discipline, HD was perfectly positioned to facilitate focus group discussions with midwives, whilst also remaining independent of the acupuncture intervention under examination. The format employed was that of facilitated semi-structured group discussion, prompted by the flexible open-ended questioning prompts provided in Fig. 2. Anonymity was re-affirmed to encourage open and honest feedback. In total, 10 midwives participated in the two separate focus groups conducted in the hospital during routine meeting times, with eight continuity of care model midwives attending the first and eight standard model of care midwives attending the second. Of those midwives in attendance, some had cared for the women enrolled in the RCT, whereas others had gained knowledge of the RCT during the running of the trial. Midwives were provided with morning tea in recognition of their contributions.

2.5. Ethics approval

Ethics approval for the midwife focus groups was sought as an amendment to the RCT approval from South West Sydney Local Health District (SWSHD-REC/14/11/POCI/400), and was obtained on November 18th, 2015. Ethics approval for the in-depth interviews was similarly sought as an amendment to the RCT approval from Western Sydney University Human Research Ethics Committee (H10991) and was granted on June 7th, 2016.

2.6. Data analysis and interpretation

Digitally recorded focus groups and in-depth interviews were transcribed by an independent professional transcription service and de-identified prior to being provided to the interviewers (HD and CE) for verification of transcript content. The transcripts were then independently read and re-read by researchers (HL, HD and SG) for the purpose of discernment of emergent themes, which were analysed using thematic analysis. 

Thematic analysis

A. Can you tell me what you think about acupuncture in general?

B. Have you had any personal experience with acupuncture? If so, could you tell me about them? If not, had you ever considered using it and if so, what for?

C. Have you ever recommended acupuncture to any of the women in your care? If so, can you explain to me your reasons for your recommendation?

D. What do you think about using acupuncture for women with antenatal depression?

E. What are your opinions about incorporating acupuncture into mainstream care, for example, having an onsite acupuncturist in hospitals or community health services?

F. What would be the barriers to this happening?

G. How would you see this being facilitated best?

Fig. 1. In depth interview questioning prompts.
involved immersion in the data by both listening to the recordings and reading the transcripts. Following this, key concepts were
underlined and labelled and then grouped together to form themes
and subthemes, until no further development of themes was
judged to be possible and data saturation had been reached. Quirk,
a qualitative data analysis software, was also utilised to
create nodes and concepts and allow for merging, theming and
collating of the in-depth interview and focus group data sets.
Coding provided by these two different methods was then
compared and contrasted between researchers (HK, BD and SG),
for the purpose of deciding upon the final coded structure.
Verifications of this final format in reference to recorded
transcripts, were also independently performed by researchers
(CE and CS).

Interpretation of findings utilised the qualitative interpretivist
paradigm that enables the uncovering of meaning through
reflections stimulated by the interactive dialogue between the
researcher and participant(s). Complementarity was also
employed to integrate the findings from the two different data
sets, as in this approach the findings from one method can be used
for the purposes of elaboration, enhancement, illustration or
clarification of the results obtained from the other.

As the researchers involved in the design of this study were
comprised of practitioners of acupuncture, midwifery and medi-
cine, it was considered imperative to incorporate reflexivity into
the research design as a strategy to consider how their personal
experiences, as well as biases and beliefs, may have impacted upon
the research and thus the ‘trustworthiness’ of findings. Consequently,
the potential inclusion of bias was actively monitored at the design,
analysis, interpretation and reporting stages of the study, by all of the
involved researchers.

Table 1
Demographic details of interviewed doctors and midwifery managers.

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3. Results

3.1. Demographic details of doctors and maternity service managers

Demographic data was provided by nine of the 11 interviewed
participants, with two not returning forms; however their gender
and professions were included in Table 1. The majority of the
interviewees were female (81%). Two professionals had spent less
than five years in their area of expertise, however most (85%) had
worked for more than 20 years in their current roles. Five of the
nine participants were born outside of Australia and of the four
born within Australia, none were of Aboriginal or Torres Strait
Islander heritage. With respect to general practitioners, all
indicated they provided shared antenatal care. Demographics
were not collected from focus group participants in an attempt to
maintain their anonymity, as it was considered possible that detail
provided regarding the region in which the ICT was conducted, as
well as the models of midwifery care performed, when combined
with normality, age and years in the profession, could enable
identification.

3.2. Thematic findings

3.2.1. It’s worth giving it a go

This overarching theme summarises the collective sentiment
participants came to after exploring their opinions around
acupuncture and their experiences of caring for women with
depression during pregnancy.

Initially participants were asked to identify their knowledge of
acupuncture in general and then to explore a mixture of both their

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professional and personal experiences. Participants felt that “if it doesn’t do any harm, I’m not against it.”

The participants were then specifically encouraged to consider the potential use of acupuncture for women with prenatal depression. Issues around “the dilemma of maternal health” treatment during pregnancy were discussed, particularly in relation to how “pregnancy adds limitations around options.”

The opinion of “if it doesn’t do any harm, I’m not against it” alongside consideration of the complexities provided by “the dilemma of maternal health” treatment during pregnancy, led to discussion around the possible implementation of acupuncture into the current Australian maternity model in “Making it mainstream.”” Barriers and facilitators were then identified and found to be understood by the different “philosophical beliefs” each profession was aligned with. Themes, subthemes and concepts identified are summarised in Table 2.

3.3. If it doesn’t do any harm, I’m not against it

This theme represented the attitudes, feelings and experiences participants had around acupuncture. The subtheme of “using it and seeing its use” particularly explored previous experiences and consisted of the concepts “client and family perspectives.” “I’ve had acupuncture before and practice interactions.” Participants prior knowledge of acupuncture was found to be varied, ranging from limited, “Well, I don’t know very much about it” (CP) to quite extensive, “I actually learned acupuncture briefly myself” (QB), however, overall, a generally respectful and open attitude towards acupuncture appeared to predominance.

“I think it is an intervention that one should be open to because it comes from a culture that’s been going for a very long time and you wouldn’t expect interventions to last 5000 years if there wasn’t some validity to it” (CP).”

“...as long as it’s not doing any harm then certainly – I would never talk anybody out of it. I like them to go and try it and then let me know what they think” (KB).

Acupuncture was also recognised as a “complement and accompaniment to medicine” (MMS), “I think... it’s good for some chronic conditions and particularly for the conditions that Western medicine has no...cure” (QB), as well as an alternative option for individuals with complex issues; “I think that is to be able to offer a non pill resource is actually very helpful” (CP), as “medicine is very dynamic and there’s still a lot of stuff we don’t know yet” (CP).

Potential issues were nonetheless raised regarding efficacy and safety. With respect to efficacy, opinions varied from “I’d want to know that there’s no potential risks to the mother” (CP), and that “it doesn’t lead to avoidance of therapies that would be beneficial” (QB), to feeling acupuncture offered a “safer intervention” of “lower risk” with no “side effects that could actually reduce the need for ‘chemicals’” (MMS). Reliability of research for assessing efficacy was however seen as a difficulty as, “I’m very aware of the set of mixed messages from the research that has been published...efficacy, poor quality” (PV) and, not wanting “people to waste their time” (CP) or “money” (QB).

3.3.1. Using it and seeing its use

In the subtheme experience of acupuncture was found to have come from a variety of sources. Some practitioners had exposure to acupuncture from their country of origin and/or cultural background, “from my personal background we do believe in acupuncture and we do it back home” (PV). Others had referred women to acupuncture in their workplace, “when I worked in a birth centre, we always talked about that in terms of breast and body and so forth” (MMS). One practitioner had observed acupuncture being used, “so I’ve seen it being done but actually I haven’t had it done to myself” (QB).

The midwives also shared their experiences of being involved in the wards in which the RCT was run, reporting that they had received positive feedback from study recipients regarding the acupuncture session, “a few women that have been through the study, they’ve just mentioned, helpful, very relaxing afterward” (MMS), as well as their own observations, “they’re very happy when they’re leaving...they’ve come in and made a special effort...so they’re obviously getting something out of it” (MWS).

Further exploration of participants’ knowledge of and experience with acupuncture was provided in the concepts “client and family perspectives,” “I’ve had acupuncture before” and “practitioner interactions.”

3.3.2. Client and family perspectives

Some participants actively referred clients to acupuncture treatment for specific issues and others found clients had self-referred and then reported their experiences back to them, “I know that there have been lots of women who have used it and come back with positive feedback from it” (MWS).

The different medical issues participants were aware that acupuncture could be used for included; “very difficult pain syndromes” (QB), “nasty cases of hyperemesis” (QB), “chronic headaches” (QB), “musculoskeletal conditions” (CP), “chronic pain” (PV), “during pregnancy for back pain” (CP), “difrcet” (MMS), “sleep issues” (MMS), “infertility” (QB). Some practitioners had family or friends who had used acupuncture for a variety of issues including, “I’ve had friends and family that have used it to quit smoking” (MWS) and a GP whose

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<th>Table 2: Table of themes.</th>
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<td><strong>Theme</strong></td>
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<td><em>If it doesn’t do any harm, I’m not against it</em></td>
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<td><strong>Philosophical beliefs</strong></td>
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Acupuncture was also discussed as a “no other alternative” (MW) from the client perspective, due to many women being “reluctant to go and see a psychologist, psychiatrist, or medication” (MW), especially if the “treatment would be worse” (PP). “If I can, I’ll do it more acceptable to see an acupuncturist than to see the psychologist, but I always need to remind myself that nobody wants to see a psychologist. They’re even more enthusiastic about seeing a psychologist. So if acupuncture’s going to do the trick, then let’s get on with it” (PY).

It was also recognized that not all pregnant women experiencing depression would choose acupuncture as a treatment, due to “a fear of needles” (MW), as well as a lack of knowledge, as it might be hard to convince a patient who does not know anything about it” (GP).

3.4.2. Practitioner interactions

Having personal interactions with acupuncture clients seemed to increase the confidence participants had regarding acupuncture as a treatment. “I think having face-to-face acupuncture working amongst us has introduced not just the women, but the midwives to different alternative therapies… the way they communicated what they were doing and what the points were was very calming and you feel yourself just relax instantly. You can see why people who have depression have been referred to them because what it does for you is the宁静” (MW).

“There’s only one person that I refer people to and that’s GP, who’s the one who I personally know and I know his experience in acupuncture and I know his demeanor and his process is as GP” (GP).

A number of participants expressed a desire to meet practitioners, so they could ask about qualifications and levels of knowledge, as well as who to refer to, knowing that “too a background of science” (MSM), was reassuring for some participants.

“I like to even meet with them, and I know what they are good at and what they are interested in, so I can refer appropriate patients to them” (OB).

In the theme “It doesn’t do any harm, I’m not against it,” the opinions and experiences of participants regarding acupuncture were captured. Overall, they were favourable and positively influencing further discussion around the use of acupuncture in antenatal mental health.

3.4. The domain of mental health

In the major theme, the domain of mental health, the participants reported having experience caring for clients with mental health concerns during pregnancy and discussed the many different issues surrounding treatment and resource availability. “Treatment has a lot of side effects” (OB). It was acknowledged by participants that depression is rarely successfully managed by one treatment type alone. “Depression is a complicated business. You cannot have one possible remedy” (PSV). With recognized treatments, including “cognitive behavioral approach” (OB) and medication being limited due to varied effects, acupuncture was seen as an extra option.

“I would say, at the moment we have very limited resources and even know how best to treat women, and I think that would just be another option that we could explore” (NSM).

“So, I would be very enthusiastic about the possibility of acupuncture for antenatal depression. I’m very positive about investigating it—it’s very positive” (OB).

It was felt that rates of mental health issues had increased, especially in women accessing maternity services, “especially after pregnancy and when depression is such a huge part of every healing we do” (MW). Consequently, the benefits of also focusing on antenatal depression was seen as important.

“At the moment I have been in postpartum depression and this is very much an antenatal period. I think, clearly also has its own effects. I think for birth itself. So, it’s globally—I think it’s very important investigation” (OB).

Acupuncture was also discussed as a “no other alternative” (MW) from the clients’ perspective, due to many women being “reluctant to go and see a psychologist, psychiatrist, or medication” (MW), especially if the “treatment would be worse” (PP). “If I can, I’ll do it more acceptable to see an acupuncturist than to see the psychologist, but I always need to remind myself that nobody wants to see a psychologist. They’re even more enthusiastic about seeing a psychologist. So if acupuncture’s going to do the trick, then let’s get on with it” (PY).

It was also recognized that not all pregnant women experiencing depression would choose acupuncture as a treatment, due to “a fear of needles” (MW), as well as a lack of knowledge, as it might be hard to convince a patient who does not know anything about it” (GP).

3.4.1. Pregnancy adds limitations around options

This subtheme focused on the issue of medicating during pregnancy, with practitioners acknowledging that many women refrain from taking medication, due to not wanting to have a negative “impact on their baby” (PSV), and prefer instead “a management option that doesn’t include medication” (OB).

Practitioners similarly faced difficulties regarding medication, due to having to “always have the best to try to convince the patient, take the medication because it’s going to help you and only try to convince them that there is not much side effect of this medication” (PSV), as well as feeling concerned about “an over reliance on medication, which really in the cold light of day is far less than it is made out to be” (OB).

Having considered the limitations faced when treating antenatal mental health concerns, as well as their overall positive impressions of acupuncture, participants arrived at a position that “it’s worth giving it a go. With this in mind, practitioners went on to discuss possible barriers and facilitators to implementing acupuncture, in the major theme “Making it mainstream”.

3.5. Making it mainstream

Participants identified a number of potential facilitators and barriers to implementation, the overall feeling however, was that the option of acupuncture should be available to all women experiencing depression in pregnancy. “I think it should be widely distributed. It should be provided at hospital, in clinic or in GP centres as well” (GP).
Having a positive viewpoint was seen as an important to overcoming barriers. If you believe that you’ve got a winner, you’ve got to think about what is it that’s going to move the barrier” (OR).

Advising the benefits alongside women’s experiences of the treatment was also seen as important: “When you’re promoting a service or promoting a modal, the women’s side – their side on the story is huge”. This combined information could then be used to encourage implementation, “I think you talk about it big enough and loud enough and you really get it out there, you get the evidence out there, and have patient stories associated with it” (MSW).

3.5.1. Barriers

When participants discussed barriers, four key areas were identified in the concepts, ‘evidence and mechanism’, ‘space and place’, ‘cost is always a barrier’, and ‘hospital bureaucracy’.

3.5.2. Evidence and mechanism

Participants identified a lack of knowledge “What the evidence is” (GP), as well the “lack of a well-advertised body of supportive knowledge” (GP) as barriers. Practitioners wanted to see “if it’s got proven actions . . . whether it’s got recommendations” (GP) and the “quality of evidence” (GP). Rigorous methodology designs such as “a randomised double blind controlled trial” (GP), of “a very big and convincing trial of a very well-specified group of women with particular personality and other attributes, and more than an IDEOS score” (PSY) was discussed as necessary to convince some participants; however, for others, “a carefully designed observational study” (OR) or “a prospective study” (GP) would also be acceptable.

Not having endorsement from national professional groups was also seen as a hindrance. “So if acupuncture is not recommended by the Royal Australian College of General Practitioners (RACGP) as well as it might affect some doctors wanting to do it” (GP).

Participants additionally indicated wanting to “know mechanisms” (OR) of acupuncture,

“I’m interested in learning about how it works. That’s the most important thing as a physician. The more you can understand the physiology of any procedure or any intervention, gives you a better understanding of what’s going on and how much you can prescribe such interventions in the future” (GP).

“Explaining (to clients) how it works” (GP) was also identified as a possible issue, although some doctors also acknowledged that “we don’t know how this precipitates work so, you know, if we can manage postpartum or PTSD, that’s probably given an explanation from the acupuncture people about the magic, I could probably make that work too” (GP). They also said “there’s always the concern that it won’t work, but that’s no different to anything that I offer” (GP).

3.5.3. Space and place

Hospital antenatal clinics were seen as a barrier, “because it’s hard to get a time slot” (MSW) on “antenatal clinics don’t seem to have a spare slot” (PSY). This busy environment was also seen as a reason for not conducive to acupuncture treatment, when “a good, quiet environment” (OR) was expected.

“I guess it’s better if you have a separate clinic. Patients come in, you have your room, close the door and make patient feel comfortable to talk to the patient, and do the acupuncture, and they are in there. That may be a better environment, rather than a busy clinic, many people in the corridor, in and out” (OR).

Another area of concern was the location of the hospital to the community to ensure that “people don’t have to travel for it” (OR), especially “if they’ve got other children” (PSY), and childcare commitments.

3.5.4. Cost is always a barrier

The funding associated with acupuncture was discussed in depth and seen as a major barrier. “The disadvantage is number one the cost” (GP), and the feeling that “a resource poor environment you could see lots of arguments against formally incorporating it in the suite of services that you offer” (OR).

How the service could be funded was separated into several different options, “it’s either going to get cost shifted to Medicare, which is how we pay for the antenatal clinic, or an unassessed, or we’ll charge the patient” (OR). In the case of charging women experiencing depression, options explored included privately charging clients without rebates or subsidising treatments with Medicare funding.

Paying for the treatment in full was seen as a potential barrier to accessing the service. “I think if this is not offered free or rebatable in some way, I just can’t see women taking it up” (PSY), with others also reinforcing this view, “sometimes women are reluctant to go to acupuncture because of the cost of it” (MW), particularly in low socio-economic status areas in which “most people can’t afford it” (GP). Instead it was discussed that women may choose a mental health treatment based on affordability “if I see a psychiatrist’s Medicare, then I get medication it’s PBS [pharmaceutical benefits scheme]. So I can do it the way that easier” (MW). However, some midwives also argued that when reimbursable options are limited, such as for pregnant women experiencing depression, “most of our women though are pretty happy to pay for a session, a couple of sessions” (MW), as “they’re desperate . . . they try anything” (MW).

To access partial funding through Medicare was identified to be a complex process, even thought it was seen as the preferred option to some, “I think a partially funded, I think that’s fair, going both ways” (MSW). The other option was full Medicare funding, so treatment could be accessed “free on GP management plans” (GP), as in the case with “psychology, there are mental health care plans which subsidise it” (GP), however others expressed views that both were unlikely, “I don’t see Medicare being involved with this at all. Good luck with that” (GP).

3.5.5. Hospital bureaucracy

The final identified barrier against implementation was “bureaucracy and the limitations of the public health system” (GP), as to obtain incorporation, it was felt that “you have to go from the top” (PSY).

“I believe it’s got nothing to do with the physical health service. We need to approach things from the top not from our level” (PSY).

One obstruction also added that the procedure new services had to go through prior to providing treatment in a hospital setting, were complex and likely prohibitive. “There is . . . a formal process . . . everyone who works in the hospital has to have hospital employment. It has to be accredited by the accreditation committee . . . it may be accredited, it may not be accredited” (OR).

However, once hospital management was supportive of incorporating acupuncture, others felt that there would be very few barriers left: “Once you overcome the top of the problem or the management, the hierarchy management, there is not much of an unbelievable issue that will happen to our level, because we already have an antenatal service” (PSY).

3.5.6. Philosophical beliefs

In the etheme ‘philosophical beliefs’, workplace culture and philosophical standpoints were seen to be influential to the acceptance of acupuncture into mainstream care. The differing theoretical paradigms and experiences of the professionals was seen to be important in shaping these beliefs. “The midwives seem...
to be open to acupuncture (PSY) compared to doctors who have been medically trained for their whole career in primary care (MSSM).

It was felt there was "an intrinsic motivation about anything that's aligned because it's an alternative" (OB) in mainstream care, and that "even the word complementary will set people off, so think that's perhaps the first roadblock" (OB). Midwives shared this perspective stating that in their view, a major barrier to implementation would be the "doctors saying stuff" (MW), as well as medical "culture" (MW), as they are "quite opposed to things that aren't researched based and have any kind of medical interrelationship" (MW). One service manager expressed an alternative view however, that "the doctors wouldn't be supportive" (MSM), yet also acknowledged "it was good I suppose [name of acupuncture] had a background of science so was able to stand her ground with the medical officers questioning" (MM), and perhaps that was what had made a difference.

Experience of working in areas away from large hospitals was also seen to influence practitioners' acceptance of acupuncture. Examples given were working in a birth centre where midwives were expected to "look further than just you, know the drug chart" (MSM) as well as working in a women's health centre.

I worked at a women's health centre, they had all the different sorts of approaches to health there which was great." (GP).

Another perspective presented by several midwives was that the holistic approach of acupuncture, could provide "a good alternative that would benefit many in hospital settings, as time pressured doctors often pushed what they considered to be the more effective but less time-consuming treatments" (MM), however acupuncture may be able to fill this need, as "every part of the patient would be addressed, the woman as a whole, not just a symptom or pregnancy" (MN), whilst at the same time taking some of the pressure off the midwives.

3.5. Facilitators

Facilitation of acupuncture can be facilitated, with participants highlighting the need for "education and engagement" (MSM).

The challenge with implementing anything new is how you go about setting it up. You know, it's the work you do before, educating stuff about it, letting them know it's here and what it's for and letting them ask questions and you know, experiencing it themselves if they want to" (MSM).

A variety of suggestions were suggested including "having a candidate in the conference" (KN), "attending a workshop" (OB) and "an entire - learning module" (GP). It was also considered important that the mechanisms of acupuncture action should be discussed, as "even specifying in them just do it, how did you do it" (OB).

Raising awareness of the professional standing of acupuncturists was also identified, as a number of doctors indicated not knowing "it's a great deal about the current regulation process in Australia for acupuncture and it's a prevailing body" (GP).

Facilitated engagement was additionally suggested by the inclusion of senior doctors in research design, "I guess I - you and we need to talk, or maybe you review group, and then myself and a senior doctor maybe, just need to know, and learn to approve." (OB).

Increasing "Evidence and Mechanism" and the benefit of accessing acupuncture at a "One stop shop" were also seen as important facilitating concepts.

3.5.3. Evidence and mechanism

Although limited research evidence was an identified barrier to the implementation of acupuncture for antenatal mental health, research showing beneficial effects of acupuncture across a scope of issues and disorders was seen as a facilitator to acceptance in mainstream care.

"I think probably the greatest exposure I've seen it used in the medical world is a few years ago I know the National Institute of Clinical Excellence (NICE) guidelines from the UK approved it for use in headaches." (GP).

Participants also felt that in medicine "things change" (GP) and acupuncture had the potential to "be a new and promising idea" (GP) and that "potentially, it's there" (MSSM). Allowing ideas around acupuncture to emerge encouraged a view "to broaden our horizon if we're going to see advancements in medicine in our country" (GP).

"It's just like information technology, when new technological advancements are discovered every day, medicine is still a huge ground for new information. That's why I really encourage such opportunities to see how best we can improve whatever we're doing right now." (GP).

The fact that theRCU had been conducted also involved the collection of blood and saliva samples for psychometric testing was seen as "a very comprehensive approach" (OB), that if shown to be reliable, could provide "fairly solid evidence of effectiveness" (OB), and a major potential facilitator.

3.5.4. One stop shop

To make acupuncture acceptable for women experiencing depression in pregnancy there was agreement that "it would be important" (GP). Factors considered likely to facilitate uptake included locating treatment "close to public transport" (MSM); offering services at convenient times; "could be done on the same day as we have our clinics" (GP) and being considered of family commitment, as many women have "a lot of other children" (MSM).

Making acupuncture treatment available at the "location where the patient goes for most of their antenatal visits" (GP), whether that is hospital or "in GP surgeries" (GP) was considered to offer the most benefit to women, as that way they only needed to make the "one journey" (MSM).

"I think if it's in a hospital, in a clinic, women are more likely to access it, then because they're already here doing their clinic visit. So then they will think okay, I've got the time now to go up and have the acupuncture." (MW).

In addition, it was considered that in these locations, acupuncture would be more acceptable as it "would be more normalised if it was in the hospital setting" (MW).

An overriding view presented was that having an acupuncture on site would be "prettier" (MW), not just for maternity services, but for other conditions as well.

"So you wanted to have an acupuncture that worked across the hospital, not just in antenatal depression because you want something that can provide services to cancer patients and people with different issues." (MSM).

4. Discussion

This study served to explore the perspectives and beliefs of doctors, midwives and maternity service managers regarding the use of acupuncture as an additional therapeutic option for antenatal depression, as well as views in relation to potential barriers and facilitators to implementation into mainstream care. To the best of our knowledge, this is the first in-depth interview and focus group evaluation of stakeholders' opinions and attitudes in this regard. The overall opinion to emerge from the research was
that in relation to 'acupuncture for antenatal depression: it's worth giving it a go'. This conclusion came about after consideration of two main themes, the dilemma of mental health and if it doesn't do any harm, I'm not against it. In which the limitations of conventional approaches, particularly in the antenatal period, as well as experiences of, or feedback in relation to acupuncture had been considered. The major finding was that conventional health professionals were generally receptive to the use of acupuncture for antenatal depression, providing that they could be assured of the safety, quality and efficacy of the intervention.

The second component of the study then focused on the third theme ‘making it mainstream’, in which potential ‘barriers’ and ‘facilitators’ to implementation, underpinned by various philosophical and religious concerns and conscientious considerations, such as endorsement, costs and space allocation.

An interesting perspective to emerge from the study was the general openness with which the interviewed doctors considered the use of acupuncture for antenatal mental health concerns. Such finding was in contrast to the perspectives presented by midwives in this study, as a large number of midwives were more concerned and had reservations regarding acupuncture. One major finding was that many midwives held a cautious and sceptical view of acupuncture, particularly when it came to the purported benefits of its use for antenatal depression. 

A recent national survey of 128 obstetricians in the USA however also reported support for CM use during pregnancy, with 62% of respondents having recommended CM to pregnant women under their care, as well as reporting personal use in 45% of cases, including during pregnancy in 38% of female practitioners. It is possible that attitudes towards CM may differ between midwives and medical doctors, with the former being more inclined to recommend CM for antenatal depression.

The findings highlight the need for further research and education on the effectiveness and safety of acupuncture for antenatal depression. There is a growing body of evidence supporting the use of acupuncture for various maternal health conditions, including depression. However, more research is needed to establish its efficacy and safety in this specific population. The demand for alternative therapies in obstetrics and gynecology is increasing, and acupuncture is gaining popularity as a complementary treatment option.

In conclusion, acupuncture for antenatal depression is a promising approach that warrants further investigation. The benefits of incorporating acupuncture into routine obstetric care cannot be underestimated, and it offers a non-invasive, safe, and effective method for managing antenatal depression. The findings of this study underscore the potential of acupuncture as a complementary therapy in obstetrics, highlighting the need for further research and collaboration between healthcare professionals to optimize its integration into routine antenatal care.
5. Conclusion

This qualitative exploration of the opinions of doctors, midwives, and maternity service managers regarding the possibility of introducing acupuncture into mainstream care as an additional therapeutic option for antenatal depression identified that overall, views were aligned and open to this possibility, providing acupuncture was safe and could be shown to be effective. Despite coming from a variety of different philosophical beliefs, doctors and maternity service professionals positions were found to converge to the point of “if it doesn’t do any harm” then it is worth giving it a go, which appeared to be receptive of both the diffusion faced when treating this population, as well as patient preference. Consideration was then provided regarding potential barriers and facilitators to implementation, highlighting bureaucratic, financial, and structural considerations that would need to be overcome, as well as the necessity for further education and knowledge dissemination.

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Conflict of interest

SO is currently practicing as an acupuncturist in private practice. CF is currently practicing as a general practitioner and acupuncturist in private practice. CE and CS are part of NCM. As a medical research institute, NCM receives research grants and donations from foundations, universities, government agencies, individuals and industry. Sponsors and donors provide funding for work to advance the mission and vision of the institute. Though authors, the subject of this article was not undertaken as part of a contractual relationship with any organisation, other than the funding declared in the ‘Acknowledgements’ section, it should also be noted that NCM conducts clinical trials relevant to this topic area, for which further details can be obtained on request. HD and HR are privately practicing midwives and declare no competing interests. The researchers wish to declare that there are no actual or potential conflicts of interest in relation to this manuscript.

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References


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being reported in at risk populations such as those with personal and or family histories of mental illness, as well as exposure to social adversity, violence and abuse. Unintended, associated negative maternal-infant outcomes include increased risk of neglected and/or harmed infants, obstetric and breastfeeding complications, reduced maternal responsiveness and postnatal depression. Long term impacts can similarly be extensive, with attention to physiological, psychosocial and developmental issues being reported, along with a propensity towards disorganised attachment, anti-social behaviour and longer term mental health vulnerability.

Conventional treatments include psychotherapy for mild cases and antidepressants for moderately to severely depressed. During pregnancy, alternatives to medication are suggested whenever possible, however if required, the minimum effective dose of those displaying the most favourable safety profiles are recommended. Evaluation of safety is nonetheless difficult, as data from observational studies is often conflicting. As the debate regarding the possible impacts of methodological disparity and inadequate adjustment of confounders. With antenatal antidepressant medication exposure rates potentially as high as 13%, possible detrimental impacts to fetal and maternal health. Risks may be more acceptable with considerably therapeutic effect. However, the British Association for Psychopharmacology guidelines in 2015 report modest antidepressant response rates of 18% and in addition that 35-40% of affected individuals continue to have clinically important symptoms. Consequently, some women with antenatal depression will benefit from antidepressant treatment, but a substantial proportion of patients will not [p.11]. Practitioner prescribing reflects these difficulties, with pregnant women experiencing depression reportedly receiving a range of treatment recommendations from the complete exclusion of medication to increased dosing that adjusts for pregnancy related pharmacokinetic changes. Provider opinion disparity has additionally resulted in some women receiving conflicting safety advice.

Not surprisingly, many pregnant women experiencing depression face difficulty evaluating the risks of whether or not to take medication, with as many as 52% in one study being identified as having moderate to high levels of decisional conflict. A large proportion of women choose to discontinue medication during pregnancy, with two thirds indicating use to be acceptable.
Women instead indicate preferences for psychotherapy, non-pharmacological options, or no treatment if medication is the only option. With approximately only 10% of women experiencing perinatal depression obtaining adequate treatment using conventional approaches, it is understandable that some seek out alternatives. Two very recent studies have confirmed this trend, identifying that 33% of 217 Australian women surveyed in the perinatal period would choose ‘natural, herbal or traditional Chinese medicine’, if they became aware of experiencing depression and anxiety, as well as 45% of 1022 pregnant American women scoring 12 or more on the Edinburgh Depression Scale (EDS), indicating consideration of complementary health approaches for stress and or weight management. It is possible that the higher proportion of women displaying interest in other care reflected actual expressed dissatisfaction with conventional treatment options.

As many pregnant women clearly desire non-medicated approaches to mental health management and patient preferences are imperative considerations in treatment and care, it is important to explore ‘not only the effectiveness of CAM therapies, but also women’s experiences of receiving them’ [p. 92], as to gain invaluable detail regarding why a treatment did or did not work, as well as participants values and levels of satisfaction. To date three randomised controlled trials (RCTs) have been conducted evaluating acupuncture for the treatment of antenatal mental health concerns, however women’s experiences of receiving the interventions have not been collected. To this aim, we conducted an additional RCT examining acupuncture as a therapeutic option for antenatal mental health concerns in women scoring 13 or more on the EDS, that also included a qualitative component to specifically explore women’s experiences of mental health issues and conventional treatments, knowledge of and views of acupuncture, reasons for enrolling in the RCT and experiences of receiving the acupuncture intervention. This paper will report on the qualitative study exploring women’s experiences of receiving acupuncture for depression in pregnancy. The main findings of the RCT will be reported elsewhere.

Table 1
Demographic details of interviewed women.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age at interview</th>
<th>Relationship status</th>
<th>Highest level of education</th>
<th>Employment status</th>
<th>Number of children</th>
<th>IQ depressive episode</th>
<th>Length of depressive episode</th>
<th>Medicated at study entry</th>
<th>Previous use of acupuncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 New Zealand</td>
<td>21</td>
<td>Married living as married</td>
<td>Vocational college</td>
<td>Full-time</td>
<td>1</td>
<td>22</td>
<td>5</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2 New Zealand</td>
<td>22</td>
<td>Married living as married</td>
<td>Vocational college</td>
<td>Not working</td>
<td>0</td>
<td>15</td>
<td>7</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>3 Australian</td>
<td>21</td>
<td>Married living as married</td>
<td>Vocational college</td>
<td>Full-time</td>
<td>0</td>
<td>12</td>
<td>11</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>4 Australian</td>
<td>39</td>
<td>Married living as married</td>
<td>Vocational college</td>
<td>Not working</td>
<td>2</td>
<td>25</td>
<td>14</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>5 Australian</td>
<td>40</td>
<td>Married living as married</td>
<td>Undergraduate degree</td>
<td>Full-time</td>
<td>1</td>
<td>20</td>
<td>19</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>6 Australian</td>
<td>27</td>
<td>Married living as married</td>
<td>Year 11 High School</td>
<td>Part-time</td>
<td>2</td>
<td>14</td>
<td>13</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>7 Australian</td>
<td>39</td>
<td>Married living as married</td>
<td>Vocational college</td>
<td>Part-time</td>
<td>8</td>
<td>23</td>
<td>26</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>8 Australian</td>
<td>36</td>
<td>Married living as married</td>
<td>Vocational college</td>
<td>Full-time</td>
<td>1</td>
<td>12</td>
<td>26</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Key: PND: postnatal depression; SNRI: serotonin-noradrenaline reuptake inhibitors.

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1. Results

1.1. Participant experience and characteristics

Participant characteristics are presented in Table 1. Participants’ ages ranged from 21 to 40 years. All of the women were either married or living as a couple. The majority held a vocational qualification and were employed on a full or part-time basis. Most of the women had previous treatment with a physician. All women however had previous histories of mental illness, with index episodes ranging from 5 to 20 years prior to their current pregnancy, as well as an experience with using antidepressant medication and/or counseling or psychotherapy. These women were treated at a clinic, two with antidepressants of the SNRI class and the other, with an anti-epileptic for the management of the bipolar disorder.

1.2. Findings

The overarching theme identified from the data was ‘feeling trapped between a rock and a hard place’, along with the three supporting themes: ‘feeling stuck’; ‘give it a go’ and gaining relief.

Several sub-themes were also identified within each major theme, as represented in Fig. 2.

1.2.1. Feeling trapped between a rock and a hard place

The overarching theme ‘feeling trapped between a rock and a hard place’ captured the dilemma women experiencing depression during pregnancy faced when considering therapeutic options for the management of their symptoms, as well as the potential detrimental impacts of non-treatment or medication to both themselves and their offspring. Upon recognising their depressive episode, the women articulated ‘feeling stuck’ due to the difficulties they faced ‘living with mental health issues’, along with the knowledge that for them, previous experience with conventional ‘treatment is hit and miss’ and additionally limited during pregnancy. When queried about their reasons for joining the study, the women indicated their willingness to use acupuncture and it was given to them, as they acknowledged they needed help, but also that they didn’t know what to expect. ‘I heard about acupuncture but …’ and had some concerns, I was uncertain. Perceived beneficial effects described in gaining relief encompassed the women and...

![Diagram](image-url)
Concerns about managing in the postnatal period were also expressed, when "you’re feeling a little bit overwhelmed from either lack of sleep or emotion" (Sarah).

3.4. Treatment is hit and miss

Discussions regarding experiences with conventional treatment options revealed mixed success, as well as an overall predominance of dissatisfaction.

"Some counsellors are good, some aren’t so good" (Sarah).

Under the subtheme treatment is hit and miss was the concept that some counsellors are good while some are not so good. One participant reported having had positive experiences with counselling; however, she now felt that this was no longer an option to pursue, "because I did what I needed to say" (Bree). Another expressed mixed success with clearly more negative than positive outcomes, stating "some of them [counsellors] are not so good and some of them are good" (Sarah), "...for some reason once something changes they don’t know how to keep me on the same level!", and also that, "I didn’t find it all that helpful because of the way they at some point talked you all the time” (Anabel).

Others were less positive, reporting going along "to talk about it [depression] and work it out and that sort of stuff. Honestly, I don’t really think any of it helped too much" (Madison), as well as: "I didn’t find it helpful. Bringing up the things that happen and talking about it, I don’t find resolving it just made it worse I think... it brought up memories that I didn’t even know I had... that upset me... if I’ve suppressed these feelings or memories, then I’ve suppressed them for a reason" (Georgia).

"Feeling drugged"

Overall dissatisfaction with medication was also the predominately expressed view in the concept ‘feeling drugged’. Only one participant appeared not to question taking medication, even though she had received conflicting advice. She reported her perinatal psychiatrist had suggested "I’m someone who can never come of it... actually at the end of my last pregnancy – they increased my dose". This had occurred after a general practitioner had told her in the previous pregnancy to come "straight off my antidepressant because I was going to murder my baby", however after doing that, she had had "a really hard time" (Dianne).

Anabel similarly reported noticing some benefits from medication, however she also stated that she “didn’t like it” and consequently experimented with taking only a “small dose at a time”, to try to balance herself out, whilst at the same time, minimising the unpleasant effects.

Other much stronger views of dislike of medication were expressed, with non-effectiveness and side-effects being two of the major reasons cited:

"I honestly didn’t even think the medication was working. To me it didn’t affect me. Well it doesn’t do a way that it holds you back, I feel it makes you a different person, like it takes away your opinions... it was just I didn’t have a voice because I was just drugged up... I didn’t feel that I was myself and I didn’t want that...", "... and there are all of the side effects that came with it, it was just not good" (Georgia).

"One made me sick all the time. One made me yawn all the time... lexapro or something like that, made me violently sick all the time” (Sarah).

"I didn’t want to harm my baby"

In the additional concept ‘I didn’t want to harm my baby’, uncertainty regarding fetal toxicity was the other major reason indicated for ruling out medication.

"I had tried different medications in the past and didn’t really want to take anything while I was pregnant because I know whatever you take obviously can affect the baby. That’s why I..."
was really against medication I guess for depression during this pregnancy” (Sarah).

3.5. Give it a go

Recognising not wanting “to have anxiety or depression at all” (Georgia) or “to be on tablets either” (Georgia), all of the women indicated in the second major theme, ‘give it a go’, how they became willing to try acupuncture as they got to that “...point where I’m definitely not going to run down help” (Bree). This theme clearly reflected the sense of frustration these women felt with their narrowed treatment options as most had "heard about acupuncture but...” had very little knowledge of what it entailed and, unsurprisingly, also expressed some fears about treatment, in ‘I was uncertain’.

Heard about acupuncture but...”

In the subtheme heard about acupuncture but...” knowledge of acupuncture was found to range from having heard of it but “I never really knew anything about acupuncture” (Annabel) to familiarity with it for specific clinical applications, such as neck pain, stress relief, fertility, and to “bring on labour or to help ease out labour when it finally comes” (Maddison). With the exception of bring on labour, the women generally hadn’t really specifically heard anything about it during pregnancy” (Maddison), which in the case of Maddison had recently changed, after bloggers on a Facebook “mum’s group” reported “that’s safe during pregnancy”, noting for knowledge of use for mental health issues similarly revealed little knowledge of or consideration of the possibility, apart from again in Maddison’s case, in which she indicated she had “definitely heard that it was good for stress relief”.

“I was uncertain”

With respect to the utilisation of a predominantly unknown therapy that involved the use of needles, it was not surprising that some of the five acupuncture naïve women expressed apprehension in the concept I was uncertain, as “I never had acupuncture before so I wasn’t really aware of what would happen and I was a bit nervous” (Georgia).

In regard to a fear of needles, a range of views was expressed from “I was very scared of the acupuncture because I don’t like needles” (Annabel), to “I didn’t expect it was going to hurt because I’ve never heard anyone complain that acupuncture hurts” (Maddison).

Prompted prompted responses regarding the women’s actual experiences of the needles revealed all were comfortable with the technique, even the most needle phobic participant, who stated that “...the first couple of times that I got it done... I got a bit scared”, but then when asked how it actually was, she stated “It was good”. She was asked to consider why her experience was so different to her friend and she suggested it was because “it doesn’t draw blood” (Annabel).

Others also reported positive experiences:

“I knew enough about acupuncture to know that they don’t insert them really deep or anything like that” but “the first time - I’m wondering if this is going to sting a little bit but, no it wasn’t”. “It was comfortable” (Maddison); “I never even once felt a needle hurt me” (Georgia); and “honestly everything was great” (Isabella).

A range of pre-session views were also expressed regarding potential treatment benefits. A number of the women approached the idea of effectiveness from an optimally positive point of view, being “interested in the acupuncture and interested to see if you could be helped with depression during pregnancy” (Katie); whereas for others, scepticism dominated:

“I didn’t think it would make me worse. I wasn’t optimistic that it would make me better. I kept going to myself like if it was definitely didn’t think it would cure anything really” (Bree).

“I was very sceptical about acupuncture because I had done it before. I paid for acupuncture to be done 12 sessions previously for IVF. That never helped. So I was very sceptical that this would even help at all - I went in there thinking acupuncture, what a load of crap. It’s not going to help” (Sarah).

Despite some scepticism, hope that acupuncture would help was also expressed “I had doubts but also sat back and went, I just want to try it” (Sarah), particularly as it was offering a different approach “I only just went into it with an open mind just hoping that something alternative would help apart from being medicated or having those feelings” (Isabella).

3.6. Gaining relief

The third major theme to emerge was ‘gaining relief’, in which the women described their largely unexpected positive experiences of acupuncture, as ‘a pleasant surprise’.

‘A pleasant surprise’

Prompted to describe the sessions, the women reported that treatment commenced with a “good conversation about what I was at and what I was feeling and... a general medical history”, followed by a weekly “good discussion about what was going on” and “if I was getting or feeling any better throughout” (Isabella). Participants additionally reported noticing “it was never the same process every week” (Georgia) and that the individualised treatment tailoring “speaking to me, what I was feeling like, and what pressure points on that particular day were going to help me” (Sarah).

Sarah who had previously received acupuncture for fertility and IVF support discerned additional differences. When comparing the acupuncture delivered to the study to that she had received in shopping malls for fertility, she stated the study acupuncture “...wasn’t just like out of the textbook where okay this needle is going to do the same job for everybody...” Similarily, recalling the IVF support delivered acupuncture, Sarah also noticed: “...you didn’t walk out of the session feeling any different... definitely didn’t help with... me being able to relax whereas the acupuncture in this study... actually allowed me to be able to temporarily switch my brain off or not go back to a certain thing that’s irritating me or upsetting me, or has helped me better to relax... I definitely wasn’t expecting that” (Sarah).

In addition to relaxation, all participants described other beneficial effects such as refreshment, calmness, an enhanced ability to cope and increased positivity and motivation:

“I felt a lot more relaxed... I don’t know how to explain it. I felt fresh for the new week... So instead of me going from being - clearly from the end of the last week to being able to cope again. So I could handle with the whole having to get our house ready for a baby... It was a stressful time” (Annabel);

“...It was like I just took a step back from what I used to and I just let it go. I just felt really at ease with certain things, I wasn’t worried about anything. Like I was at a normal level of worry, not overreacting, heart palpitations, shaking type of stuff: yeah, I wasn’t on edge” (Georgia);

“...definitely... feeling really good... it must have brought me down a notch... I felt more positive and I knew I felt more motivated again” (Bree).

In order to gain greater detail about perceived treatment effects, the women were specifically prompted to consider how long they left the treatment effect lasted for and whether perceived benefits
appeared to be cumulative. Consistently the women reported that “over time” the effects of acupuncture continued. Sarah stated, “Well I was definitely able to relax during the sessions… and I started to realise that I was getting benefits, even afterwards…” (Odele).

... “It’s sort of had some ongoing benefits… I found each time did allow me to extend how long a time period I could relax for” (Sarah). A sense of ‘lightness’ was also commonly described, “I kept feeling lighter… it really felt like a weight had been lifted off my shoulders” (Madison), “I just felt like I was not necessarily feeling but just happy to go along with the rest of the day” (Sarah). At the time of the interview, Georgia described still feeling the benefits, “I still find it lasting now… I’m much more ‘me’ just chilled out and feeling… relaxed… more energy and a lot more focused… I feel good within myself… I’m not as negative… I’m a lot happier… in my body I feel fantastic” (Georgia). The women also reported noticing other improvements; “I could take a deep breath and not burst anymore, like I no longer had the pain in my chest… sciatic nerve – had that really bad and she helped me with that, yeah which was awesome…” I hadn’t had one pain relief tablet since she started… I was just in pain with a lot of other things in my body, but during the course she has helped that even if she didn’t mean to” (Georgia).

... that night afterwards I was getting up a lot less frequently to go to the toilet… I was able to sleep more, I was able to have less dreams or less nightmares, I was able to turn my brain off and to sleep, which normally I couldn’t say there for three or four hours before I’m even able to get to sleep” (Sarah). When asked whether partners, other family members and friends had noticed changes in their moods, participants typically indicated that that had been the case: “He’s [partner] really come out of these sessions and you… you always seem so much brighter… didn’t end up falling asleep… my partner has turned around quite a few times and said you know, I wonder if it was the acupuncture… he’s mentioned to a couple of our doctors… and even just friends… she’s brighter and chatty, I wonder if it was because of that” (Marion). “Oh, huge difference. He just said like ‘I can talk to you now’ … he used to talk to me and I was always on the defence… he noticed it – even my children, I pick them up from school and ‘are you okay mum?’ ‘Yeah, why?’ ‘You’re happy, you’re happy’ (Georgia). The interviewer also prompted the women to provide their views regarding whether they felt the benefits they experienced could simply be due to time out and having someone to talk too. Overwhelming the participants responded that they did not feel this to be the case, indicating that they were able to discern the differences: “I tend to talk to people anyway so I don’t know that just the talking, I’ve got a good support network so I think the talking and the therapy kind of combined were what helped” (Isabella).

“I definitely did relax more than if I was lying down” (Odele). Only one of the participants indicated being unsure about how much of the effect was just from time out for herself; however, she also stated “… it made me calmer and more motivated, but overall, even if it was just … having the quiet time every week; it was … a positive experience and I’m glad I did it” (Odele). Warming to “… keep going to the end of the pregnancy because … the sessions have helped me this far” (Sarah) was additionally expressed, along with a willingness to have acupuncture again. Typical statements included: “I will definitely go back after I have the baby” (Isabella) and “I’m looking forward to doing it in the future” (Sarah). Sarah also indicated she would definitely recommend it “… even if you’re not stressed and having a really, really easy pregnancy…” I found it very relaxing” (Sarah). With regard to recommending acupuncture to friends and family, responses were similar, “I’ve told her [friend experiencing depression] if she ever feels pregnant to do the acupuncture or to even go do it now…” because I found it helped” (Anabel). And my daughter has really bad anxiety, she’s medicated for it, I will be recommending it to my daughter” (Sarah).

When quizzed about whether acupuncture should only be available for those who have a diagnosed illness, Isabella stated “Maybe it was for everybody it would keep some people out of that category instead of getting into it and then seeking help”. She also suggested that she felt it would be useful for general health maintenance, “not even pregnant, just lifestyle… not even if it was that stressed, because I think it helped me immensely in just the growth of me”. Cost was however discussed as a barrier for some, with Isabella indicating she would not have had as many treatments for that reason, however Sarah considered the “benefits far outweigh whatever cost is or time is involved in getting it done”. Reflecting on the experiences gained from treatment, the participants indicated their views of acupuncture had changed, even amongst those who were initially the most sceptical, such as Sarah, “I’m surprised at the benefits that I’ve gotten out of it because I honestly didn’t think it was going to work. I thought it was going to be a load of hogwash…” and Isabella, “… I never really considered it [I] would help me before but I think that it did, it kept me very level headed and allowed me to unwind really well…” Georgia also stated she was “very impressed” and Madison indicated it ‘really made me realise’ this actually has some meaning…

Rather than feeling trapped between mood disturbance and exhausted therapeutic options, acupuncture provided hope (Sarah), for the future, as being able to “look forward to something when you’re depressed or want to get out of bed when you don’t want to get out of bed…” that you know is going to help… it’s definitely promising” (Sarah). Hope was also expressed regarding the assimilation of the research findings into clinical practice, “I just hope that it goes ahead and works and people don’t shy their nose up just because they’re [acupuncture] not like a doctor, you know” (Georgia). Overall the sentiment expressed by the women is typified by the following overarching quote: “I think that when you Google depression and when its says how to fix it, I think acupuncture should be at the top because I don’t believe that anyone should be on prescription drugs for the rest of their life, because it doesn’t help you. It doesn’t cure you. It just takes half of your personality away… I definitely think acupuncture should be offered to everyone and it should be more commonly known, because I didn’t know about it until this study…” (Georgia).

4. Discussion

The findings of this study which to the best of our knowledge are the first to report on women’s experiences of receiving acupuncture for antenatal mental health concerns, is in alignment.
with previous research indicating that pregnant women experiencing depression face additional complexity when deciding upon an a cure of action for the management of their symptoms.14,15 For the women in this study, these difficulties culminated in a sense of ‘feeling trapped between a rock and a hard place’, as a consequence of unsatisfactory experiences with conventional treatments and/or medications becoming undesirable during pregnancy. Recognising their need, and not being willing to pass up on an opportunity to help, the women in this study decided to try acupuncture and ‘give it a go’, even though they also had limited knowledge of its application, and some reservations. Upon completing the course, the women reported gaining ‘relief’ from their symptoms, which they felt was ongoing, and aided them in better managing their changing lives. The women additionally indicated feeling a sense of hope for their futures, as having gained experience of a therapy they may not have accessed, they now had an additional therapeutic option to consider in times of need.

Further exploration of this sense of ‘feeling stuck’ was revealed to have occurred due to the convergence of three main factors. Firstly, all of the participants had long histories of living with mental health issues as well as the awareness that if they ‘get worse’, and/or ‘go back down’, hence they also knew the many pregnancy and lifestyle changes ahead, would continue to challenge their mental health. Secondly, having long histories of mental illness meant that these women also had extensive experience with conventional treatments, which they predominantly described as unsatisfactory in treatment effectiveness, that similarly mirrored dissatisfaction with conventional approaches9,16 and/or provider services21,22 reported in other mental populations affected by depression. Specifically with respect to counselling or psychotherapy, participants responses reflected previous research that demonstrated that trauma revelation can be stressful.17,18 ‘Symptom management issues met inadequate’ and that some providers appeared to be inadequate.19 A number of women also expressed a view that upon ‘saying what was needed to be said’, this service could no longer provide with them any additional benefit. Reported dislike of medication, due to unpleasant material side effects,20 was similarly re-iterated in this study in ‘feeling trapped’, along with evidence of inadequate management preventing utilisation.21,22 The third consideration was in relation to the potential risks of medication, with the majority of study participants reporting not being medicated. Of these, some expressed strong views regarding not being willing to risk foetal impacts in ‘I don’t want to harm my baby’, whereas others indicated it was the combination of potential foetal impacts alongside the disability of maternal side effects, that ruled medication for them. Fears regarding in-utero antidepressant safety and the corresponding reluctance, or refusal to take medication9,19 has similarly been reported in other mental populations experiencing depression. Research additionally indicates that many women find treatment decision making difficult,14,15 especially when presented with conflicting safety information and the disparate views of some providers.20 In this study, only one participant revealed having received conflicting advice regarding foetal risks, however, due to a severe relapse upon cessation in her first pregnancy, she appeared resigned to the need for medication in her second. For some individuals, however, taking medication reportedly contributed to feelings of shame and guilt.

It was this sense of feeling trapped in mental health symptomology that lead the women in the study to consider acupuncture as a novel approach to addressing their antenatal depressive concerns, and ultimately to ‘give it a go’. Despite having ‘heard about acupuncture but knowing little of it and also feeling ‘uncertain’, the women struggling with an atmosphere of scepticism yet desperation, from a position of desperation but desperation. This apparent lack of knowledge amongst participants of the increasing use of complementary medicines including acupuncture for pregnancy related complaints20,21 and/or mental health concerns17 was surprising, however possibly reflective of the relatively low socioeconomic status of the region involved in the study. Whilst this factor likely contributed to the difficulties experienced recruiting women into the RCT, it may also have conferred an advantage from the perspective that the study participants were unlikely to have had specific expectations in regard to positive treatment effects. As has been reported elsewhere, the participants did however indicate that the receipt of positive reports, recommendations from friends and family,24 reassurances of safety24 and hope of potential benefits,24 were all considerations that influenced their decision to engage with this approach.

After completion of the course of acupuncture, the participants described ‘gaining relief’ and the positive changes they, their friends and family members had noticed in their mental health symptomology. This came ‘as a pleasant surprise, particularly for the most sceptical, benefits to mood, energy, motivation, interpersonal relationships and the ability to cope detailed. Similarly, these were also reported to occur after use of acupuncture in 157 surveyed participants with serious mental illness.23 Additional improvements to bladder control, sleep quality and pain reduction described, whilst not directly targeted, are also potential outcomes of the whole systems balancing approach employed in Chinese medicine.24 Broad ranging improvements across physical, psychological and social domains such as these, have also been reported to have occurred in qualitative and mixed methods investigations assessing acupuncture effects in general populations.25–28 In addition, the benefits described were congruent with quantitatively assessed mood score improvements observed in clinical trials evaluating acupuncture for antenatal mental health concerns,29–31 as well as in systematic reviews examining acupuncture for the treatment of depression.30–33 Individualised treatment tailoring, also fundamental to this approach,6,8 was similarly discerned by participants, with women reporting feeling attended to, and as though treatment had been specifically designed to address their needs on that particular day.

In addition to providing more specifically directed treatment approach, this approach also increase the possibilities for empathic woman centeredness longer consultation times and opportunities to be heard; all of which have been indicated by perinatal populations experiencing depression to increase the likelihood of engagement with treatment.34 A number of women also indicated that acupuncture had provided them with hope, as it had facilitated for them an unexpected way out of the severity of their antenatal depression and anxiety. Whilst the therapeutic impact that hope can provide is difficult to quantify, the placebo like benefits that are recognised as important components in symptom relief and recovery from medical conditions.66

Whilst some of the participants had reported positive experiences with psychological approaches and/or the need for medication, all concluded that they had no real option for any of the therapies tried and/or of limited additional value, either due to insufficient effect despite utilisation, or the belief that they could no longer benefit. Views such as these, as well as those indicative of a much stronger dissatisfaction with conventional options have likewise been reported to influence future treatment decisions29,35 and invariably contribute to why less than 30% of perinatal women experiencing depression at mental or significant mental health outcomes under 6% complete conventional treatment courses36 and no more than 50% complete help.37 This lack of engagement with conventional approaches, as well as the increasing interest in complementary medical therapies and the public desire for more personalised treatments, indicates the need for a more comprehensive understanding of the benefits and disadvantages of different treatments in perinatal women with depression, as well as the potential role of acupuncture in the face of the growing need for treatment options with safety and efficacy.

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provide such a possibility, as it is a therapy that aligns with the ideals of many, for non-toxic wholistic approaches to health care. That also when correctly administered is safe and promisingly effective for the improvement of depressive symptomology and overall wellbeing.

4.1 Strengths and limitations

The strength of this qualitative study is that by providing assurances of anonymity as well as having interviews undertaken by an independent non-acupuncturist researcher, that the feedback provided was likely to be more honest, and in addition, that potential biases during the interview process were minimized. It is also reassuring that views expressed closely reflect findings previously reported in other populations affected by depression.

There are however also some limitations, for example, the number of women interviewed for this study was small, and even though saturation of emergent themes did occur, the self-selection process of volunteering in the clinical trial may have resulted in views being expressed that are non-representative of large populations of people and as such provide limited insights for what might inform practice both within Australia and overseas. In addition, the majority of the interviewees were Australian born Caucasian women, hence their opinions may not necessarily reflect those of pregnant women experiencing depression from different cultural backgrounds. However, this sample was representative of a demographic in Australia that typically seeks out acupuncture.

Other potential sources of bias arising from the acupuncturist also being the principle researcher may additionally remain, despite the incorporation of the process of reflexivity, as well as monitoring of data interpretation and analysis by co-authors (HI) and (CS).

5. Conclusion

This study provides supportive evidence that acupuncture may be a suitable additional treatment option for women inadequately managed by or unable to pursue conventional options during the antenatal period. Consequently, acupuncture may play a valuable role in a much-needed narrowing of the current treatment gap. Further research investigating acupuncture effectiveness for mental health concerns during pregnancy, as well as the acceptability of this option for a larger population of women experiencing depression during the perinatal period is however recommended.

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Conflicts of interest

(SO) is currently practicing as an acupuncturist in private practice. (SO) and (CS) are part of NICM. As a medical research institute, NICM receives research grants and donations from foundations, universities, government agencies, individuals, and industry. Studies are undertaken with the aim to advance the vision and mission of the Institute. The project that is the subject of this article was not undertaken as part of a contractual relationship with any organisation, other than the funding declared in the 'Funding' section. It should also be noted that NICM conducts clinical trials relevant to this topic area, for which further details can be provided on request. (HI) declare no competing interests.

Ethical statement

1. Approval was sought from South Western Sydney Local Health District as an amendment to the main RCT study.
2. The approval number was SWLH18/HREC/14/DPLD/1/400.
3. Approval for this amendment was gained on 8th October 2018.

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References


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34. Berger R. Now I see it, now I don’t: researcher’s position and reflexivity in qualitative research. Qual Res 2010;10(2):219-34.