The effectiveness of acupuncture in the treatment of primary dysmenorrhea: A mixed methods study

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Dedication

This thesis is dedicated to three very special people who have shaped my life and put my feet upon the path that has ended up here.

My father, Graeme Armour, who passed away before I was ever an acupuncturist, my mother Patsy Armour, who has always showered me with love and supported my academic endeavors, no matter how left field, and most recently my wife, Susanne, whose period pain inspired me to start looking for alternatives to the medication which never really worked for her.
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No thesis is the product of one person. Without the love, support and understanding of others, I would never have been able to finish this study.

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Lastly, but definitely not least, the wonderful woman in my life who has put up with me sitting glued to a computer for days and days at a time, mumbling about menstruation, my wonderful, understanding and thoughtful wife Susanne. I honestly couldn’t have done it without you.
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.

Michael Armour

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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>CAM</td>
<td>Complementary and alternative medicine</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<td>CMSS</td>
<td>Cox menstrual symptom score</td>
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<td>COC</td>
<td>Combined oral contraceptive</td>
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<td>DDX</td>
<td>Differential diagnosis</td>
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<td>FSH</td>
<td>Follicle stimulating hormone</td>
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<td>HLoC</td>
<td>Health locus of control</td>
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<td>LH</td>
<td>Luteinising hormone</td>
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<tr>
<td>MMR</td>
<td>Mixed methods research</td>
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<tr>
<td>MPQ</td>
<td>McGill pain questionnaire</td>
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<tr>
<td>NRS</td>
<td>Numeric rating scale</td>
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<td>NSAID</td>
<td>Non-steroidal anti-inflammatory</td>
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<tr>
<td>OCP</td>
<td>Oral contraceptive pill</td>
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<tr>
<td>OR</td>
<td>Odds ratio</td>
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<tr>
<td>OTC</td>
<td>Over the counter</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>SF-36</td>
<td>Short form (36) health survey</td>
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<tr>
<td>TCM</td>
<td>Traditional Chinese medicine</td>
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<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
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<tr>
<td>VRS</td>
<td>Verbal rating scale</td>
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Abstract

Primary dysmenorrhea is the most common gynaecological complaint amongst adolescents. It affects up to three quarters of women at some stage of their reproductive life. Primary dysmenorrhea is also responsible for a significant number of days absent from work or school each month. Women often do not seek medical attention for primary dysmenorrhea and instead use self-care to manage their symptoms. If they do consult a medical practitioner, women are usually advised to take non-steroidal anti-inflammatory (NSAIDs) medication or go on the oral contraceptive pill (COC), however, for at least a quarter of all women there is a lack of efficacy with these medications. Traditional Chinese medicine (TCM) acupuncture has shown promise in the treatment of primary dysmenorrhea, however, several important questions remain. The overarching aim of this thesis is to examine the treatment of primary dysmenorrhea in contemporary clinical acupuncture practice, and examine the therapeutic effects of acupuncture treatment on the symptoms of primary dysmenorrhea.

A mixed methods research (MMR) approach was used to undertake four studies. Quantitative methods were used for an online and postal practitioner survey examining how gynaecological conditions were treated in contemporary clinical practice and a randomised controlled trial (RCT) examining the effect of timing and mode of stimulation of acupuncture on primary dysmenorrhea. Qualitative methods, using thematic analysis, were used for practitioners in the form of semi-structured interviews and focus groups discussing treatment of primary dysmenorrhea in the community, and for trial participants in the form of semi-structured interviews examining their experiences as part of the RCT. NIVO was used to manage and code these datasets. These methods were used to answer five research questions.

The first research question examined how acupuncture treatment for primary dysmenorrhea was delivered in clinical practice in New Zealand and Australia. The survey of 377 New Zealand and Australian acupuncture practitioners found
use of a variety of methods when treating primary dysmenorrhea in clinical practice, with diet and lifestyle advice being rated by practitioners as an important adjunct to acupuncture and moxibustion itself.

The second research question explored what components of the acupuncture treatment do practitioners and patients consider important for successful treatment? Analysis of data from two focus groups and semi-structured interviews of nine practitioners and 12 study participants found both practitioners and study participants strongly valued the partnership that occurred, characterised by trust, support and shared decision making. Both moxibustion and self-care advice were recommended by practitioners and participants commented on the therapeutic benefits they received from these co-interventions.

The third study question examined the effect of changing the timing of treatment or the mode of acupuncture stimulation on pain and quality of life for women with primary dysmenorrhea. A pilot randomised controlled trial of 74 women with primary dysmenorrhea was performed with four groups: 1) low frequency manual acupuncture (LF–MA), 2) high frequency manual acupuncture (HF–MA), 3) low frequency electro-acupuncture (LF–EA) and 4) high frequency electro-acupuncture (HF–EA). Participants were randomly assigned to one of the four groups (LF–MA n=19, HF–MA n=18, LF–EA n=18, HF–EA n=19). Twelve treatments were performed over three menstrual cycles, either once per week (LF groups), or three times in the week prior to menses (HF groups). All groups received a treatment in the first 48 hours of menses. Primary outcomes found the reduction in peak and average menstrual pain measured via numeric rating scale at one, two, three and four months from trial entry. At four months post-trial entry all groups showed statistically (p<.001) and clinically significant reductions in peak and average menstrual pain. Manual acupuncture showed a greater reduction in the worst menstrual pain scores compared to electro-acupuncture (p=0.047). Duration of pain decreased by over 40% in all groups and analgesic usage was significantly reduced in both the
manual acupuncture groups compared with electro-acupuncture (p=0.005). Health related quality of life, as measured by the SF-36, increased in all groups at four months from trial entry.

The fourth research question explored women’s perception of primary dysmenorrhea and what constitutes a normal menstrual cycle following their completion of the acupuncture intervention. Participants in the study felt that TCM provided an alternative way of looking at their menstrual cycle and changed their perception of what they felt was a normal period, and no longer feeling that period pain was an inevitable part of their menstrual cycle.

The final research question was, what role does self-care advice play in the treatment of primary dysmenorrhea, do patients follow that advice and what value do they assign to it? Analysis of data from semi-structured interviews of 12 study participants found that women in the study usually followed the TCM self-care advice given and often felt it was responsible for positive changes in their menstrual symptoms. Interview participants commented that TCM self-care advice empowered them to take more control over their own health.

In conclusion, TCM acupuncture, irrespective of treatment timing, provided significant clinical benefits for women with primary dysmenorrhea, with reductions in pain severity, duration, secondary menstrual symptoms and analgesic intake. Both practitioners and participants felt that acupuncture treatment consisted of “more than needles”, with the partnership between patient and practitioner of vital importance in engendering trust and providing support. TCM Self-care advice appears to increase enablement, possibly via increasing women’s health locus of control and should be considered a characteristic component of TCM acupuncture treatment.
Chapter One: Introduction and background

This chapter outlines the context of the study.

Dysmenorrhea, particularly primary dysmenorrhea, is a common problem, especially amongst younger women. The societal impact of this condition is significant, academically and economically. Dysmenorrhea also reduces quality of life and has significant psychological comorbidities.

In this chapter, a range of effective treatments will be discussed, however, not all women receive relief or take advantage of these. This chapter will also examine the prevalence of complementary and alternative medicine (CAM) therapies and remedies for dysmenorrhea, and the possible role of acupuncture in treating women’s health. The final section of this chapter outlines the rationale and significance of the study, and the structure of this thesis.

1.1 Dysmenorrhea

Dysmenorrhea can be described as painful uterine cramps of menstrual origin (Proctor & Farquhar 2006) and is classified as primary or secondary dysmenorrhea. The focus of this research is on primary dysmenorrhea, the most common form of period pain in young women (French 2008), and the most frequently under-reported cause of period pain (Jamieson & Steege 1996).

Primary dysmenorrhea is defined as pain in the absence of any organic cause and is most common in women under the age of 25, with pain starting within three years of menarche (Coco 1999; Wong et al. 2009). Primary dysmenorrhea’s characteristic symptom is crampy, colicky spasms of pain in the suprapubic area, occurring within 8–72 hours of menstruation and peaking within the first few days as menstrual flow increases (Bettendorf, Shay & Tu 2008; Coco 1999; Proctor & Farquhar 2006). In addition to painful cramps,
many women with primary dysmenorrhea experience other menstrual-related symptoms, including back and thigh pain, headaches, diarrhoea, nausea and vomiting (Proctor & Farquhar 2006).

Primary dysmenorrhea can usually be diagnosed by means of a thorough history taking, as well as abdominal or pelvic examination. This applies to most patients who have typical symptoms and no risk factors for secondary causes (Coco 1999; French 2008).

1.2 Prevalence of primary dysmenorrhea

Studies describing the prevalence of primary dysmenorrhea report wide ranges of rates. A recent review of high-quality studies found prevalence rates to range from 16.8–81% (Latthe et al. 2006a). In a review of younger women under 20 years of age, higher prevalence rates of 43–91% were found (Zahradnik, Hanjalic-Beck & Groth 2010).

These wide-ranging rates are most likely explained by the varying criteria used to assess dysmenorrhea between surveys, and the descriptions used to classify the severity of pain (Gagua, Tkeshelashvili & Gagua 2012; Jamieson & Steege 1996). No set definition for the severity of dysmenorrhea exists, however, clinicians tend to use a scale of mild, moderate or severe depending on how daily living is impacted (Neinstein 2007). In addition, the demographics of the sample itself exert a significant influence on measurement of rates, with younger, adolescent females experiencing more severe and frequent dysmenorrhea than women over 20, and the risk and severity of pain decreasing as women continue to age (Burnett et al. 2005; Tavallaee et al. 2011; Zahradnik, Hanjalic-Beck & Groth 2010).

Cultural and social factors are likely to influence the prevalence and reporting of dysmenorrhea (Harlow & Campbell 2004; Ortiz et al. 2009). There is variance in the prevalence of dysmenorrhea reported in surveys between different cultural
groups, even when geographical locations are similar (Ortiz et al. 2009; Wong & Khoo 2010). It is currently unclear if different rates of prevalence are due to biological or cultural factors. The difference in prevalence may be due, at least in part, to the presence of a “culture of silence” around menstrual issues in some traditional cultures. There is evidence of this with women under-reporting primary dysmenorrhea in surveys, but showing similar rates across cultures in physicians’ consultations (Harlow & Campbell 2004).

1.2.1 Factors influencing the prevalence of primary dysmenorrhea

Very few protective and risk factors have been found to be consistent across surveys of different populations. These protective and risk factors appear to be population dependent and linked to the socio-cultural background of the participants surveyed (Banikarim, Chacko & Kelder 2000). Therefore different cultural contexts may raise or lower the threshold for what is considered, by women or society, as “period pain”, and in turn predictive factors may be exposed or concealed in different populations.

Due to the conflicting results from survey data between populations, Latthe and colleagues (2006) performed a systematic review and meta-analysis on predictive / risk and protective factors in pelvic pain (Latthe et al. 2006b). The authors found in the 63 studies that evaluated risk factors for dysmenorrhea that the following were predictive or risk factors for dysmenorrhea: age <30, low body mass index (BMI), smoking, onset of menarche <12 years of age, longer cycle, heavier menstrual flow, nulliparity, premenstrual syndrome, sterilization, suspected pelvic inflammatory disease, sexual abuse and psychological symptoms.

Protective factors were found to be childbirth at a younger age, exercise and combined oral contraceptive pill (the COC pill) usage. Ju and colleagues (2014) in their review found similar results with age, parity and COC pill usage being
protective factors while stress and family history were found to be risk factors (Ju, Jones & Mishra 2014).

1.3 Physiological basis of primary dysmenorrhea

The largest contributing physiological factor in primary dysmenorrhea is increased amounts of prostaglandins present in the menstrual fluid (Dawood 2006). If there is no pregnancy after ovulation, progesterone levels decline in the late luteal phase of the cycle. Reduction in progesterone levels destabilises cell membranes in endometrial tissue and causes the hydrolysis of cell membrane phospholipids (mainly Omega-6) to form arachadonic acid. Arachadonic acid is converted via the cyclooxygenase pathway to prostaglandins $\text{PGE}_2$ and $\text{PGF}_{2\alpha}$ (Dawood 2006; Morrow & Naumburg 2009; Zahradnik, Hanjalic-Beck & Groth 2010).

Figure 1.1: Proposed pathophysiology of dysmenorrhea.

From (Harel 2008).

These excess prostaglandins are released when the endometrial lining breaks down during menses. Prostaglandins, especially $\text{PGF}_{2\alpha}$, stimulate myometrial contractions, reducing uterine blood flow and causing uterine hypoxia. This is responsible for the painful cramping that characterises primary dysmenorrhea (Dawood 2006; Zahradnik, Hanjalic-Beck & Groth 2010). Prostaglandins also
sensitise pain receptors directly (Buster 1986), which lowers the pain threshold, causing a higher perceived pain from the myometrial contractions. In comparison to eumenorrheic women (women with a normal menstrual cycle), women with dysmenorrhea have double the amount of PGF$_{2\alpha}$ in the menstrual fluid (Chan & Hill 1978). Similarly, levels of PGF$_{2\alpha}$ in the endometrium of women with dysmenorrhea are four times higher than eumenorrheic women on the first day of menses (Lundstrom & Green 1978), when pain from dysmenorrhea is usually the most severe (Harel 2008).

In most, but not all women with primary dysmenorrhea, there is a temporal correlation between the severity of dysmenorrhea and the amount of prostaglandins in the menstrual fluid (Dawood 2006; Weissman et al. 2004). This continuously changing level of prostaglandin in the menstrual fluid is responsible for the intermittent, cyclic nature of the pain in primary dysmenorrhea (Dawood 1981). Blocking prostaglandin production via medication leads to lower levels of prostaglandins in menstrual fluid and clinically significant reductions in symptoms (Chan, Fuchs & Powell 1983).

Secondary symptoms associated with primary dysmenorrhea, such as headache, nausea and vomiting, are due to prostaglandins and their metabolites entering general circulation (Howard et al. 2000) and are similar to those side effects seen in women who have induction of labour via prostaglandin gel (Dawood 2006).

Prostaglandins are implicated as the primary cause for the pain and secondary symptoms of primary dysmenorrhea, however it is possible that multiple pathways are involved. The role of other components in the pathway, outlined in Figure 1.1 above, are less well investigated. Prostacyclin (PGI$_2$), a uterine relaxant, appears to be reduced in women with primary dysmenorrhea (Wilhelmsson et al. 1983). This may explain why some women with normal levels of PGF$_{2\alpha}$ still suffer from dysmenorrhea, since lower levels of PGI$_2$ enhance the contractile activity of PGF$_{2\alpha}$. Leukotriene levels are elevated in
women with primary dysmenorrhea, compared with eumenorrheic women (Rees et al. 1987) and increased levels of leukotrienes have been correlated with increased severity of dysmenorrhea (Nigam et al. 1991). It is therefore likely that they contribute at least some component to increased uterine contractility (Dawood 2006). However, usage of a leukotriene receptor antagonist does not reduce dysmenorrhea symptoms in adolescents compared to placebo (Harel et al. 2004).

Doppler ultrasound scans show that women with dysmenorrhea have reduced perfusion of the small uterine arteries, not only during menstruation but also throughout the luteal and follicular phases as well (Dmitrović 2000). This alteration in perfusion of uterine arteries also appears to be cyclical, with the reduction in blood flow most pronounced at night, and corresponding to an increase in self-reported pain (Celik et al. 2009). Changes in perfusion of the small arteries may be related to the actions of a number of reproductive hormones, including vasopressin and oxytocin, which act as potent vasoconstrictors that have the most pronounced effect on these small arteries (Akerlund 1994). These reproductive hormone levels appear to be different in women with dysmenorrhea compared with eumenorrheic women, suggesting a potential contribution towards the pathogenesis of primary dysmenorrhea (Liedman et al. 2008).

Vasopressin is considered a possible factor in primary dysmenorrhea, due to its stimulating effect on uterine contractility and subsequent ischemic pain, due to constriction of uterine arteries (Chen et al. 1999). It is unclear the extent to which circulating vasopressin levels change in women with dysmenorrhea and its contribution to overall pathology. Ekstrom and colleagues found that in women taking the COC pill, vasopressin levels, and subsequently dysmenorrheic pain, were reduced. This effect seemed to be independent of any changes in PGF$_{2\alpha}$ levels (Ekström et al. 1992). In contrast, Valentin and colleagues found that plasma concentrations of vasopressin were similar in dysmenorrheic and
eumenorrheic women, and the use of a vasopressin antagonist did not alter dysmenorrhea symptoms (Valentin et al. 2000).

Low levels of nitric oxide (NO) have also been implicated in the pathogenesis of primary dysmenorrhea via an increase in lipid peroxidation and oxidative stress (Dikensoy et al. 2008; Sun et al. 2005), however, it is currently unclear how much of a role this plays in the symptoms of primary dysmenorrhea (Harel 2008).

Stress may affect primary dysmenorrhea via two mechanisms. Firstly, an increase in stress levels causes a decrease in release of follicle stimulating hormone (FSH) and luteinising hormone (LH), decreasing progesterone levels in the luteal phase and subsequently increasing prostaglandin production (Chatterton 1990). Secondly, cortisol and adrenaline levels are increased during periods of stress mediated via an increase in adrenocorticotropic hormone (ACTH) (Wadhwa et al. 1996). Both increased cortisol (Casey, MacDonald & Mitchell 1985) and increased adrenaline (Wadhwa et al. 1996) affect prostaglandin synthesis.

Figure 1.2 summarises the possibly contributing psychological and physiological factors in primary dysmenorrhea.

In addition to changes during menses, experimental data suggests the effects of dysmenorrhea persist after the menstrual period itself and involve central pain processing changes. Vincent and colleagues (2011) studied brain activation in women with dysmenorrhea and found that there was suppression of the hypothalomo-pituitary axis (HPA) and alterations in processing of noxious stimuli (Vincent et al. 2011). Brinkert and colleagues (2007) found similar increases in hyperalgesia and hypersensitivity of the colon in women with dysmenorrhea who did not have a history of gastrointestinal symptoms (Brinkert et al. 2007). These centrally related changes in pain processing, and hypersensitivity of unrelated viscera, are similar to those seen in other chronic pain conditions. These central changes, along with the plasticity of the nervous
Dysmenorrhea is comorbid with a number of idiopathic pain disorders, such as fibromyalgia (Yunus, Masi & Aldag 1989) and irritable bowel syndrome (Jamieson & Steege 1996). Bettendorf and colleagues (2008) in their recent review conclude, “in some women dysmenorrhea may reflect not just peripheral uterine inflammation, but also changes in general pain sensitivity and individual
perception of pain.” This may explain the comorbidity of primary dysmenorrhea and other idiopathic pain disorders (Bettendorf, Shay & Tu 2008).

1.4 The impact of primary dysmenorrhea

Primary dysmenorrhea is responsible for a decrease in quality of life (Burnett et al. 2005; Campbell & McGrath 1997; Hillen et al. 1999), absenteeism from work or school (Zahradnik, Hanjalic-Beck & Groth 2010), reduced participation in sport and social activities (Banikarim, Chacko & Kelder 2000), altered pain perception (Bettendorf, Shay & Tu 2008) and problems sleeping (Baker et al. 1999). Despite this, women under-report dysmenorrhea during medical consultations (Jamieson & Steege, 1996; Sundell, Milsom, & Andersch, 1990).

Population surveys show that most adolescents believe that period pain is a normal part of the menstrual cycle (Banikarim, Chacko & Kelder 2000; O’Connell, Davis & Westhoff 2006; Wong 2011), and to manage their pain they self-medicate with common over the counter (OTC) pain medications, along with rest and heat, rather than seek medical advice (Banikarim, Chacko & Kelder 2000; Campbell & McGrath 1997; Chang & Chuang 2012; Chia et al. 2013; Hillen et al. 1999; Johnson 1988; Klein & Litt 1981; Ortiz et al. 2007; Ortiz et al. 2009; Wong & Khoo 2010; Wong 2011). When adolescents self-medicate, they often choose sub-therapeutic doses, giving suboptimal pain relief (Campbell & McGrath 1997; O’Connell, Davis & Westhoff 2006). This is a concern as inadequately treated primary dysmenorrhea causes an increase in absenteeism from work or school and influences academic performance (Banikarim, Chacko & Kelder 2000).

Menstrual pain and related distress can cause changes in social or working function, as well as influence long-term changes in social roles, which impacts on quality of life. In school age and working women across a wide spectrum of social and cultural groups, this causes educational and work absence respectively (Banikarim, Chacko & Kelder 2000; Burnett et al. 2005; Hillen et al.
In the USA primary dysmenorrhea is the leading cause of school absenteeism (Davis & Westhoff 2001). A recent review estimates the loss of at least one day per month from work or study by 10–30% of women in the USA (Zahradnik, Hanjalic-Beck & Groth 2010), while longitudinal data from Sweden shows that 5–14% of women were frequently absent due to dysmenorrhea (Andersch & Milsom 1982).

Primary dysmenorrhea does not only cause absenteeism. When women are present at school it can affect classroom concentration, test-taking skills and overall grades (Banikarim, Chacko & Kelder 2000). Survey data shows that 45% of Australian adolescents (Hillen et al. 1999), 59% of Hispanic adolescents (Banikarim, Chacko & Kelder 2000) and 47% of Italian university students (Grandi et al. 2012) have had academic or classroom performance affected, due to dysmenorrhea. Hillen and colleagues succinctly sum up the possible impact of these academic restrictions: “School attendance and ability to concentrate on studies in Grades 11 and 12 are vital, as achievement in these high school years has significant long-term consequences for an individual.” (Hillen et al. 1999)

1.5 Current biomedical interventions for the management of primary dysmenorrhea

Consensus guidelines (Lefebvre et al. 2005) and reviews of the evidence (Coco 1999; Dawood 2006; Harel 2008; Marjoribanks et al. 2010; Proctor & Farquhar 2006) suggest that non-steroidal anti-inflammatory medications (NSAIDs) are an effective first line treatment for primary dysmenorrhea. NSAIDs reduce pain in dysmenorrhea via two mechanisms, direct reduction of prostaglandin synthesis via inhibition of cyclooxygenase (COX-1 and COX-2) and a direct central pain-killing effect (Dawood 2006).
Common NSAIDs, such as ibuprofen, naproxen and aspirin, are all superior to placebo for pain relief in primary dysmenorrhea (odds ratio [OR] 4.14, 95% confidence interval [CI] 3.52 to 4.86), however, it is unclear if any one of these medications was superior to the others, due to small sample sizes of randomised controlled trials (Marjoribanks et al. 2010). Paracetamol, a common OTC medication used by many women, does not appear to be any more effective than a placebo (Zhang & Li Wan Po 1998) and significantly less effective than NSAIDs (OR for NSAID 1.90, 95% CI 1.05 to 3.44) (Marjoribanks et al. 2010). More than half of women will have satisfactory levels of pain relief using NSAIDs (Marjoribanks et al. 2010).

However, adverse effects are associated with use of NSAIDs, and are significant when compared to placebo (OR 1.37, 95% CI 1.12 to 1.66). These include nausea, epigastric pain, indigestion, drowsiness, headache, dizziness and dryness of the mouth (Griffin 1998; Marjoribanks et al. 2010). Naproxen is most likely to cause both gastrointestinal (OR 2.30, 95% CI 1.02 to 5.19) and neurological (OR 2.20, 95% CI 1.11 to 4.35) adverse events. Monthly ingestion also raises other concerns about long-term effects of such medications, including increased risk of cardiovascular events (Roumie et al. 2009; Shi & Klotz 2008; Trelle et al. 2011). Unless contraindicated due to hypersensitivity or risk factors for gastrointestinal complications, NSAIDs are considered to be the first choice in the treatment of primary dysmenorrhea (Proctor & Farquhar 2006).

The COC pill is a common second line of treatment for primary dysmenorrhea (Proctor & Farquhar 2006; Zahradnik, Hanjalic-Beck & Groth 2010), though it may be used as a first line treatment when long-term contraception is required (Wong et al. 2009). The COC pill’s primary mechanism for reducing the symptoms of primary dysmenorrhea is via the direct reduction in thickness of the uterine lining, by suppression of ovulation (Wong et al. 2009). A reduction in thickness of the lining causes less tissue to be available for prostaglandin production and therefore less prostaglandins in the menstrual fluid (Chan &
Surveys examining menstrual health amongst women have shown an inverse relationship between contraceptive usage and self-reported period pain (Grandi et al. 2012; Latthe et al. 2006b; Santer, Warner & Wyke 2005). A recent Cochrane review of the COC pill with both medium- and low-dose estrogen showed a significant reduction in pain (OR 2.99, 95% CI 1.76 to 5.07) compared to a placebo. However, the authors concluded ‘oral contraceptives are widely advocated as standard treatment for women with primary dysmenorrhea yet this review has found only scant rigorous clinical evidence to support this practice’ (Wong et al. 2009).

Common side-effects of the COC pill in the general population are nausea, vomiting, headaches, weight gain, breast tenderness, increased hair growth and depression. These side-effects occur in over 50% of women, but often disappear after several months (Bagshaw 1995). The most recent Cochrane review showed no difference between placebo and the COC pill in terms of adverse events when treating dysmenorrhea (OR 1.45, 95% CI 0.71 to 2.94) (Wong et al. 2009). Women with dysmenorrhea experience symptoms identical to the COC pill adverse events, therefore it is unclear if these are simply effects from underlying pathology (O’Connell, Davis & Kerns 2007) or possibly due to adverse effects from the COC pill (Hendrix & Alexander 2002; O’Connell, Davis & Kerns 2007).

Other pharmacological approaches used for dysmenorrhea include COX-2 inhibitors, glycerol trinitrate, and nifedipine. However, these are not commonly used, either due to concerns over safety (in the case of COX-2) or the high incidence of unpleasant adverse events (Dawood 2006).

While NSAIDs and the COC pill are effective for many women, approximately 25% of women have pain that is refractory to either of these standard treatments (Dawood 1990; Howard et al. 2000). In addition to the 25% of women that do not achieve relief with standard treatment, cultural differences also affect the usage of analgesics and the oral contraceptive pill, with Chinese
women using significantly less NSAIDs or the oral contraceptive to control their menstrual pain than Australian women (Zhu et al. 2010). Therefore, with the current mainstream treatment selection, there are several groups who may not be getting satisfactory levels of pain relief, namely women who:

- are resistant to NSAID treatment and do not desire contraception,
- are sensitive to NSAID treatment or have risk factors which prevent NSAID usage and do not desire contraception,
- are resistant to both NSAID and COC treatment,
- have risk factors contraindicating COC treatment,
- wish to avoid or limit pharmaceutical intake for personal, cultural, health or religious reasons.

Lack of satisfactory pain relief and effective medical interventions in primary dysmenorrhea leads to an uptake of self-care strategies by women (MacKichan et al. 2011). Complementary medicine usage is often a significant component of self-care (MacKichan et al. 2011; Ryan et al. 2009). Many women already use various forms of complementary medicine to manage their menstrual pain in addition to, or instead of, pharmaceutical pain relief, due to a lack of perceived effectiveness (Chang & Chuang 2012; Chia et al. 2013; MacKichan et al. 2011) or a dislike of using analgesic medication (Chen et al. 2006).

1.6 Complementary and alternative medicine (CAM) interventions for primary dysmenorrhea

1.6.1 Prevalence of CAM in New Zealand and Australia

Rates of CAM usage reported in surveys can vary significantly, based on the definition of CAM used. Recent discussion around moving towards an operational rather than theoretical definition of CAM (Wieland, Manheimer & Berman 2011) is important to be able to reliably compare CAM usage between
populations as what may be considered CAM in some populations may be considered part of mainstream medical practice in others. For example while acupuncture is considered CAM in Australia, in China it is often considered part of the mainstream medical system (Birch & Felt 1999) and practiced in the hospital system (Robinson et al. 2012).

CAM usage amongst Australian women is high, with 44% having consulted a CAM practitioner in the previous 12 months, while 90% of women had used some form of self-prescribed CAM in the previous 12 months (Adams et al. 2011). No similar nor recent gender-specific community data is available for New Zealand, but a cross-sectional survey of almost 13,000 New Zealanders in 2002/2003 reported 23% of those sampled had used a form of CAM therapy in the previous 12 months (Pledger, Cumming & Burnette 2010). New Zealand surveys undertaken in a clinical setting have found that between 38%–56% of patients presenting to emergency departments have used a CAM remedy or CAM therapy in their lifetime (Nicholson 2006; Yates, Armour & Pena 2009). Given the age of this data, it is probable that usage rates have increased to a similar level as Australia.

1.6.2 Predictive factors for CAM usage

Strong predictive factors for CAM usage in New Zealand and Australia have been identified as being female, <65 years old, well-educated and with chronic, unresolved health problems (MacLennan, Wilson & Taylor 1996; Pledger, Cumming & Burnette 2010; Shorofi 2011; Thomson et al. 2012; Xue et al. 2007; Yates, Armour & Pena 2009). There is some evidence that rural women in Australia have slightly higher CAM usage than those in urban areas, however, the reasoning for this is still unclear (Adams et al. 2011; Adams, Sibbritt & Lui 2011).

While different types of CAM therapy are considered varyingly important in different countries, the key demographics of the CAM user are predominantly
well-educated, affluent females, and those <65 years, with supporting data from other countries, including the UK (Ryan et al. 2009), Canada (Millar 1997), USA (Barnes, Bloom & Nahin 2008; Eisenberg et al. 1998; Ernst 2000; Gray et al. 2002) and Ireland (Chang et al. 2011).

1.6.3 CAM usage in primary dysmenorrhea

Primary dysmenorrhea is a chronic health condition that is often managed with self-care. Women with primary dysmenorrhea are likely to use CAM therapies in their self-care. Most surveys of women with primary dysmenorrhea do not include questions regarding CAM usage, however, those that do show that CAM usage is a part of women’s self-care. A variety of CAM modalities are used by women, including acupressure (Chen et al. 2006), aromatherapy (Chen et al. 2006), dietary supplements (Chia et al. 2013), herbal remedies (Banikarim, Chacko & Kelder 2000; Chen et al. 2006; Chia et al. 2013; Hillen et al. 1999; Wong & Khoo 2010) and self-massage (Wong & Khoo 2010). Many of these studies around CAM usage were undertaken over 10 years ago. Given the upward trend in CAM usage were undertaken over 10 years ago. Given the upward trend in CAM usage (Horneber et al. 2011), it is likely that CAM usage among this group of women has also increased.

Research to evaluate the efficacy and effectiveness of CAM therapies in the treatment of primary dysmenorrhea is relatively recent, however, there is growing evidence in the efficacy of CAM therapies in the treatment of primary dysmenorrhea. A review of 13 randomised controlled trials (RCTs) on CAM therapies/remedies undertaken in 2003 showed some evidence for a low-fat vegetarian diet, vitamin E supplementation, vitamin B1 supplementation, fish oil supplementation, Chinese herbal medicine, exercise, acupuncture and chiropractic (Fugh-Berman & Kronenberg 2003). The review author noted that most of the trials had small sample sizes, and that some of the results, especially that of vitamin B1, were implausibly large. A 2001 Cochrane review for herbal and dietary therapies found similar results, with magnesium showing promise in the treatment of primary dysmenorrhea, however, this was based on three
small studies (Proctor & Murphy 2001). There have also been reviews showing the positive effect of acupressure (Cho & Hwang 2010a), Chinese herbal medicine (Zhu et al. 2008), transcutaneous electrical nerve stimulation (TENS) (Proctor et al. 1996a) and behavioural interventions (Proctor et al. 1996c). There does not appear to be any evidence of effectiveness for spinal manipulation (Proctor et al. 1996b).

More recent studies have found that krill oil is also effective for menstrual pain and secondary symptoms (Sampalis et al. 2003). Both fish oil and krill oil have a plausible mechanism of action. Effectiveness in reducing period pain is most likely due to competition by omega-3 for the enzyme prostaglandin synthetase, with omega-3 fatty acids producing less potent versions of leukotrienes and prostaglandins than those of omega-6 (Hansen 1983).

Vitamin E supplementation may work via a similar mechanism, by reducing the formation of prostaglandin E2 (Panganamala & Cornwell 1982).

Fennel has also been shown to reduce the symptoms of primary dysmenorrhea; this may be related to its anti-spasmodic qualities reducing uterine cramping or due to increasing the rate of discharge of menstrual blood (Ghodsi & Asltoghiri 2014; Modaress Nejad & Asadipour 2006; Namavar Jahromi, Tartifizadeh & Khabnadideh 2003; Nasehi et al. 2013).

Ginger (Rahnama et al. 2012; Shirvani, Motahari-Tabari & Alipour 2014), valerian (Mirabi et al. 2011), rosa damascena (Bani et al. 2014) and fenugreek (Younesy et al. 2014) have all shown promise in the treatment of primary dysmenorrhea due to their anti-spasmodic or anti-inflammatory actions.

There are several recent studies evaluating the effect of yoga on primary dysmenorrhea, the positive effects of which are most likely modulated by a reduction in stress levels (Chien, Chang & Liu 2012; Rakhshaee 2011; Rani et al. 2013).
Aromatherapy self-massage, using topically applied oils, has also shown significant reductions in the symptoms of primary dysmenorrhea (Han et al. 2006; Marzouk, El-Nemer & Baraka 2013; Sadeghi Aval Shahr et al. 2014).

It appears that there is preliminary evidence of effectiveness for many of the remedies that women choose as part of their CAM self-care for primary dysmenorrhea, including aromatherapy, massage, acupressure and herbal remedies.

Therefore, given the chronic nature of primary dysmenorrhea and the poor symptom control that at least 25% of women have with current pharmacological treatments, along with the increasing use of CAM therapies and remedies, it is possible that many women with primary dysmenorrhea use or may have used complementary therapies to manage their symptoms.

1.7 Acupuncture: a promising CAM therapy for primary dysmenorrhea

Acupuncture is a component of traditional East Asian medicine, with various forms of acupuncture being present historically in Japan, China and Korea (Ma 1992; White & Ernst 2004). One of the most important works in the acupuncture canon, the Huang Di Nei Jing (The Yellow Emporers Classic of Medicine) was written between the 5th to 1st centuries BCE; this was the first text to discard supernatural causes for ill health and to systematise many of the theories, such as meridians, that underlie acupuncture practice even to this day (Unschuld, Tessenow & Zheng 2011). Around 259 CE the Zhen Jiu Jia Yi Jing (A Classic of Acupuncture and Moxibustion) was published. This text was the first to include specific indications for gynaecological disorders and discussed their symptomology in a way that we can still identify with today (Ma 1992). By 9 CE acupuncture, along with diet, herbal medicine, moxibustion (heat) and tuina
(massage) was one of the major components of Traditional Chinese Medicine (TCM) (Ma 1992).

“Fuke”, translated as “gynaecology”, was a significant medical specialisation by the time of the Song dynasty (960-1279 CE), with new emphasis on the importance of blood in women and on regulating the menstrual cycle to prevent or cure disease (Furth 1998). Contemporary acupuncture practice is ‘richly heterogeneous’ with the theoretical base being constantly transformed and refined by clinical experience, and altered depending on the cultural milieu in which it is practiced (Schnyer, Birch & MacPherson 2007).

Acupuncture has become a popular CAM therapy for a variety of women’s health conditions in recent years, with a number of surveys and clinical trials being conducted on menstrual health, pregnancy and fertility related complaints (Cochrane et al. 2014; Smith & Carmady 2010; Smith, Bateson & Weisberg 2013). CAM use is relatively high in patients undergoing therapy for infertility in the UK (Coulson & Jenkins 2005), USA (Smith et al. 2010) and Australia (Stankiewicz et al. 2007), however, there is variation in the modalities used in different settings. Acupuncture is the most common CAM therapy used for infertility in the USA (Smith et al. 2010; Weiss, Harris & Smith 2011), while reflexology and acupuncture were most commonly used in the UK (Coulson & Jenkins 2005). Surveys of acupuncturists in the UK show that demand for fertility related treatment increased significantly between 2002–2009 (Hopton et al. 2012). This may have been influenced by the evidence base for acupuncture for infertility that began with a RCT published by Paulus and colleagues (Paulus et al. 2002).

Women also present to acupuncturists for a variety of pregnancy related conditions, including back pain, sciatica and nausea (Steel et al. 2012). European acupuncturists indicate that acupuncture shows significant promise in treating gynaecological conditions (Robinson et al. 2012) and patients present to acupuncturists in the community with gynaecological complaints (Hopton et al.
There are plausible physiological mechanisms that could explain practitioner’s usage of acupuncture to treat primary dysmenorrhea in clinical practice.

**Figure 1.3: TCM physiology of the menstrual cycle**

![Diagram of TCM physiology of the menstrual cycle](image)

### 1.7.1 TCM physiology of the menstrual cycle

TCM understanding of normal physiology needs to be described in terms of the fundamental components of Chinese medical theory; Yin and Yang, Organs (ZangFu), Channels (JingLuo) and Fundamental substances (Qi, Blood and Jing). Figure 1.3 outlines this relationship.

The beginning of the reproductive cycle (menarche) is described in the oldest extant TCM text; the ‘Simple Questions’ chapter of the Huang Di Nei Jing explains the beginnings of the menstrual cycle as follows:

“With two times seven, the heavenly gui arrives, the controlling vessel [ren mai] is passable and the great throughfare vessel [chong mai] abounds [with qi]. The
monthly affair moves down in due time and hence, [a woman] may have children” (Unschuld, Tessenow & Zheng)

The most important organ of menstruation is of course the Uterus (Bao Gong). As the classic text ‘Elementary Medicine’ cited in Maciocia (2011) explains ‘Men store Essence, women the Uterus and fetus...Women take Blood as their foundation’ (Maciocia 2011). The Uterus in TCM is viewed as one of the six “curious” or “extraordinary” organs named as such due to having a Zang form (hollow) but Fu function (continuous discharge) and are therefore both Zang and Fu, hence their designation as curious or extraordinary. The uterus itself has 2 specific channels associated with it, the Bao Mai that connects the Heart and the Uterus and the Bao Luo that connects the Kidneys and Uterus (Lyttleton 2004) thus the Uterus has the strongest links to these two specific organs. In addition the Uterus is connected to other zangfu related to gynecological function via 4 other extraordinary channels; the Chong Mai, Dai Mai, Du Mai and Ren Mai.

The uterus in TCM is defined in broader terms than its biomedical counterpart, incorporating the cervix, fallopian tubes and the ovaries as well as the uterus itself (Lyttleton 2004).

Apart from the uterus the three main organs associated with the female reproductive system are the Spleen, Liver and Kidney (Liang 2010) with some authors also emphasizing the role of the heart in addition to these (Maciocia 2011) while others demote the spleen and liver to secondary importance (Lyttleton 2004).

The Kidney is the most important “conventional” Zangfu in gynecology for several reasons. Firstly, the kidneys responsible (along with heart-yang) for the formation of “heavenly gui” from kidney yin (Fu 1992). Secondly the kidneys produce the fire of the life gate (Ming Men). This ministerial fire arises between
the two kidneys and is responsible for the warming of the uterus and the generation of kidney water.

The Liver is arguably the second most important conventional zang fu as it stores blood made by the Spleen and moves this blood to the uterus at the appropriate time for menstruation. The Liver Qi is very important with respect to this function as the Qi moves the blood. If the Liver Qi does not flow freely prior to the period this is a common cause of dysmenorrhea. The blood and Qi from the liver can be considered to be the Yin and Yang functions of the liver respectively. Therefore like most yin and yang functions they are interdependent and thus an issue with Liver Qi can affect Liver Blood and vice versa.

Finally the Spleen is responsible for the production of Qi and Blood from food and drink. The Liver is reliant on proper spleen functioning to provide Blood for storage and distribution to the Uterus.

The role of these organs in the normal menstrual cycle is as follows:

During the menstrual cycle itself (Day 1 – Day 5 approximately) Blood is moving which is made possible by the supply of Liver-Blood and the free flow of the Liver Qi. Any disruption to this free flow of Qi and Blood will manifest as changes in the menstrual flow (pain, scanty flow, spotting etc). After the menstrual phase is complete but prior to ovulation the Blood and Yin have been depleted due to the loss of Blood during the menses and the Chong Mai and Ren Mai are depleted due to supplying the now depleted Blood and Yin. During the mid cycle phase (from Day 14 (ovulation) to approximately Day 21) the Chong Mai and Ren mai are being refilled with Blood and Yin. From Day 21-Day 28 the Yang Qi rises and the Liver-Qi begins to mobilize in preparation for the period as this is necessary to begin the movement of Liver-Blood.
1.7.2 Pathophysiology of dysmenorrhea according to TCM

Four major factors are considered to contribute to the pathophysiology of primary dysmenorrhea according to TCM. Emotional strain, in the form of anger, stress, frustration or resentment is one of the most common aetiologies, causing stagnation of the Liver Qi which in turn often causes blood stagnation in the uterus. Another very common cause of dysmenorrhea is exposure to cold and dampness in the environment, especially during the years of puberty. Both cold and damp slow the flow of qi and blood and contribute to qi and blood stagnation. Overwork or chronic illness can also lead to dysmenorrhea by exhausting the qi and blood, which causes the Chong and Ren mai to become empty, and the lack of qi prevents free movement and causes stagnation and therefore pain. Finally any activities that damage the Kidney Qi, such as excessive sexual activity or repeated childbirth, can cause dysmenorrhea via a similar mechanism to overwork or chronic illness, once again causing stagnation and therefore pain. Therefore stagnation, whether mild or severe, underlies the pathophysiology of primary dysmenorrhea.

Once primary dysmenorrhea occurs it can be differentiated into a number of patterns, the most common presented in a number of English and Chinese texts are outlined in Appendix A1. These patterns inform multiple aspects of TCM acupuncture treatment. The importance of pattern differentiation is discussed in later sections.

1.7.3 Acupuncture treatment of primary dysmenorrhea: mechanisms of action

The exact mechanism of acupuncture to treat period pain is unclear. However, there has been extensive research into the mechanisms by which acupuncture may exert its pain-relieving effects, with current evidence suggesting that endogenous opioids, modulation of neurotransmitters (such as dopamine), and anti-inflammatory effects mediated via the hypothalamus–pituitary–adrenal
(HPA) axis may all play a role (Cabioglu & Surucu 2009; Napadow et al. 2008; Wang, Kain & White 2008).

Animal models suggest that needling regulates neuro-endocrine activities including levels of progesterone (Liu et al. 2009) and needling point SP6 has been shown to increase ovarian blood flow via a reflex response in rats (Stener-Victorin, Fujisawa & Kurosawa 2006). A similar reflex response increasing uterine blood flow via SP6 has been found in humans (Meiqing, Jiang & Lufen 2003; Stener-Victorin et al. 1996) and appears to be related to some of the analgesic benefits of acupuncture in primary dysmenorrhea (Ma et al. 2010; Yu et al. 2010). Prostaglandins, especially PGF$_{2a}$ have been implicated as the primary cause of symptoms in primary dysmenorrhea (Coco 1999; Dawood 1981). Shi and colleagues (2011) found that there was no reduction in prostaglandin levels after one session of electro-acupuncture (Shi et al. 2011), however, this was limited by a small sample size and the fact that only one treatment session was given. Lin and colleagues (2008) found that after three months of acupuncture treatment there was a reduction in PGF$_{2a}$ levels (Lin, Liu & Huang 2008). A recent meta-analysis, including Chinese language research, has shown that the effect of acupuncture on prostaglandins is still unclear due to poor trial methodology and small sample sizes (Xu et al. 2014b).

Smith and colleagues (2011) propose a descending pain modulation hypothesis, where pain relief in primary dysmenorrhea occurs via stimulation of acupuncture points that transmit signals via afferent pathways to the midbrain. This information is integrated and changes women’s perception of pain. This alteration in descending pain modulation changes the perceived pain intensity (Smith et al. 2011). Changes in brain function from acupuncture often occurs not only during, but also post-treatment (Napadow et al. 2008), which may explain why there are often delayed reductions in pain such as found in Smith and colleagues (2011) study. Given alterations in central pain processing that are present in primary dysmenorrhea (Brinkert et al. 2007; Vincent et al. 2011), acupuncture’s multi-modal action appears well suited to treat this condition.
Overall, current experimental data supports three possible, non-exclusive mechanisms for the observed long-term effects of acupuncture on primary dysmenorrhea:

1) Descending pain modulation,
2) An increase in uterine blood flow via ovarian sympathetic nerve reflex and,
3) A change in prostaglandin levels.

Because of the quick onset of the pain-relieving effect of acupuncture observed in some studies (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011), it is likely that the immediate analgesic effects observed are modulated, at least in part, by endogenous opioid release (Wang, Kain & White 2008). Endogenous opioid release is strongly activated by electro-acupuncture (Mayor 2013) and follows a similar time course to the pain reduction observed in studies using electro-acupuncture for primary dysmenorrhea (Liu et al. 2011; Liu et al. 2014), beginning within 10 minutes, peaking after 30–40 minutes, and then beginning to return towards baseline. The longer-term benefits found in many of the studies can be explained by one of more of the following: changes in pain perception, changes in uterine blood flow, and changes in prostaglandin levels. While mechanistic studies have shown promise in the treatment of primary dysmenorrhea, clinical studies are still unclear about the magnitude of the effect of acupuncture treatment. Recent, systematic reviews have found conflicting results (Cho & Hwang 2010b; Smith et al. 2011b) on the effectiveness of acupuncture for primary dysmenorrhea. These will be explored further in Chapter 2. The contradiction between research and clinical practice is common in the literature and is one of the current paradoxes of acupuncture research.

1.8 Paradoxes in the literature

A recent whitepaper by Langevin and colleagues (Langevin et al. 2011) outlined the current methodological issues regarding research into acupuncture.
Langevin and colleagues (2011) suggest that a shift away from repeating efficacy trials is necessary to resolve the current paradoxes underlying acupuncture research. The two paradoxes currently present in acupuncture literature are as follows:

1) Well-designed trials report that acupuncture is superior to usual care for a number of conditions (Cummings 2009; Molsberger et al. 2010; Witt et al. 2008), however, sham controlled trials tend to show little difference between verum and sham treatment (Cherkin et al. 2009; Smith et al. 2011). This is at odds with both TCM theory and clinical experience.

2) Animal and human experiments report that physiological effects vary as a result of needling parameters such as depth and stimulation, however, these effects do not appear to be significant in clinical trials.

Fønnebø and colleagues (2007) also observed that there is a significant “gap” between the clinical trials, showing little difference in efficacy and the widespread usage and patient-reported effectiveness of these therapies (Fønnebø et al. 2007). It appears that the outcomes of RCTs on acupuncture are at odds with the experiences of the patients who use it (Gould & MacPherson 2001; Kaptchuk 2001; Rugg et al. 2011). Patients themselves are not driven by evidence of efficacy as much as they are by recommendations from friends and family (Bishop et al. 2011; Verhoef et al. 2007), however, we can reasonably assume that these recommendations come from a background of positive experience with that particular modality. Therefore if, as Fønnebø (2007) suggests, patients are not “completely misguided,” we need to structure our research in such a way as to bridge the “gap” between the clinical experience of patients and the evidence produced by research. A suggested solution to bridging this gap involves understanding the inherent complexity of an acupuncture treatment delivered in clinical practice.
1.9 Complex interventions

The Medical Research Council (MRC) defines complex interventions as “built up from a number of components, which may act both independently and interdependently” (Campbell et al. 2000), often with a high degree of flexibility and tailoring of the intervention (Craig et al. 2008). A simplified “rule of thumb” is that most non-pharmaceutical interventions are complex (Paterson et al. 2009). The concept of complex interventions acknowledges that it is often not a single, active component that can be manipulated in clinical trials. A recent definition of complex interventions moves beyond the idea of multiple mechanistic components working together, as in a mechanical watch, and is more accurately reflected by the complexity of an ecosystem, where the environment is in constant flux and changes are interdependent on numerous factors, both known and unknown (Cohn et al. 2013).

1.9.1 Acupuncture as a complex intervention: implications for trial design

Acupuncture, in common with many other CAM or non-pharmacological therapies, is a complex intervention (MacPherson & Schroer 2007; Paterson & Britten 2004; Paterson & Dieppe 2005; Schnyer et al. 2008). Inherent in the idea of complex interventions is the concept that a mixture of specific and non-specific mechanisms contribute to the action of the therapy.

A typical acupuncture consultation typically includes but is not limited to: history taking, self-care and lifestyle advice, TCM diagnosis and explanation, palpation of the pulse and other parts of the body, observation of the tongue, insertion and manipulation of needles, as well as common co-modalities, such as moxibustion and cupping (Langevin et al. 2011; MacPherson, Thorpe & Thomas 2006; Paterson & Britten 2004). The specific and non-specific components of an acupuncture treatment have been listed by one group of acupuncture researchers (Langevin et al. 2011) as:
• **Non-specific components**: Time, attention, credibility, expectation

• **Specific, non-needling components**: History, diagnosis, education, palpation, moxibustion

• **Needling components**: Location, insertion depth, stimulation, needle size and number

Further characterisation of the components of acupuncture and its effects have been described by Paterson and Dieppe (Paterson & Dieppe 2005). They describe the components of acupuncture treatment as characteristic (specific) and incidental (non-specific, placebo, context) effects. Characteristic factors are “therapeutic actions or strategies that are theoretically derived, unique to a specific treatment, and believed to be causally responsible for the outcome” (Paterson & Dieppe 2005, p. 1202). Components of the acupuncture treatment, such as history taking and diagnosis, are characteristic components of acupuncture treatment as they are based on the TCM framework, woven throughout the treatment and considered to have therapeutic effect (Paterson & Britten 2004; Paterson & Dieppe 2005). The belief that only the insertion of needles is considered to be causally responsible for the therapeutic effect underestimates the effect of the acupuncture treatment as a whole (Paterson & Dieppe 2005).

This simplification of acupuncture is a common criticism of acupuncture efficacy studies, as they are not representing acupuncture as practiced in the community (Kaptchuk, Chen & Song 2010). For this reason, there has been a recent emphasis amongst acupuncture researchers on shifting the focus to the use of effectiveness studies of whole systems (Langevin et al. 2011; Witt 2011). This change in focus is proposed until the mechanism(s) of action of acupuncture are better understood, and the subsequent development of a suitable placebo has been achieved. Therefore recommendations that the “whole system” is first understood and then examined as a whole, rather than investigating individual components (MacPherson et al. 2008; Verhoef et al. 2005).
1.10 Acupuncture practice in New Zealand and Australia

The first step in designing clinically representative research is to understand how the intervention is delivered in the community of interest. Acupuncture is now one of the most common forms of CAM therapy in Australia (Shorofi 2011; Thomson et al. 2012). Acupuncture treatment can take place within a number of different theoretical frameworks, with the following being most common outside of Asia: Traditional Chinese, Five Element, Japanese or Biomedical (sometimes called “Western”) (Bovey, Lorenc & Robinson 2010; Hopton et al. 2012; Moore 2014; Robinson et al. 2012; White 2000). These frameworks dictate many facets of the treatment, including diagnosis, point location, point selection, co-interventions such as moxibustion, needling style, retention time for needles, and stimulation style. While this heterogeneity in clinical practice allows both acupuncture consumers and clinicians significant freedom to find a style that suits often this diversity of treatment is not incorporated in clinical research. Therefore, the importance of the framework when evaluating and designing clinically relevant interventions is critical.

The STRICTA guidelines (MacPherson et al. 2010) explain the importance of discussing the theoretical framework choice and rationale for point selection, as results will often only apply to the theoretical framework in which the trial was undertaken. Without the framework and explanation for why particular points were chosen it is difficult to contextualise the result and relate the outcomes to clinical practice.

Acupuncture is commonly practiced within the TCM framework in New Zealand (P McBride, NZRA president, personal communication, September 2012) and Australia (Moore 2014). The TCM framework also includes modalities such as herbal medicine, moxibustion, qi gong, cupping and self-care. New Zealand and Australian practitioners are usually working in private practice (Moore 2014) rather than a hospital environment, in contrast to most Chinese practitioners (Robinson et al. 2012) and many practitioners in the UK (Hopton et al. 2012).
Acupuncturists are often generalists (Chi et al. 1996), however, specialisation is becoming more common, with obstetrics and gynecology (OB/GYN) the most common area of specialisation reported by practitioners in the EU (Robinson et al. 2012). Therefore, it is likely that acupuncturists in New Zealand and Australia will also show similar rates of specialisation in the treatment of gynaecological conditions, however, data on specialisation is currently lacking.

1.11 Designing clinically relevant trials: the importance of practitioner involvement

Stomski (2008) and Moore (2014) found that acupuncturists in Australia look positively on research, value its evidence and are favourably inclined to incorporate it into their practice (Moore 2014; Stomski, Grimmer-Somers & Petkov 2008). A barrier to the uptake of research in clinical practice for many acupuncturists is the lack of relevance of randomised controlled trials to clinical practice, due to the absence of many characteristic clinical aspects, such as individualisation of treatment (Jackson & Scambler 2007; Kaptchuk, Chen & Song 2010; Ryan 2006; Seem et al. 2003). Given the strong link between practice specialisation and research priorities, Robinson and colleagues (2012) conclude that future research must be based on, and relevant to, clinical practice. Linde (2007) suggest that research should be around questions that directly affect or interest practitioners, such as optimal treatment numbers, or comparisons between different types of acupuncture intervention (Linde, Hammerschlag & Lao 2007). There is an emphasis in the literature on the importance of practice-driven research to avoid producing results that neither inform nor enhance clinical practice (Bovey 2010; Fønnebø et al. 2007; Langevin et al. 2011; Verhoef et al. 2005).

There is currently no information published on how acupuncture practitioners in New Zealand and Australia treat primary dysmenorrhea in clinical practice. It is important that future research studies mirror clinical practice, to optimise the
potential for research outcomes reflecting those seen in the clinical practice of acupuncturists.

Before clinically relevant trials can be developed there first needs to be an understanding of how acupuncture is practiced in the community when treating primary dysmenorrhea. This is to ensure that there is sufficient “model validity”, that the research design incorporates the theory of healing and the normal therapeutic context of the intervention (Verhoef et al. 2005). Lewith (cited in Verhoef et al. 2005) describes the criteria to assess model validity as including representiveness, equipoise and credulity, model congruity and context. Representiveness — whether the intervention is consistent with current practice — and model congruity — whether the diagnosis, intervention and outcome fit the framework — need to be investigated prior to the design of the trial. Without this in-depth understanding of how the framework is used in practice, it is impossible to conduct a trial with significant model validity for TCM.

Previous research approaches used to design research protocols that reflect clinical practice have involved surveys of practitioners and a Delphi Process to achieve consensus from stakeholders. Two surveys by Sherman and colleagues (Sherman et al. 2005; Sherman, Hogeboom & Cherkin 2001) have examined various components of acupuncture clinical practice by involving acupuncturists of differing theoretical frameworks, experience and educational qualifications. Their findings suggest that survey data can provide considerable information about the diversity of clinical practice.

The Delphi Method has also been widely used. Recently there have been a number of attempts to use the Delphi Method to design trial protocols by expert consensus, for TCM (Cochrane, Smith & Possamai-Inesedy 2011; MacPherson & Schroer 2007; Sinclair-Lian et al. 2006), Japanese (Schnyer et al. 2008) and Western/biomedical-style acupuncture (Cotchett et al. 2011). A potential criticism of this approach of seeking expert consensus is due to the loosely
defined criteria for “expert”. There may be substantial differences between what textbook authors and researchers consider correct point choices and what acupuncturists in clinical practice use. Alraek (2011) and colleagues (Alraek, Borud & White 2011) found that when they compared the expert consensus for the pragmatic ACUFLASH trial to what the practitioners used in the study (Borud et al. 2009), they found that while there was significant similarity on the patterns of disharmony present, the acupuncture points used had very little overlap between the two groups. This suggests that expert consensus may only be of limited benefit regarding certain aspects of clinical practice (i.e. point choice or treatment frequency), possibly due to the fact that in clinical practice acupuncturists tend to stick to points that they have experience with and confidence in their effectiveness.

Developing a clinically relevant design is about the balance between a loosely and tightly specified intervention (MacPherson & Schroer 2007). A technique that has been successfully used to maintain this balance in a number of acupuncture clinical trials is manualisation (Schnyer & Allen 2002; Schnyer et al. 2006; Schnyer et al. 2008). Manualisation is a procedure that “allows practitioners to adjust acupuncture treatments to study participants’ unique diagnoses, allowing the delivery of ecologically valid treatments within a predefined framework that can be replicated. The treatments are ‘standardised’ not by the selection of fixed point formulae, but by providing an algorithm that can be adapted to each patient.” Schnyer and Allen (2002) emphasise the importance of incorporating the “collective experience” of acupuncture practitioners in the community when designing these treatment manuals (Schnyer & Allen 2002).

Data from targeted surveys may lack some of the depth necessary to accurately determine all aspects of clinical practice that need to be either replicated or controlled when designing clinical trials. A possible solution previously suggested (Schnyer & Allen 2002; Schnyer et al. 2006) and used successfully (Schnyer et al. 2006) is the addition of focus groups comprised of experienced
practitioners. This allows collection of data from a variety of backgrounds, which can be used as an adjunct to survey data and to clarify clinical problems. This would also engender discussion with regard to treatment protocols.

**1.12 Individualisation of treatment in TCM: the importance of flexibility in diagnosis, point selection and co-interventions**

In effectiveness studies, one of the most important considerations relating to clinical applicability of a research treatment protocol is the extent to which the intervention is individualised. In the community it is likely that the majority of clinical practice is characterised by a significant degree of individualisation due to the way TCM views the treatment of disease.

Disease in TCM is viewed in terms of patterns of disharmony, where the body has lost its adaptive ability and this has caused an upset in the harmony, or equilibrium, present in the body. Disease is thus a manifestation of “a pattern of disharmonious relationships” within the body (Beinfield & Korngold 1991, p. 36). Therefore it is not the disease itself that is being treated but the underlying imbalance; by rearranging the pattern of disharmony into one of harmony and balance, the condition itself is treated (Beinfield & Korngold 1991). The TCM framework tends to view the process of restoring health to the patient in terms of regulating Qi flow; with treatment modalities based around this fundamental notion of moving Qi (Jackson & Scambler 2007; Schroer et al. 2011).

Diagnosis in TCM relies on integrating both objective and subjective information and “weaving” this together into a clinical picture that represents the current pattern of disharmony (Schnyer, Birch & MacPherson 2007). Diagnoses often change from treatment to treatment, with practitioners updating their diagnosis based on symptoms, tongue and pulse. The flexibility in diagnosis, including the continual reassessment of the “pattern” of disharmony, is considered one of the key features of TCM by practitioners (Ryan 2005).
a TCM diagnosis is determined, treatment is based on the aphorism “yi bing tong zhi, tong bing yi zhi”, translated to mean “different diseases, same treatment: same disease, different treatment” (Flaws & Sionneau 2001, p. 2). Clinically this is usually implemented as bian zheng lun zhi, or treatment administered based on pattern discrimination. The diagnosis is intimately linked with the choice of acupuncture points, the rationale being that the chosen points will alter Qi in such a way as to reintroduce balance to the body. The grounding of the diagnosis within the underlying TCM framework, and the weaving of this diagnosis throughout the treatment session, means that the diagnostic process is a characteristic component of acupuncture treatment (Paterson & Dieppe 2005).

Surveys (Moore 2014; Sherman et al. 2005; Sherman, Hogeboom & Cherkin 2001) and qualitative studies of acupuncture practitioners treating chronic health conditions, including lower back pain (MacPherson, Thorpe & Thomas 2006), depression (MacPherson & Schroer 2007), endometriosis (Schnyer et al. 2008) and infertility (Cochrane, Smith & Possamai-Inesedy 2011) provide data that supports the importance of individualisation of treatment based on TCM patterns and the high incidence of use of co-interventions in clinical practice. For example, in 1997 Sherman and colleagues (2001) surveyed 56 acupuncturists in Washington State on diagnosis and treatment of Lower Back Pain (LBP). A wide variety of acupuncture points were used to treat LBP, but there was general consensus on the number of treatments needed to show an effective result. There was a high frequency of commonly used co-interventions, such as electro-acupuncture, moxibustion, massage and Chinese herbal medicine.

Further work by Sherman and colleagues (2005) examined the use of other co-interventions by acupuncturists. They collected data from 50 acupuncturists of varying theoretical backgrounds (TCM being the most common) who were seeing at least 10 patients per week in Washington and Massachusetts (Sherman et al. 2005). The authors found that the number of adjunctive
treatments was high (>75% of visits), especially heat in the form of heat lamps or moxibustion. Two thirds of treatments included at least one form of self-care advice, with diet and nutrition from a TCM perspective being the most common.

This work by Sherman (Sherman et al. 2005; Sherman, Hogeboom & Cherkin 2001) supports similar findings from other studies of practitioners, with the diagnostic pattern differentiation and point selection appearing to be heavily practitioner dependant (Birkeflet, Laake & Vøllestad 2014; Hogeboom, Sherman & Cherkin 2001; Kalauokalani, Sherman & Cherkin 2001). Although there is debate on the importance of individualisation in clinical outcomes for pain (Cherkin et al. 2009) the wide variety of acupuncture points used, and ubiquitous use of co-interventions, suggests that TCM differential diagnostic treatment is characteristic of clinical practice. Thus if pattern differentiation is not included in a study, translating the findings of the study back to clinical practice, where the framework places such an emphasis on individualisation of treatment may be difficult due to practitioners reluctance to incorporate standardised treatment in their practice (Kaptchuk, Chen & Song 2010). Therefore a fixed intervention, without any co-interventions, is not appropriate to examine the effectiveness of community delivered acupuncture. To date there has been no study exploring the diagnostic and treatment principles used by practitioners when treating primary dysmenorrhea.

1.13 Self-care: a characteristic component of acupuncture treatment

An important component of TCM acupuncture is the dispensing of self-care advice. Self-care is a broad concept incorporating efforts by the patient towards reduction of symptoms, maintenance of good health and prevention of poor health (Barofsky, 1978). Surveys show that self-care advice is commonly given as part of acupuncture treatment (Hopton et al. 2012; Moore 2014; Robinson et al. 2012), and has been considered vital to include in clinical trials (MacPherson
The importance of TCM self-care advice has been discussed by other acupuncture practitioners when treating a variety of conditions, including musculoskeletal conditions (MacPherson & Thomas 2008; MacPherson, Thorpe & Thomas 2006), a variety of internal medicine disorders (Evans et al. 2011), and depression (MacPherson & Schroer 2007; MacPherson et al. 2014). Macpherson and Schroer (2007) found that the majority of practitioners in their study consider these “auxiliary” techniques, such as self-care advice, to be important theory-driven components of treatment (MacPherson & Schroer 2007).

Self-care, as delivered in acupuncture consultations, has the following attributes:

1) Grounded in the practitioners theoretical framework: TCM acupuncturists deliver advice grounded in TCM theory, Western acupuncturists deliver advice grounded in biomedical theory (Hopton et al. 2012).

2) Individualised to the diagnosis of the patient, based on (1) (Evans et al. 2011; MacPherson, Thorpe & Thomas 2006)

3) Integrated throughout the consultation rather than given as a discrete intervention (Evans et al. 2011; MacPherson & Thomas 2008; MacPherson, Thorpe & Thomas 2006)

Common components of self-care talk in acupuncture consultations cover diet, over-the-counter medications, physical activity, rest and relaxation, practice of related therapies (i.e. Qi Gong) and protection from the elements (Paterson et al. 2012). Acupuncture practitioners view this advice as “empowering” rather than “instructional”, and an important factor in allowing patients to move from passive to active roles with regards to their health (MacPherson & Thomas 2008). Feelings of empowerment and increased agency have been expressed by patients who have undergone both TCM (Cassidy 1998; Gould & MacPherson 2001; Hopton, Eldred & MacPherson 2014; Paterson & Britten 2004) and Five-
element acupuncture (Rugg et al. 2011). This self-care advice, often delivered using a different theoretical framework from the predominant biomedical paradigm, also allows patients to come to a different understanding of their current condition (Gould & MacPherson 2001; MacPherson, Thorpe & Thomas 2006; Paterson et al. 2012). Patients see it as an important component and fundamentally different from the advice they received from orthodox medical practitioners (Evans et al. 2011; Walker et al. 2003). It is plausible that self-care advice is at least partially responsible for the changes in attitudes related to the presenting complaint that is often seen in acupuncture patients (Gould & MacPherson 2001).

One study showed TCM self-care advice, delivered via the internet, improved self-care scores, but did not show any additional benefits on pain reduction compared to auricular acupressure alone in women with primary dysmenorrhea (Yeh et al. 2013). Despite practitioners’ belief that adherence to this advice gives better outcomes (MacPherson & Thomas 2008), there have been no studies examining patient compliance to this self-care advice and its relationship to patient health.

1.14 Summary and research rationale

The prevalence of primary dysmenorrhea, the impact it has upon the lives of women, incomplete pain relief from current treatments, recurrent absenteeism or reduced performance at work or school, highlights a need for an effective treatment that targets the multifaceted symptoms of primary dysmenorrhea. Current biomedical interventions appear to provide some relief, but these therapies are not effective for all women or may be avoided due to personal, cultural or religious beliefs. Due to this perceived lack of efficacy of current treatments, the use of self-care, including CAM treatments, is common amongst women with primary dysmenorrhea.
Mechanistic studies show plausible mechanisms by which acupuncture may reduce the symptoms of primary dysmenorrhea, and systematic reviews of clinical research shows promise with the treatment of primary dysmenorrhea (this will be discussed in depth in Chapter 2). However, clinical effectiveness remains unclear due to the number of low-quality trials and a significant gap between the interventions as delivered in many trials, and acupuncture as delivered in clinical practice in Australia and New Zealand.

Acupuncture as delivered in clinical practice is a complex intervention with flexible treatment based on specific diagnostic considerations and the common use of co-interventions. To date, there is no research on how New Zealand and Australian acupuncturists deliver treatments for primary dysmenorrhea in clinical practice. This information is vital to being able to develop a treatment that provides information on clinical effectiveness and informs clinical practice. A practitioner survey and subsequent focus groups appears to be an appropriate method for collecting reliable data on clinical practice, which can be used to design a clinically relevant trial incorporating characteristic TCM components. Another important gap in clinical understanding is that, despite the importance placed on self-care advice by acupuncture practitioners, it is currently unknown if patients take that advice and if it contributes to clinical outcomes. Due to the common usage of self-care in primary dysmenorrhea in the community, it is likely that self-care advice, delivered in the context of the acupuncture treatment, would have a significant uptake and its role in clinical outcomes could be examined.

1.15 Research aim and research questions

The overarching aim of this thesis is to examine the treatment of primary dysmenorrhea in contemporary clinical acupuncture practice and the therapeutic effects of acupuncture treatment on the symptoms of primary
dysmenorrhea. This thesis uses a mixed-methods approach, and incorporates four studies addressing the following research questions.

1) How is acupuncture treatment for primary dysmenorrhea delivered in clinical practice in New Zealand and Australia?
2) What components of the acupuncture treatment do practitioners and patients consider important for successful treatment?
3) In a population of women with primary dysmenorrhea, what effect does changing the timing of treatment or the mode of stimulation have on pain and quality of life?
4) Does acupuncture treatment change women’s perception of primary dysmenorrhea and what constitutes a normal menstrual cycle?
5) What role does self-care advice play in the treatment of primary dysmenorrhea, do patients follow that advice and what value do they assign to it?

1.16 Overview of thesis

Chapter Two reviews the current scientific literature on acupuncture for primary dysmenorrhea. Methodological shortcomings and the lack of clarity around the appropriate “dosage” of the intervention are discussed along with the clinical applicability of results.

Chapter Three discusses the methodology of this mixed-methods thesis, including theoretical framework, paradigm and methods of integration. Methodology for the four phases of this thesis: a practitioner survey, practitioner focus groups and interviews, a randomised controlled trial and post-trial semi-structured interviews will be outlined.

Chapter Four discusses the results of the practitioner survey of acupuncturists in New Zealand and Australia. Thematic analysis of data from focus groups and semi-structured interviews with experienced acupuncture practitioners in the
area of women’s health is presented. A discussion of how this data informed a manualised protocol is also covered.

Chapter Five discusses the results of the randomised controlled trial on the effect of changing modes of stimulation and treatment timing using acupuncture on women with primary dysmenorrhea.

Chapter Six discusses the results of the thematic analysis of post-trial interviews with women who participated in the randomised controlled trial.

Chapter Seven discusses how the findings from the previous four phases were integrated and discusses the meta-themes and meta-inferences that were found.

Chapter Eight discusses the results of this thesis in the context of the existing literature, the implications for clinical practice and future research, and the strengths and limitations of these studies.
Chapter Two: Acupuncture for the treatment of primary dysmenorrhea: a narrative review of the literature on dosage and clinical relevance

2.1 Introduction

Chapter One outlined the complexity of the acupuncture intervention and introduced important components that are part of the Traditional Chinese Medicine (TCM) theoretical framework, including flexibility in diagnosis and point selection, and the importance of co-interventions, such as moxibustion and self-care. This chapter will discuss treatment dosage, an important and often overlooked component of delivering acupuncture in clinical trials.

A review of acupuncture clinical trials and systematic reviews to treat primary dysmenorrhea is also reported, with the aim of examining treatment effects, the doses of acupuncture used, and a review of examined randomised controlled trials (RCTs) to determine if dosage impacts upon the clinical outcomes.

In addition, this chapter examines existing RCTs to determine if the characteristic components of acupuncture, including self-care advice and moxibustion, are present, and if not, the impact their absence has on the clinical validity of these trials.

2.2 Issues with current research on acupuncture for primary dysmenorrhea

A significant number of acupuncture trials for the treatment of primary dysmenorrhea have been carried out since 1987, with most trials being
published since 2008, reflecting the increased interest in acupuncture for gynaecological issues. Recent systematic reviews on using acupuncture for primary dysmenorrhea have concluded that while acupuncture shows promise there is a need for further, high-quality trials as the evidence is still unclear (Cho & Hwang 2010b; Smith et al. 2011b). The high level of heterogeneity in acupuncture trials is a significant barrier to obtaining useful clinical guidance from systematic reviews. This is especially true when those reviews include criteria for methodological quality, but do not take into account the quality of the acupuncture intervention itself, interventions which may be far different from clinical practice (White et al. 2008). The adequacy of the acupuncture intervention is at least as important as trial methodology, but is often overlooked when evaluating the quality of an intervention for inclusion in a systematic review (Birch 1997; Birch 2003).

There are two main areas where RCTs could fail to deliver an adequate representation of acupuncture: the “dosage” of acupuncture delivered and how closely the intervention delivered approximates the clinical setting. The impact of these two factors were raised in a recent critique (Zhang, Xing & Smith 2012) for the journal FACT (Focus on Alternative and Complementary Therapies) of Smith and colleagues study on acupuncture for primary dysmenorrhea (Smith et al. 2011). The authors state that one of the main reasons for the Smith trials’ lack of significant difference between true and sham acupuncture was that the acupuncture intervention given was an inadequate “dosage” of treatment and therefore delivered a sub-optimal therapeutic effect.

The authors of this critique raise two important questions that are currently unclear:

1) What is the effect of changing acupuncture “dosage” on outcomes in primary dysmenorrhea?; and
2) To what extent do clinical trials reflect acupuncture given in the community, as a “dose” of acupuncture in China may be very different to that given in Australia?

### 2.2.1 Clinical applicability of research

How the theoretical framework and clinical setting are incorporated into trial design are two important factors in determining how adequately the trial intervention represents clinical practice. For example, what is representative of an acupuncture treatment in China may be very different to a representative treatment in New Zealand or Australia (Linde, Hammerschlag & Lao 2007). Differences in clinical practice between China and western countries, such as New Zealand and Australia, could significantly influence the outcome of treatment (Wu 2009). In their summary of responses to recent acupuncture RCTs, Kaptchuk and colleagues (2010) discuss potential pitfalls observed in RCTs and include “point selection, frequency and scheduling of treatments, style of acupuncture, and absence of ancillary treatments” as key areas where RCTs may not match clinical practice (Kaptchuk, Chen & Song 2010). As discussed in Chapter One, flexibility in diagnosis and point selection and the usage of co-interventions (ancillary treatments) are characteristic components of TCM acupuncture. Trials that do not incorporate these features are unlikely to provide useful information to practitioners as they minimalise the theoretical framework and therefore do not reflect their clinical setting.

### 2.2.2 Components of an acupuncture dose

Acupuncture does not have the same regulatory “gatekeepers” as pharmaceutical interventions. This has led to scant “bottom–up” research, which would have necessarily included investigations of suitable dosage for different conditions (Fønnebø et al. 2007). In the same way as there being a difference between taking medication once per week versus daily administration, different doses of acupuncture are likely to have a different
impact on clinical outcomes. The importance of reporting acupuncture specific
dosage components in clinical trials was first outlined in the STRICTA guidelines
(MacPherson et al. 2002; MacPherson et al. 2010). While components of dosage
are becoming increasingly well reported in clinical trials (Hammerschlag et al.
2011), until recently there has been little effort to ensure a high-quality,
adequately dosed intervention is delivered (White et al. 2008).

In an effort to understand what constitutes a high-quality, representative
intervention, Smith and colleagues (2011) used the Delphi Process to identify
components that were considered by acupuncture researchers to be evidence of
the quality and adequacy of an acupuncture intervention. Components that
were identified and considered to form part of the “dose” of acupuncture
included the number of needles, type of stimulation, duration of retention and
number of treatments. Point selection, based on a credible therapeutic rationale
which links point selection to desired outcomes, was also considered to be vital
(Smith et al. 2011a). While not discussed by Smith (2011) in cyclical conditions
such as primary dysmenorrhea, the timing of the treatment relative to the
menstrual cycle may also play a role according to the TCM understanding of the
menstrual cycle. White and colleagues (White et al. 2008), in their review on
determining acupuncture “dosage,” found that most systematic reviews that
attempted to discuss whether the “dose” of acupuncture was adequate included
components of the number of treatment sessions, the number of acupuncture
needles, the length of session and mode of stimulation. Hao and colleagues (Hao
et al. 2013) found that components of dosage that affected the outcomes for
tension-type headache were mode of stimulation, needle retention time and
frequency of treatment. Therefore there is both theoretical and empirical
support for alterations of dosage impacting therapeutic outcomes.

2.2.3 The presence of a dose-response relationship in acupuncture

There is some evidence of a dose-response relationship when using
acupuncture. Stener-Victorin (Stener-Victorin et al. 1996) found a dose-
response relationship between the number of treatments and uterine blood flow in infertile women when using electro-acupuncture. Women with primary dysmenorrhea show a reduced uterine blood flow (Celik et al. 2009; Dmitrović 2000), therefore this dose-response relationship may influence the reduction of menstrual pain. There is also evidence that when acupuncture is used for non-gynaecological pain conditions, a dose-response relationship occurs with increasing frequency of treatment (Ceccherelli et al. 2003; Ezzo et al. 2000; Harris et al. 2005). However, one recent, well-designed study has challenged this dose-response relationship in lower back pain (Yuan et al. 2009). Other complex interventions, such as physiotherapy with Transcutaneous Electrical Nerve Stimulation (TENS) (Bjordal, Johnson & Ljunggreen 2003), massage (Sherman et al. 2014) and psychotherapy (Freedman et al. 1999) show clear dose-response relationships. While theoretically sound, the current evidence for a dose-response when treating primary dysmenorrhea is unclear.

2.2.4 Purpose of this review

A critical summary of recent, systematic reviews and clinical trials published since the recent, systematic reviews will be discussed. Methodological shortcomings and how these affect the reliability of the evidence will be examined.

To explore the effect of different dosage components of acupuncture on clinical outcomes for primary dysmenorrhea. The following dosage components will be examined as per Smith (2011) and White (2008): the number of needles used, duration of retention, frequency and total number of treatments, timing of treatments and type of stimulation. Additionally, the model validity of trials will also be discussed, examining the flexibility in diagnosis and point selection, and the use of co-interventions such as moxibustion.
2.3 Search strategy

To examine the effect of acupuncture for the treatment of primary dysmenorrhea, a review was undertaken of the literature published since the most recent Cochrane review for dysmenorrhea (Smith et al. 2011b). A modified version of the Cochrane search strategy was used. Databases searched included Medline, PsychINFO, Google Scholar, CINAHL, EMBASE, Cochrane Library menstrual disorders subfertility group, Proquest and Web of Knowledge. Appendix A22 contains the full search strategies used for each of the included databases. Only papers published with English language full text were included. Articles that used acupressure, non-penetrating acupuncture, non-standard
acupuncture (e.g. eye acupuncture) acupoint injections, TENS, or moxibustion alone were not included. Only RCTs were included; quasi-randomised or non-randomised trials were excluded. Studies with a diagnosis of primary dysmenorrhea, or mixed primary and secondary dysmenorrhea were included; papers that examined secondary dysmenorrhea only were excluded. Outcome measures needed to include menstrual pain, measured by any conventional pain scale or measure. Databases were searched from March 2010 (the date of the last Cochrane systematic review search) until February 2015 using the keywords ‘acupuncture’ and ‘dysmenorrhea’. A total of 383 articles were returned, 280 studies were identified as duplicates, and 103 articles were screened for eligibility (See Figure 2.1). Two trials (Liu et al. 2012; Shi et al. 2014) were excluded as they are subsets of the dataset in Liu (2014). This left 11 eligible studies.

In addition to individual papers, systematic reviews undertaken in the last five years (from January 2010 onwards) were also examined as these contain trials that would otherwise not be accessible in English language databases.

2.4 Findings of recent systematic reviews

Two recent systematic reviews have examined the effect of acupuncture treatment on primary dysmenorrhea and were included (Cho & Hwang 2010b; Smith et al. 2011b). One review and meta-analysis (Xu et al. 2014a) was excluded as it included mostly observational Chinese trials with the majority of the trials examining moxibustion alone as an intervention, and “clinical efficacy” scores, such as “total effective rate”, rather than pain scores or scales. Studies involving penetrating acupuncture were not practiced within the TCM framework but rather as ‘acupoint therapy’, using techniques such as indwelling thread. In addition there was no detail reported in this review on treatment protocols, such as number of treatments, and therefore does not provide any useful information and is therefore excluded from this review.
Cho and colleagues (2010) reviewed 27 RCTs, involving 2960 subjects, published prior to July 2008. Trials used a mixture of acupuncture “styles”, including body acupuncture, ear acupuncture, ear acupressure and electro-acupuncture. The majority of the trials (23 of 27) were published in China in Chinese, three in Korean and one in English. Just over half of the trials (18 of 27) used a physical examination method to exclude secondary dysmenorrhea. Most trials compared acupuncture to pharmaceutical medication (15 of 27), or herbal medicine (seven of 27). Twelve of the 15 trials compared acupuncture to pharmacological interventions such as NSAIDs. Only those trials using body acupuncture or electro-acupuncture were examined. Different styles of acupuncture, such as manual and electro-acupuncture, were analysed separately. No pooled data was available for acupuncture versus NSAIDs, but individual trials showed relative risk (RR) for pain relief ranging from 1.02–1.85 and standard mean difference (SMD) of symptom improvement ranging from 0.17–0.92. Six of the seven studies comparing acupuncture with herbal medicine showed superior pain relief for those receiving acupuncture. Only one (Helms 1987) of the three studies which examined acupuncture versus sham acupuncture showed acupuncture as having significantly lower pain scores than the sham controls (SMD = 1.51). The two other trials by Lee and colleagues (2007) and Youn and colleagues (2008) were not available in English or indexed by MEDLINE but were summarised in the systematic review, and reported as showing no difference between true and sham acupuncture in menstrual pain score (SMD 0.11, 95% CI -0.45 to 0.68) and (SMD 0.54, 95% CI -0.12 to 1.19) respectively (Lee et al. 2007; Youn et al. 2008).

Cho and colleagues’ review was appraised using the CASP: Systematic Review checklist (CASP: Systematic Reviews n.d.) and found to be high quality (Table 2.1). However, the studies included were almost of uniformly low quality with unclear levels of bias present due to poor reporting; 66% did not give details of randomisation, 100% did not give details of allocation concealment, 88% either did not blind participants or did not give details of blinding, 81% had an unclear
risk of bias due to incomplete outcome reporting and 51% used insensitive, subjective or non-standard criteria to measure pain relief. The authors acknowledge that the review had significant limitations, including publication bias, significant methodological bias and significant heterogeneity for both clinical outcomes and methodology (Cho & Hwang 2010b).

In addition, the inclusion criteria for this review included auricular acupressure, laser acupuncture and acupoint injection. This raises questions on how broadly to define an acupuncture treatment (Langevin et al. 2011).

Smith and colleagues (2011) reviewed ten RCTs involving 1025 women, and included trials published prior to March 2010. There were four studies undertaken in China, three in Taiwan and three in the English-speaking west (Australia, Germany and Canada). Given the focus on acupuncture, the four trials that used acupressure will not be discussed here, leaving six trials with 673 women in total. Most trials used fixed sets of acupuncture points, rather than adjusting point selection on a per patient basis, as would be common in the community. One acupuncture trial used the numeric rating scale (NRS) (Witt et al. 2008), one trial used the McGill pain questionnaire (Smith et al. 2011), while the remaining four trials used un-validated outcome measures. Intention to treat analysis was only performed in two of the six trials (Smith et al. 2011; Witt et al. 2008). Methodological quality was high in the two most recent trials published in English (Smith et al. 2011; Witt et al. 2008). Manual and electro-acupuncture was not separately analysed. Smith and colleagues found that acupuncture was superior to both Chinese herbal medicine for short-term symptom improvement (odds ratio [OR] 7.00, 95% CI 2.22 to 22.06) and pain relief (SMD -1.34, 95% CI -1.74 to -0.95), and NSAIDs for short-term symptom improvement (OR 3.25; 95% CI 1.53 to 6.86) and pain relief (SMD -0.70; 95% CI -1.08 to -0.32). No trials to date have examined acupuncture versus oral contraceptive pills. Smith and colleagues noted that there were substantial limitations of these RCTs, including limited reporting of any symptoms other
than pain in most trials, short follow-up timeframes and only one trial reporting any adverse events.

The review by Smith and colleagues (2011) was appraised using CASP: Systematic Review checklist (CASP: Systematic Reviews n.d.) (Table 2.1) and it was found to be high quality. In contrast to the review by Cho and colleagues (2010), the inclusion criteria for trials was limited to trials where randomisation was present; this excluded the majority of the trials analysed by Cho (2010) and gave four trials in common between the two reviews. For those trials included in the review by Smith and colleagues (2011), 20% did not report sequence generation, 30% did not report allocation concealment, 20% did not use allocation concealment, 80% did not blind participants, 20% had incomplete outcome reporting and 50% had unclear levels of bias from other sources.

Overall trial quality was assessed as higher in the studies included in the review by Smith and colleagues (2011) compared with the studies included in Cho (2010). However, these results must be interpreted with caution as both trials involving NSAIDs included in the review by Smith and colleagues (2011) had methodological flaws. Zhi and colleagues (Zhi 2007) used a possibly sub-therapeutic dose of ibuprofen (Marjoribanks et al. 2010), an unusual and poorly documented style of “superficial” indwelling acupuncture and non-standard outcome measures. The study by Jiang and colleagues (Jiang 2007) lacked blinding, baseline characteristics and used an “effectiveness” rate to determine success.
### Table 2.1: CASP Analysis for Two Recent Systematic Reviews

<table>
<thead>
<tr>
<th>CASP Question</th>
<th>Cho and Hwang 2010</th>
<th>Smith et al 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the review ask a clearly focused question</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Did the review include the right type of study</td>
<td>No – inclusion of auricular acupressure and acupoint injection</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Did the reviewers try to identify all relevant studies</td>
<td>Yes</td>
<td>Yes – with a caveat that some non English studies may have been missed</td>
</tr>
<tr>
<td>4. Did the reviewers assess the quality of the included studies</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5. If the results of the studies have been combined, was it reasonable to do so</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6. How are the results presented and what is the main result</td>
<td>Figures of forest plots of RR for pain relief and SMD for symptom improvement. Wide range of RR dependent on the subtype of acupuncture treatment. RR figures based on insensitive outcome measures therefore may overestimate effect.</td>
<td>Methodological Quality and Risk of Bias summarized in figures. Figures of forest plots for SMD for short-term pain relief and OR for short-term symptom improvement. Limited evidence for acupuncture’s effectiveness in reducing menstrual pain and symptoms of dysmenorrhea.</td>
</tr>
<tr>
<td>7. How precise are these results</td>
<td>95% CI reported for pain relief and symptom improvement for all studies. Lower bounds of many RR confidence intervals are below or close to 1.</td>
<td>95% CI reported for all outcome measures in figures and text.</td>
</tr>
<tr>
<td>8. Can the results be applied to the local population</td>
<td>No – high proportion of Chinese studies that have a much higher frequency of treatment than usually given in community acupuncture in the west. Cultural expectations on acupuncture effectiveness also an important factor</td>
<td>Yes – 3 of the trials were undertaken using more common treatment frequencies for community delivered acupuncture in the west.</td>
</tr>
<tr>
<td>9. Were all important outcomes considered</td>
<td>Can’t tell – poor reporting outside of primary outcomes of pain or symptom improvement in the studies used in the review</td>
<td>Can’t tell – Many trials lacked complete reporting such as adverse events or quality of life. Follow up periods were short to medium for most studies. One trial examined cost-benefit analysis of acupuncture vs. usual care but this was not discussed</td>
</tr>
<tr>
<td>10. Should policy or practice change as a result of the evidence contained in this review</td>
<td>No – issues with poor methodological quality of the studies included in the review preclude any useful results.</td>
<td>Can’t tell – evidence currently not compelling enough to recommend acupuncture for dysmenorrhea due to unclear risk of bias in many of the studies included in the review</td>
</tr>
</tbody>
</table>
2.5 Findings of RCTs undertaken since the Cochrane systematic review

Eleven RCTs have been undertaken since March 2010 that met our inclusion criteria. Manual and electro-acupuncture studies were critically analysed separately, methodological shortcomings identified and their impact discussed. Studies using electro-acupuncture are detailed in Table 2.2 and studies using a manual acupuncture intervention are detailed in Table 2.3.

2.5.1 Electro-acupuncture at fixed points versus wait-list control

Four RCTs (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011) examined the effect of electro-acupuncture at SP6, GB39 or an unrelated acupoint versus wait-list control on various parameters related to primary dysmenorrhea. The author's choice of the SP6 or GB39 points was due to their location on the L4-S1 nerve that innervates the uterus. All four RCTs measured pain scores on a 100mm visual analogue scale (VAS) and three studies (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010) used the cox menstrual symptom scale (RSS-COX1) to evaluate menstrual symptoms.

1) Ma (2010) found that SP6 had the greatest pain reduction on the VAS (SMD -23.19mm) compared to control at 30 minutes post-intervention. SP6 also had the greatest reduction in verbal rating scale and RSS-COX1 scores over both the current and subsequent menstrual period.

2) Liu (2011) found pain at 60 minutes on the VAS decreased significantly in groups being treated via SP6 (SMD -15.56mm), GB39 (SMD -18.14mm) and a non-acupoint (SMD -10.96mm). Compared to the non-acupoint only GB39 showed significantly greater reductions in pain. GB39 also showed a significant reduction in RSS-COX1 during the subsequent menstrual period while SP6 did not.
3) Shi (2011) found that pain reduction on a VAS was similarly reduced amongst all acupuncture groups (SP6, GB39 and non-acupoint) compared to no acupuncture but no significant differences between groups were found. None of the acupuncture groups caused a change in prostaglandin levels.

4) Liu (2014) found that at 60 minutes post treatment SP6 caused a significantly greater reduction (-4.0mm) in VAS recorded pain than GB39 or a non-acupoint. However, this difference is below the threshold of clinical relevance (Dworkin et al. 2008). All groups showed improvements in pain on the verbal rating scale and RSS-COX1 with no significant differences between groups.

All authors concluded that electro-acupuncture had a significant effect on pain, however, the results were conflicting on the relative magnitude of each point’s pain-relieving effect. The authors suggest this is due to the close location of SP6, GB39 and the unrelated acupoint, activating the same L5-S1 spinal nerve segment. Therefore the effect of the point selection based on TCM principles, rather than anatomy, is unclear. These four studies suggest immediate (0–60 minutes post intervention) pain-relieving effects are unrelated to changes in prostaglandin levels or changes in uterine blood flow, however, the small sample size of Ma (2010) may have prevented any changes in uterine blood flow between groups being detected.

2.5.2 Electro-acupuncture versus herbal medicine

Miao (2014) compared electro-acupuncture with Tao Hong Si Wu Tang versus electro-acupuncture and a placebo herbal medicine, and found that the electro-acupuncture / Tao Hong Si Wu Tang combination was superior (Miao et al. 2014). However, an unusual, non-validated four-stage self-report scale was used for pain and the “placebo” herbal combination contained active ingredients. This makes the contribution of the electro-acupuncture itself very difficult to determine.
<table>
<thead>
<tr>
<th>Study/location</th>
<th>Participants (n)/Age (y)</th>
<th>Entry Criteria</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liu 2011 China</td>
<td>194/15-30</td>
<td>Primary dysmenorrhea confirmed via physical exam. Analgesic usage prohibited.</td>
<td>Electro-acupuncture (SP6)</td>
<td>- Electro acupuncture (GB39 or unrelated acupoint) - Wait list control</td>
<td>VAS for pain RSS-COX1 RSS-COX2</td>
<td>All EA groups had a significant reduction in pain (P &lt; .05). SP6 and GB39 had the greatest pain reduction (P &lt; .05) Small reduction in RSS-COX1 in GB39 group (P = 0.025)</td>
</tr>
<tr>
<td>Shi 2011 China</td>
<td>40/15-30</td>
<td>Primary dysmenorrhea: unclear if confirmed by physical exam. Pain &gt; 40mm on 100mms VAS. Analgesic usage prohibited.</td>
<td>Electro-acupuncture (SP6)</td>
<td>- Electro acupuncture (GB39 or unrelated acupoint) - Wait list control</td>
<td>VAS for pain Plasma prostaglandin levels</td>
<td>All EA groups had a reduction in pain (P &lt; .05). No group specific differences in prostaglandin levels.</td>
</tr>
<tr>
<td>Ma 2010 China</td>
<td>52/15-30</td>
<td>Primary dysmenorrhea: unclear if confirmed by physical exam. Pain &gt; 40mm on 100mms VAS. Analgesic usage prohibited.</td>
<td>Electro-acupuncture</td>
<td>Wait list control</td>
<td>VAS for pain RL S/D ratio in uterine arteries.</td>
<td>All groups pain reduced from baseline at 5, 10 &amp; 30 minutes (P &lt; .0001). SP6 group had the greatest reduction in pain compared to control (-23.19mm, P &lt; .0001). No between group changes in uterine blood flow.</td>
</tr>
<tr>
<td>Liu 2014 China</td>
<td>501/15-30</td>
<td>Primary dysmenorrhea: confirmed by physical exam and ultrasound. Pain &gt; 40mm on 100mms VAS. Analgesic usage allowed when pain &gt; 80mm.</td>
<td>Electro-acupuncture (SP6)</td>
<td>Electro acupuncture (GB39 or unrelated acupoint)</td>
<td>VAS for pain RSS-COX VRS (0-7)</td>
<td>All groups showed statistical reductions from baseline in VAS. SP6 showed greater immediate pain reduction. All groups showed improvement in RSS-COX and VRS.</td>
</tr>
<tr>
<td>Miao 2014 Australia</td>
<td>128/15-40</td>
<td>Primary dysmenorrhea: unclear if confirmed by physical exam. Analgesic usage prohibited.</td>
<td>Electro-acupuncture</td>
<td>Both groups received active acupuncture treatment, one group received Tao Hong Si Wu Wan (&quot;active&quot;), while the other received Shen Qi Da Bu Wan (&quot;placebo&quot;)</td>
<td>4 grade self-report system.</td>
<td>Acupuncture plus herbal medicine (Tao Hong Si Wu Wan) superior to Acupuncture plus Shen Qi Da Bu Wan.</td>
</tr>
<tr>
<td>Study/Location</td>
<td>Participants (n)/Age (y)</td>
<td>Entry Criteria</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Results</td>
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<tr>
<td>Bu 2011 China</td>
<td>80 / 18-26</td>
<td>Primary dysmenorrhea: unclear if confirmed by physical exam. Analgesic usage unclear.</td>
<td>Manual acupuncture prior to menses (PA)</td>
<td>- Acupuncture (A): 30m 1/day for 3-7 days from 1st day of menses. - Control group: untreated</td>
<td>Cox Menstrual Symptom Scale (CMSS)</td>
<td>PA showed significant decrease in CMSS score for intensity and duration vs. control (P&lt; .01) and A (P&lt; .05)</td>
</tr>
<tr>
<td>Yu 2010 China</td>
<td>66 / mean age 22</td>
<td>Primary dysmenorrhea: unclear if confirmed by physical exam. Analgesic usage unclear but appears prohibited</td>
<td>Manual Acupuncture (SP6)</td>
<td>Manual Acupuncture (GB39)</td>
<td>Menstrual pain score (unvalidated) Uterine blood flow (Pl/RI and A/B)</td>
<td>SP6 group had a significant reduction in menstrual pain score, PI, RI and A/B values (P &lt; .01). GB39 group had no significant differences (P &gt;0.05)</td>
</tr>
<tr>
<td>Xiong 2012 China</td>
<td>135 / 17-29</td>
<td>Primary dysmenorrhea: not confirmed by physical exam. Analgesic usage prohibited.</td>
<td>Manual acupuncture with DeQi stimulation</td>
<td>Manual acupuncture without stimulation</td>
<td>VAS for pain DeQi score Belief in acupuncture score</td>
<td>Pain scores decreased in both groups (P &lt; .01). Intervention group had a greater reduction in both intensity and duration of pain (P &lt; .01). DeQi scores were higher in the intervention group (P &lt; .01)</td>
</tr>
<tr>
<td>Ma 2013 China</td>
<td>568 / 16-35</td>
<td>Primary dysmenorrhea: unclear if confirmed by physical exam. Pain score &gt; 40mm on 100mm VAS. Analgesic usage prohibited.</td>
<td>Single pt. group – 1 needle Multiple pt. group: 7 needles</td>
<td>5 groups in total: Comparing Single vs. multiple points and starting on first day of menses vs. 3-7 days prior. Control group had no treatment.</td>
<td>Cox Menstrual Symptom Scale (CMSS) VAS for pain</td>
<td>Treatment prior to menses was superior to treatment starting at menses. Multiple pts. were superior to single points.</td>
</tr>
<tr>
<td>Kiran 2013 Turkey</td>
<td>35 / 15-40</td>
<td>Primary dysmenorrhea: Self-reported. Not confirmed by physical exam. Analgesic usage unclear in Acu group.</td>
<td>Manual acupuncture</td>
<td>NSAID (naproxen sodium 550mg twice per day starting two days before menses).</td>
<td>VAS for pain</td>
<td>Both groups showed significant changes pre-post. Acupuncture showed a greater pain reduction from baseline.</td>
</tr>
</tbody>
</table>
**2.5.3 Manual acupuncture at different treatment times**

Two studies examined the effect of changing treatment times. Bu and colleagues (2011) and Ma (2013) both used manual acupuncture at different times relative to the menstrual period. Both studies concluded that treatment prior to menses produces the greatest reduction in menstrual pain and symptoms.

1) Bu and colleagues concluded that acupuncture given prior to menses was significantly better at reducing pain intensity (SMD -0.93, 95% CI -1.62 to -0.24, p<0.01) and pain duration (SMD -0.94, 95% CI -1.63 to -0.25, p<0.01) than acupuncture starting from the first day of menses as measured by Cox menstrual symptom scale (CMSS) scores. Bu and colleagues’ study suggests that intensive treatment just prior to menses is optimal, however, the generalisability of the study is compromised by the usage of a single point, small sample size and lack of blinding (Bu, Du & Chen 2011).

2) Ma and colleagues (2013) examined the effect of single versus multiple acupoints, and treating prior to or during menses, and found similar results to Bu and colleagues. Treatment prior to menses with multiple points produced the greatest reduction in pain compared with treating with the single point (Shiqizhui (EX-B8)) (SMD -3.22, 95% CI -3.55 to -2.88, p<0.01) while when treating during menses the single point was superior to multiple points (SMD -3.55, 95% CI -3.9 to -3.2, p<0.01). Overall treatment prior to menses with multiple points produced the greatest reduction in CMSS scores (Ma et al. 2013).

**2.5.4 Manual acupuncture versus manual acupuncture without stimulation**

DeQi (the arrival of Qi) is the sensation generated by the insertion and/or manipulation of an acupuncture needle in an acupuncture point (White et al. 2008; Zhang et al. 2013). This sensation is commonly described as heavy,
aching, numb, warm, tingling, or a combination of these (White et al. 2008) One study examined the effect of DeQi sensation with manual acupuncture. Xiong and colleagues (2012) compared manual acupuncture with DeQi sensation versus acupuncture without DeQi, and concluded acupuncture with strong manual stimulation produced a greater reduction in both pain intensity ($W = 2410.0, p<0.01$) and pain duration ($W = 3181.0, p<0.01$) of pain (Xiong et al. 2012). This greater pain reduction with increased DeQi sensation conflicts with the findings of Smith and colleagues (2011) and Shi and colleagues (2014), with a recent review finding mixed results on the necessity of DeQi for pain relief (Zhou & Benharash 2014).

### 2.5.5 Manual acupuncture versus non-acupuncture interventions

Two studies compared manual acupuncture versus non-acupuncture interventions.

1) Kiran (2013) compared manual acupuncture versus naproxen sodium, a common NSAID that is effective for primary dysmenorrhea. The authors found that manual acupuncture resulted in a greater decrease (69.5%) in pain measured on a VAS, compared with the NSAID group (52.2%), however, no between group statistical tests were performed by the authors. In both groups the baseline pain scores were very low (<25mm on a 100mm VAS) suggesting that women participating in this study may have had very mild dysmenorrhea.

2) Huang and colleagues (2013) compared manual acupuncture with self-administered acupressure and found that manual acupuncture was superior in reducing pain measured by VAS and the McGill pain questionnaire, however, no between group statistical tests were performed by the authors. Calculations of the SMD between groups show a non-significant difference in after-treatment scores for VAS (SMD .5mm, 95%CI -0.03 to 1.45). McGill pain data appears to be erroneous as the scores are the same (mean +/- SD) as the VAS score. Other issues
included major baseline imbalances in pain scores, which were present and unaccounted for in the analysis, and no details of the randomisation were provided.

2.5.6 **Summary of trials undertaken since the systematic review**

- Most Chinese trials limited or excluded analgesic medication during the trial. Usage of analgesic medication is very common amongst women with period pain (Campbell & McGrath 1997; Hillen et al. 1999; O’Connell, Davis & Westhoff 2006; Zhu et al. 2010), therefore many women that acupuncturists see in clinical practice in the west will be using analgesic medication to control their symptoms. This is in contrast to China where analgesic usage for menstrual pain is less commonly used (Zhu et al. 2010). The impact of concurrent analgesic usage with acupuncture on primary dysmenorrhea may affect the clinical outcomes.
- Across studies there was no clear predictor of improved outcomes. This was at least partially due to the different time courses of observation, with pain observations varying from 15 minutes after needle insertion up to 12 months post-trial.
- Comparison between studies using a single point showed similar effect to those studies using multiple points, in a similar fashion to electro-acupuncture and manual acupuncture demonstrating similar effects between trials.
- Point specificity, based on TCM considerations (i.e. GB39 versus SP6), does not show reliable differences in pain scores across trials.
- Acupuncture delivered prior to menses appears to show promise, compared with treatment during menses alone.
- Methodological issues were numerous, including lack of blinding, small sample size, severe baseline imbalance, lack of inferential statistics between treatment groups and inadequate comparison groups.
2.6 The effect of acupuncture dosage on the outcomes of primary dysmenorrhea

Studies included in the systematic review and studies published subsequently do not appear to show any clear effect of dosing based on point selection. To examine the possible effect of other dosage components and the applicability to clinical practice in New Zealand or Australia of the study intervention, 17 RCTs that involved examining the effect of penetrating acupuncture on primary dysmenorrhea, had outcomes for pain scores and published in English were included. Chinese language papers that were included in Smith’s 2011 review were also included as there was sufficient information to extract dosing information. All studies were published between 1987 and 2014, and are presented in Table 2.3. Appendix A23 provides more detail on each included study including comparator groups, outcome measures and pain related outcomes.

2.6.1 Study location

Twelve studies were undertaken in China (Bu, Du & Chen 2011; Huang et al. 2013; Jiang 2007; Li, Wang & Guo 2008; Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Ma et al. 2013; Shi et al. 2011; Xiong et al. 2012; Yu et al. 2010; Zhi 2007); two in Australia (Miao et al. 2014; Smith et al. 2011); and one each in the US (Helms 1987), Turkey (Kiran et al. 2013), and Germany (Witt et al. 2008).

2.6.2 Treatment frequency and timing

Most of the studies undertaken in China used a daily treatment frequency (Bu, Du & Chen 2011; Jiang 2007; Li, Wang & Guo 2008; Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Ma et al. 2013; Shi et al. 2011; Xiong et al. 2012). One study (Huang et al. 2013) used every three days, while the remaining three studies used a “one-off” treatment, performing the intervention only once (Shi et al. 2011; Yu et al. 2010) or once per menstrual cycle (Zhi 2007). Many of the studies using daily
treatment also used specific treatment timing prior to the menses therefore the importance of the daily treatment versus the importance of treatment timing is unclear. In contrast, the studies undertaken outside China used lower treatment frequencies: three times per menstrual cycle (Helms 1987; Smith et al. 2011), twice per menstrual cycle (Miao et al. 2014), and the fifth, second days prior to and the third day of menses (Kiran et al. 2013). The trial from Germany (Witt et al. 2008) does not specify the exact frequency of treatment, however, on average ten sessions were undertaken within three months, so the frequency is similar to Smith (2011) and Helms (1987). This difference in the treatment frequency reflects the difference in clinical practice outside China, where weekly treatment is more common.

2.6.3 Number of treatments

The total number of treatment sessions varied considerably between studies from one session up to 21 sessions. Three Chinese studies used only a single treatment session (Liu et al. 2014; Shi et al. 2011; Yu et al. 2010). Four Chinese studies (Zhi 2007)(Liu 2011, Ma 2011, Liu 2014) and one Turkish study (Kiran 2013) used three treatment sessions. Miao (2014) used six sessions, while Smith (2011) and Helms (1987) both used nine sessions over three months. Witt (2008) used on average ten (but up to 15) sessions; Huang (2013) used ten treatment sessions. Li (2008), Bu (2011) and Xiong (2012) all used approximately 15 sessions. Jiang (2007) delivered 21 treatments over three months. One trial was unclear about the exact number of treatments delivered, as there was a range from three to seven treatments per month (Ma 2013).

2.6.4 Mode of stimulation

Five of the studies undertaken in China used electro-acupuncture (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011; Zhi 2007), while the remaining seven used manual acupuncture (Bu, Du & Chen 2011; Huang et al. 2013; Jiang 2007; Li, Wang & Guo 2008; Ma et al. 2013; Xiong et al. 2012; Yu et
al. 2010). Only one of the studies undertaken outside China used electro-acupuncture (Miao et al. 2014).

### 2.6.5 Point number and selection

Seven of the studies from China (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Ma et al. 2013; Shi et al. 2011; Yu et al. 2010; Zhi 2007) used a single acupuncture point such as SP6, GB39 or EX-B8 as one of the treatment groups. Ma (2013) compared a single acupuncture point with multiple acupuncture points. Witt (2008) did not specify the number of points or needles used. All other trials used between five and 21 needles over a variety of acupuncture points.

### 2.6.6 Needle retention

Most trials retained the needles for approximately 20–30 minutes, except two trials (Ma et al. 2010; Yu et al. 2010) where needles were retained for less than ten minutes, and Kiran (2013) who retained for 15 minutes. Witt (2008) does not specify needle retention time.
### Table 2.4: Dosage Parameters of RCT’s for Primary Dysmenorrhea

<table>
<thead>
<tr>
<th>Study/Location</th>
<th># Needles</th>
<th>Total # of treatments</th>
<th>Frequency of treatments</th>
<th>Timing of treatments</th>
<th>Needle Retention (m)</th>
<th>EA parameters (Hz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miao 2014 Australia</td>
<td>8</td>
<td>6</td>
<td>2 per month for 3 months</td>
<td>2-3 days prior to menses and first 24 hours of menses</td>
<td>20</td>
<td>50</td>
</tr>
<tr>
<td>Liu 2014 China</td>
<td>4 (inc anchor points)</td>
<td>3</td>
<td>1/day for 3 days</td>
<td>First day of menstrual cycle</td>
<td>30</td>
<td>2/100</td>
</tr>
<tr>
<td>Ma 2013 China</td>
<td>1 or 9</td>
<td>9-21</td>
<td>1/day for 3-7 days per month over 3 months</td>
<td>Either 3-7 days prior to menses or from first day of menses</td>
<td>30</td>
<td>N/A</td>
</tr>
<tr>
<td>Kiran 2013 Turkey</td>
<td>21</td>
<td>3</td>
<td>3 per month for 1 month</td>
<td>5th and 2nd days prior to menses and the 3rd day of menses</td>
<td>15</td>
<td>N/A</td>
</tr>
<tr>
<td>Huang 2013 China</td>
<td>6-7</td>
<td>10</td>
<td>Every 3 days</td>
<td>Unknown</td>
<td>30</td>
<td>N/A</td>
</tr>
<tr>
<td>Xiong 2012 China</td>
<td>5</td>
<td>15</td>
<td>1/day for 5 days per month over 3 months</td>
<td>5-7 days prior to menses</td>
<td>30</td>
<td>N/A</td>
</tr>
<tr>
<td>Bu 2011 China</td>
<td>7</td>
<td>9+</td>
<td>1/day for 3-7 days per month over 3 months</td>
<td>3-7 days prior to menses</td>
<td>30</td>
<td>N/A</td>
</tr>
<tr>
<td>Liu 2011 China</td>
<td>4 (inc anchor pts)</td>
<td>3</td>
<td>1/day for 3 days</td>
<td>First 3 days of menses</td>
<td>30</td>
<td>2/100</td>
</tr>
<tr>
<td>Shi 2011 China</td>
<td>4 (inc anchor pts)</td>
<td>1</td>
<td>1/day</td>
<td>During menses (unclear)</td>
<td>30</td>
<td>2/100</td>
</tr>
<tr>
<td>Smith 2011 Australia</td>
<td>Minimum 12</td>
<td>9</td>
<td>3/month for 3 months.</td>
<td>1/week excluding menses</td>
<td>30</td>
<td>N/A</td>
</tr>
</tbody>
</table>

---

1. Electro-acupuncture stimulation parameters. Either a single frequency (X) or alternating frequency (X/X).

2. Anchor points are non-acupuncture points used in conjunction with acupuncture points to enable electro-acupuncture.
<table>
<thead>
<tr>
<th>Study/Location</th>
<th># Needles</th>
<th>Total # of treatments</th>
<th>Frequency of treatments</th>
<th>Timing of treatments</th>
<th>Needle Retention (m)</th>
<th>EA parameters (Hz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ma 2010 China</td>
<td>4 (inc Anchor pts)</td>
<td>3</td>
<td>1/day for 3 days</td>
<td>First day of menses</td>
<td>10</td>
<td>2/100</td>
</tr>
<tr>
<td>Yu 2010 China</td>
<td>2</td>
<td>1</td>
<td>1/day</td>
<td>Between 5 days prior and 2nd day of menses.</td>
<td>5</td>
<td>N/A</td>
</tr>
<tr>
<td>Li 2008 China</td>
<td>Minimum 7</td>
<td>15+</td>
<td>1/day for min 5 days for 3 months</td>
<td>3-5 days prior to menses till last day bleeding</td>
<td>30</td>
<td>N/A</td>
</tr>
<tr>
<td>Witt 2008 Germany</td>
<td>Unclear</td>
<td>Maximum 15 Mean 10</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Jiang 2007 China</td>
<td>Minimum 16</td>
<td>21</td>
<td>1/day for 7 days over 3 months</td>
<td>4 days before menses to 3rd day menses</td>
<td>30</td>
<td>N/A</td>
</tr>
<tr>
<td>Zhi 2007 China</td>
<td>2</td>
<td>3</td>
<td>1 per menstrual cycle for 3 cycles</td>
<td>1st day menses</td>
<td>30</td>
<td>60</td>
</tr>
<tr>
<td>Helms 1987 America</td>
<td>12 needles</td>
<td>9</td>
<td>3 per month for 3 months</td>
<td>1/week excluding menses</td>
<td>30-40</td>
<td>N/A</td>
</tr>
</tbody>
</table>
2.7 Clinical considerations on dosing:

There were three studies that provided valuable comparative advice for clinical practice. Bu (2011) and Ma (2013) both reported that treatment administered prior to menses provided greater pain relief than treatment that started on the first day of menses, however, the use of high-frequency daily treatment may not be applicable to clinical settings in Australia, New Zealand, Europe or the United States. The lower frequency of treatment more common in the west, including Germany, Australia and the United States, has been reflected in the trial design of most trials undertaken outside China, where the frequencies are closer to once per week (Helms 1987; Miao et al. 2014; Smith et al. 2011; Witt et al. 2008).

Zhi (2007) showed that electro-acupuncture provided greater relief than manual acupuncture, however, this was only delivered on the first day of menses per month. Given the more favourable clinical outcomes when treatment was given prior to menses, rather than administering treatment when menses started, it is possible that those trials delivering acupuncture only during menses underestimate the treatment effect (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011; Zhi 2007). Therefore the effect of treatment delivered in the week prior to menses compared with the more common frequency of once per week should be investigated further.

As previously discussed, the number of acupuncture points selected (and by proxy the number of needles used) is an important component of the acupuncture “dose”. Only one study compared single points with multiple points and found that multiple points, when delivered prior to menses, was significantly superior to a single point (EX-B8). However, when treatment was delivered during menses, the single point (EX-B8) delivered greater pain reduction than multiple points (Ma et al. 2013). This may explain why those seven studies which used single acupuncture points showed clinical effect, as all
but one (Yu et al. 2010) delivered treatment during menses itself. However, it seems unlikely based on the results of Ma (2013) that using a single point outside of menses would be as effective as using multiple points.

Maciocia (Maciocia 1998) in his popular English language textbook on obstetrics and gynaecology recommends a minimum of three months of treatment for primary dysmenorrhea, therefore single sessions, or a total course of treatment less than six sessions, would be unlikely to be considered adequate by most acupuncturists in the west. This is reinforced by the total number of treatment sessions being six (Miao et al. 2014), nine (Helms 1987; Smith et al. 2011) or ten (Witt et al. 2008) for those trials conducted in Australia, Germany or the United States. Too few treatments risks providing a sub-optimal dose of acupuncture, therefore future clinical trials should reflect the number of sessions that are likely to be given as part of a “course” of acupuncture treatments.

The mode of needle stimulation in trials for primary dysmenorrhea was either manual or electro-acupuncture. Electro-acupuncture was used in almost half of the trials undertaken in China, most commonly with a 2/100Hz frequency. Its inclusion may reflect differences in clinical practice for primary dysmenorrhea in different cultural settings, or a desire to standardise the level and strength of intervention for research. A recent survey suggests that electro-acupuncture is not as common in Chinese practice as its prevalence in dysmenorrhea studies implies (Robinson et al. 2012). Electro-acupuncture usage amongst Australian acupuncturists is similar to that reported by Robinson (2012), with most either using it occasionally (39%) or almost never / never (30%) (Moore 2014).

Mayor (2013) argues that electro-acupuncture inherently provides a greater “dose” of acupuncture, due to the greater endorphin release, than does manual acupuncture (Mayor 2013), therefore its inclusion as a dosing component appears to be justified. Given the prevalence of electro-acupuncture in the Chinese literature, the positive outcomes observed in these studies, and its role
as a component of dosage, its effect on the symptoms of primary dysmenorrhea when delivered in a clinically relevant manner should be investigated.

There are also several other caveats in causally linking Chinese dosing (such as high-frequency, daily treatment or electro-acupuncture) to improved outcomes; most research published regarding acupuncture in China tends to be positive (Vickers et al. 1998) and of low methodological quality using non-validated outcome measures (Cho & Hwang 2010b; Smith et al. 2011b; Xu et al. 2014a; Zhu, Hamilton & McNicol 2011). There is also evidence that Chinese and Australian women have significantly different menstrual characteristics relating to dysmenorrhea, such as time of onset of menstrual pain, severity of pain, duration of pain and also analgesic usage (Zhu et al. 2010). This may further increase the difficulties in interpreting the applicability of results from Chinese trials to the Australian population.

2.7 Individualisation of diagnosis, point selection and use of co-interventions

As discussed in Chapter One, differential diagnosis is a key, characteristic component of TCM acupuncture. TCM texts emphasise the importance of treating both the root (the underlying cause) and the branch (symptomatic treatment) via accurate differential diagnosis (Kaptchuk 2000). This individualisation of treatment based on differential diagnosis is considered to be fundamental to acupuncture practice (Ryan 2005). Table 2.4 shows the presence of fixed or individual treatments, as well as the theoretical rationale, point selection and presence of co-interventions in current trials. Two trials (Jiang 2007; Zhi 2007) were excluded as the data from Smith’s systematic review (Smith et al. 2011b) did not contain information on rationale and point selection.
Overall, the trials reviewed showed a lack of individualisation of treatment with only three studies (Huang et al. 2013; Smith et al. 2011; Witt et al. 2008) confirming individualisation of treatment based on diagnosis in their methods. Smith (2010) and Huang (2013) used TCM pattern differentiation to allow a selection of points based on the diagnosis and practitioner’s discrimination. Witt (2008) did not specify a specific theoretical framework, noting that there were a wide variety of styles and acupuncture techniques practiced by the treating acupuncturists.

Appendix A1 shows the common patterns of disharmony that are thought to underlie primary dysmenorrhea from a range of modern textbooks. Clinical data provides evidence of a range of patterns underlying primary dysmenorrhea, each of which would be treated with different acupuncture points (Liu et al. 2012; Zhu et al. 2009). Given this variety, trials which use the same points regardless of TCM diagnosis do not reflect the importance of differential diagnosis in the TCM framework and are unlikely to reflect the clinical setting in Australia, where 90% of practitioners consider the TCM framework fundamental in guiding their diagnosis and treatment decisions (Moore 2014).

The rationale for point selection was often not clearly stated. Xiong (2012), Smith (2010) and Helms (1987) gave clear indications in the methodology of the rationale behind their point selection, with all three using different textbooks. Other sources were given as expert opinion (Miao et al. 2014) and historical or previous usage (Ma et al. 2010; Yu et al. 2010). The lack of reporting the rationale means that the theory behind point selection was often unclear.

Point selection differed across trials, with SP6 being common to all trials except Miao (2014) and Helms (1987). Usage of a single point occurred in six studies (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Ma et al. 2013; Shi et al. 2011; Yu et al. 2010), either comparing SP6 or shiqizhui (EX-B8) with other points. The usage of SP6 is most likely due to its traditional usage in dysmenorrhea.
(Deadman, Al-Khafaji & Baker 1998), which has been reinforced with animal models providing support for the physiological effects of SP6 (Liu et al. 2009; Stener-Victorin, Fujisawa & Kurosawa 2006). Trials without the use of SP6 did not show significantly different results to those including this point, the specificity of SP6 when treating dysmenorrhea still being unclear (Chen, Chien & Liu 2013). The rationale behind the specific choice of shiqizhui (EX-B8) is not clearly stated in the articles. Some English language textbooks mention its empirical value in treating dysmenorrhea (Xiaofei & Mu 2000), while the authors (Ma et al. 2013) stated the choice was due to “clinical experience”.

Use of co-interventions was uncommon in the trials reviewed. All but one trial (Miao 2014) did not allow, or did not specify if they allowed moxibustion. Moxibustion is commonly used by practitioners (MacPherson & Schroer 2007; Moore 2014) and shows promise in reducing period pain (Akin et al. 2004; Xu et al. 2014a). None of the trials included self-care advice as part of their treatment, despite its prevalence in clinical practice (Hopton et al. 2012; Moore 2014; Robinson et al. 2012).
## Table 2.5: Style of Intervention and Sources of Clinical Information in RCTs for Primary Dysmenorrhea

<table>
<thead>
<tr>
<th>Study / location</th>
<th>Source of information on choice of pattern / point selection</th>
<th>Style of intervention (TCM differentiation / fixed)</th>
<th>Points selected</th>
<th>Other interventions (moxibustion, self-care advice, herbal medicine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liu 2014 China</td>
<td>Not stated</td>
<td>TCM fixed</td>
<td>SP6 or GB39 or “unrelated acupoint”</td>
<td>None (confirmed in text)</td>
</tr>
<tr>
<td>Miao 2014 Australia</td>
<td>Expert opinion. Expert not stated.</td>
<td>TCM fixed</td>
<td>BI31, BI32, BI33, BI34.</td>
<td>Herbal medicine (Tao Hong Si Wu Wan)</td>
</tr>
<tr>
<td>Huang 2013 China</td>
<td>Not stated</td>
<td>TCM differentiation</td>
<td>GV20, LI4, LI11 plus PC6 and Liv3 OR ST36 and SP6 OR REN4 and ST36.</td>
<td>None (confirmed in text)</td>
</tr>
<tr>
<td>Ma 2013 China</td>
<td>Not stated</td>
<td>TCM fixed</td>
<td>SP6, SP8, BI32, EX-B8 or EX-B8 alone</td>
<td>None (confirmed in text)</td>
</tr>
<tr>
<td>Kiran 2013 Turkey</td>
<td>Not stated</td>
<td>TCM fixed</td>
<td>HT7, PC6, LI4, LI10, SP6, LIV3, ST36, GB26, SP15, Ziegong, Ren4</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Xiong 2012 China</td>
<td>Textbook: Sun, GJ. Acupuncture (2000)</td>
<td>TCM fixed</td>
<td>ST36, SP6, REN3</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Smith 2011 Australia</td>
<td>Textbook: Maciocia, Obstetrics and Gynaecology (1998)</td>
<td>TCM differentiation</td>
<td>Points based on TCM pattern including SP4, ST29, REN 3, BI32, SP8, SP6</td>
<td>None (confirmed in text).</td>
</tr>
<tr>
<td>Bu 2011 China</td>
<td>Not stated</td>
<td>TCM fixed</td>
<td>SP6, BL32, SP8, Vertebra-17</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Liu 2011 China</td>
<td>Not stated</td>
<td>TCM fixed</td>
<td>SP6 or GB39 or “non-acupoint”</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Shi 2011 China</td>
<td>Not stated</td>
<td>TCM fixed</td>
<td>SP6 or GB39</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Ma 2010 China</td>
<td>Textbook (unclear reference) and previous studies</td>
<td>TCM fixed</td>
<td>SP6 or GB39 or “non-meridian point”</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Yu 2010 China</td>
<td>Historical usage</td>
<td>TCM fixed</td>
<td>SP6 or GB39</td>
<td>Not stated in text</td>
</tr>
<tr>
<td>Witt 2008 Germany</td>
<td>Unknown: chosen by individual physicians</td>
<td>Most likely TCM differentiation</td>
<td>Unknown</td>
<td>None (confirmed in text)</td>
</tr>
<tr>
<td>Helms 1987 America</td>
<td>Textbook: Mussat, Acupuncture (1980)</td>
<td>TCM fixed</td>
<td>SP4, KD3, ST36, ST30, REN2, REN4,PC6</td>
<td>Not stated in text</td>
</tr>
</tbody>
</table>
2.8 Conclusion

This review examined the clinical effectiveness of acupuncture for primary dysmenorrhea and the effect that changing dosage has on the therapeutic outcomes. We found there is a lack of clear evidence on what constitutes an adequate therapeutic dosage of acupuncture for dysmenorrhea.

- All trials comparing acupuncture to non-acupuncture interventions showed positive outcomes for pain, however, there were often significant methodological issues.
- All sham controlled trials showed no significant difference in pain outcomes for verum acupuncture compared to sham treatments.
- Trials comparing point specificity showed mixed results for pain and menstrual symptom scores.
- A single trial comparing electro-acupuncture versus manual acupuncture showed electro-acupuncture was slightly superior in “effectiveness”, but this used an uncommon, superficial style of acupuncture for both groups.
- Trials using manual acupuncture or electro-acupuncture alone showed similar outcomes, however, this was confounded by the variety of outcomes measured.
- Trials comparing treatment prior to menses showed greater clinical improvement of pain and menstrual symptom scores than those during menses.

One or more potential issues for applying trials results to clinical practice in New Zealand and Australia were found in all trials:

- Daily treatment frequency: unclear if this is applicable to practice in New Zealand and Australia.
- Lack of convincing theoretical rationale for point selection.
- Lack of individualisation of treatment based on pattern discrimination.
• Restrictions on common, characteristic components of the acupuncture intervention, such as moxibustion and self-care.

Those studies that did approximate contemporary clinical practice in the west also had issues. Smith (2011) used sham acupuncture, which may not be clinically inert (Lundeberg et al. 2008; Lundeberg et al. 2009) and may underestimate acupuncture's effect (Paterson & Dieppe 2005). Witt (2008) had excellent clinical outcomes versus usual care, however, little data was provided that could be used to optimise clinical practice due to a very loosely defined intervention. Neither Witt (2008) nor Smith (2011) discussed self-care as part of their treatment intervention. The shortcomings found in most trials suggest they may not necessarily represent a valid facsimile of acupuncture as practiced in clinical practice, due to omitting two of the critical components of acupuncture: individualised care and facilitating active participation of patients in their own recovery via self-care (MacPherson, Thorpe & Thomas 2006).

Findings from this review demonstrate that electro-acupuncture may provide more benefit than manual acupuncture for reducing menstrual pain, however, treatment was only delivered on the first day of menses and used an uncommon style of superficial acupuncture. It is unclear if the same benefit of electro-acupuncture would extend to treatments delivered outside the menstrual cycle. Treatment in the week prior to menses provides greater benefit than treatment delivered during menses, however, it is unknown if this provides more benefit than treatment delivered during other non-menstrual times.

Before the effectiveness of changing dosage can be examined, an understanding of how acupuncture is delivered in the clinical setting must be understood. This is key to ensuring that the “acupuncture” we are testing is indeed a contextually valid, representative form of acupuncture (Verhoef et al. 2005). A recent consensus document by a number of leading acupuncture researchers has given the following recommendation.
When evaluating a new intervention, its characteristics (e.g. dosage, frequency, setting) should reflect the context in which it will be deployed in the future in a usual care context. When evaluating acupuncture as an existing intervention that is widely available for the external validity of the results, it is important that the treatment protocol of the acupuncture group reflects common practice to the extent possible. (Witt et al. 2012, p. 5).

Therefore trial design must reflect both an adequate dosage but also reflect common clinical practice as much as possible within the RCT paradigm. To understand how acupuncture for primary dysmenorrhea is currently delivered in a “usual care” context, treatment characteristics must be obtained from practitioners. These characteristics refer to normal frequency and timing of treatment, the number of sessions in a typical treatment course, usual mode of stimulation and how co-interventions are commonly employed. This data can be used to form the baseline of usual acupuncture care in New Zealand and Australia. This will then allow a comparison between “usual care” and groups, where specific treatment timing and electro-acupuncture are used. Most importantly it will undertake this comparison while still reflecting the complex nature of the intervention by incorporating important characteristic components of TCM, such as individualisation of treatment and usage of co-interventions.

This trial will fulfil the aim outlined in Chapter One of exploring the effect that treatment timing and mode of stimulation will have on the outcomes of primary dysmenorrhea. To achieve this, in Chapter Three we will discuss how surveys, interviews and focus groups will be used to understand the components of a “normal” acupuncture treatment and how practitioners will be used to design the treatment protocol used in the trial itself, ensuring high external validity and results that can be used to inform optimal clinical practice.
Chapter Three: Methodology

3.1 Introduction

This chapter discusses the methodology used in this sequential, multi-phase, mixed methods study design. It explains the philosophical and theoretical underpinnings of the research, as well as the rationale for using a mixed methods design. Chapter Three contains detailed descriptions and explanations of the methodology used in each of the four phases of this study.

Phase One: New Zealand and Australian practitioner Survey
Phase Two: Practitioner focus group and semi-structured interviews
Phase Three: Randomised controlled trial (RCT)
Phase Four: Post trial interviews

3.2 Aims

The aim of this thesis is to examine the treatment of primary dysmenorrhea in contemporary clinical acupuncture practice, and the therapeutic effects of acupuncture treatment on the symptoms of primary dysmenorrhea.

There are three study objectives required to address these aims and to answer the research questions posed in Chapter One:

1) To understand contemporary acupuncture clinical practice in order to guide the development of a treatment protocol for primary dysmenorrhea. This phase of research will survey the views of acupuncturists using a survey, in-depth interviews and focus groups.

2) To determine the relative effectiveness of differing forms of needle stimulation and frequency and / or timing of treatment, by conducting a RCT using a protocol developed from data obtained from Phase One.
(practitioner survey) and Phase Two (focus groups and semi-structured interviews).

3) To determine the feasibility and acceptability of the RCT, and to seek women’s views of the intervention, including effectiveness of needling and co-interventions, the importance of self-care advice and changes in their perception of health and the normality of period pain.

3.3 Research design: mixed methods

Mixed methods research (MMR) is a more recent addition to the existing research paradigms of quantitative and qualitative, and has been called the third research paradigm (Johnson & Onwuegbuzie 2004) or the third methodological movement (Tashakkori & Teddlie 2010). A precise definition of what exactly constitutes MMR has been evolving in the literature and is still subject to debate and refinement (Tashakkori & Teddlie 2010). Early definitions of MMR focused on the methods component as typified by Greene, Caracelli and Graham in 1989, who state “we defined mixed-method designs as that that include at least one quantitative method (designed to collect numbers) and one qualitative method (designed to collect words), where neither type of method is inherently linked to any particular inquiry paradigm” (Greene, Caracelli & Graham 1989, p. 256). This has shifted in more recent years to an increased focus on methodology: a broader scope incorporating the entire line of inquiry, rather than just the methods or procedures themselves. In 1998 Tashakkori and Teddlie chose to entitle their book Mixed Methodology, which was symbolic of this shift. A more recent working definition has been offered by Johnson et al (2007), based on definitions provided by 21 researchers in mixed methods:

“Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purposes of breadth and
depth understanding and corroboration” (Johnson, Onwuegbuzie & Turner 2007, p. 123).

Creswell and Plano Clark (2010) acknowledge that there is a diversity of viewpoints around the definition of MMR, and instead propose a set of three key characteristics that encompass the diversity, but maintain the core aspects, of MMR:

1) Collection and analysis of both quantitative and qualitative data based on the research question,
2) Mixing / integration or linkage of the two forms of data either sequentially, concurrently or by embedding one within the other,
3) Framing these procedures with both philosophical worldviews and theoretical lenses and incorporation of these procedures into specific research designs (Creswell & Plano Clark 2010, p. 5).

This set of core characteristics emphasises one of the strengths of MMR; that by avoiding dogmatic adherence to either a quantitative or qualitative methodology and associated worldviews, MMR embraces a “methodological eclecticism” defined by Tashakkori and Teddlie as “selecting and then synergistically integrating the most appropriate techniques from a myriad of QUAL, QUAN, and mixed methods to more thoroughly investigate a phenomenon of interest” (Tashakkori & Teddlie 2010, p. 8).

Greene (2007) sums up the strength of this position by stating that “What matters most in guiding inquiry decisions are the substantive issues and conceptual theories relevant to the study being conducted, not philosophical paradigms in and of themselves” (Greene 2007, p. 69), hence the research

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3 Some MMR researchers use QUAN and QUAL as abbreviations for quantitative and qualitative research respectively.
question(s) rather than adherence to a specific philosophical stance dictate the best method.

3.4 Paradigm choice in MMR

Paradigms in MMR can be viewed in the following ways according to Morgan (2007), as;

- ways of perceiving and experiencing the world,
- epistemological stances linking ontology, epistemology and methodology,
- model examples of how research is conducted in a field of study, and
- “shared beliefs” among a community of researchers around items such as methods of inquiry (Morgan 2007).

Other MMR researchers have used the term “worldview” instead of paradigm, however, the key characteristics are the same (Creswell & Plano Clark 2010). Unlike traditional single-paradigm models, where positivism or constructivism needs to be chosen as the paradigm of choice, MMR embraces a “paradigm pluralism” (Tashakkori & Teddlie 2010, p. 9) where MMR serves as an umbrella that can comfortably house a variety of different paradigms based both on the research question and also the personal paradigmatic inclinations of the researcher.

Common paradigms used in MMR are “postpositivism”, “constructivism”, “participatory” and “pragmatism” (Creswell & Plano Clark 2010). All of these worldviews differ in terms of ontology, epistemology, axiology, methodology and rhetoric (Creswell 2012). Thus, the paradigm of choice will affect both assumptions on the nature of reality and how to acquire knowledge, as well as delineating methods of inquiry to attain this knowledge (Creswell & Plano Clark 2010).
Multiple paradigms can, and often are, used in different phases of the research, when researchers embrace a dialectic stance which embraces the assumption that multiple paradigms provide a greater breadth of understanding of the phenomenon being studied (Greene & Hall 2010). However, the most popular stance in MMR is the single paradigm stance (Tashakkori & Teddlie 2010). This is also known as the “alternative paradigm stance” by Greene (2007), who advances that such a stance “offers its own internal coherence and integrity and so does not present the tensions and challenges that can accompany the joint use of two more traditional paradigms” (Greene 2007, p. 82). A number of different paradigms have been offered as being suitable for this alternative stance, the most popular being one of the many forms of pragmatism (Biesta 2010; Greene 2007).

### 3.4.1 A pragmatic stance

According to Biesta and Burbules (2003), pragmatism is an American-centric, philosophical tradition based on the late nineteenth to early twentieth century writings of Charles Sanders Pierce, William James and John Dewey (Biesta & Burbules 2003). Greene (2007) notes that one difficulty when discussing pragmatism is that there is “not one pragmatism but many” (Greene 2007, p. 83), with Pierce, James and Dewey all espousing slightly different versions of pragmatism based on their own academic backgrounds.

Deweyan pragmatism endorses the view that knowledge is a combination of action and reflection, thus truth is always changing rather than being something static in the world “out there” and it is through action that we gain knowledge rather than simply philosophising (Biesta 2010). Philosophically, pragmatism accepts that there are both singular and multiple realities and includes and values both subjective and objective perspectives (Creswell & Plano Clark 2010; Feilzer 2010). This “all-encompassing” view allows the researcher to side step the “forced-choice” of postpositivism and constructivism, instead focusing on “real world” issues by gathering the different types of data needed to answer
the research question (Creswell & Plano Clark 2010; Hartrick Doane & Varcoe 2005; Feilzer 2010). In the context of mixed methods, by incorporating both quantitative and qualitative methods and integrating this data, pragmatism allows an enriched understanding of the phenomena under discussion (Yvonne Feilzer 2010).

A pragmatic framework is used in this thesis to examine acupuncture in the treatment of primary dysmenorrhea. Acupuncture, in the context of traditional Chinese medicine (TCM), is a complex intervention derived from a rich theoretical framework. Acupuncture research should be grounded in an understanding of the framework in which it is practised in the community (Fønnebø et al. 2007; Langevin et al. 2011; Verhoef et al. 2005). Previous acupuncture research has often discarded the framework while keeping what appears to be, at least nominally, acupuncture. Gaining an understanding of how acupuncture is practised in the community is vital to designing research that reflects clinical reality and enabling the generation of information relevant to clinical decision-making. Pragmatism is well suited to this practice-centred research, as it does not try to artificially separate practice from theory, instead accepting the position that “theory is always already practice” (Hartrick Doane & Varcoe 2005).

3.5 Multi-phase design

Multi-phase designs are structured in such a way that each phase builds upon the knowledge provided by the previous research phase(s) to address a number of interconnected research questions (Creswell & Plano Clark 2010). Sometimes known as a “sandwich” design, when researchers alternate quantitative and qualitative phases (Tashakkori & Teddlie 2003), multi-phase design can be used with either sequential or concurrent quantitative and qualitative (Creswell & Plano Clark 2010). Often incremental research questions are used but each is tied into an overarching objective.
Pragmatism places equal value in both subjective and objective data, not holding one superior to the other, encouraging a cyclical approach, where both inductive and deductive reasoning is used to integrate data and inform the subsequent phases of research (Tashakkori & Teddlie 2010). This translates into a dynamic, flexible approach to complex research questions, where knowledge generated in one phase will be able to substantially influence subsequent phase(s); these subsequent phases can be used to “fill in” any gaps in the knowledge generated in previous phases, and provide a fuller, more balanced understanding of acupunctures role in the treatment of primary dysmenorrhea.

3.6 Analysis and integration of multiple phases

In a multi-phase design, analysis and integration can occur at a number of stages. Onweugbuzie and Combs (Onwuegbuzie & Combs 2010) discuss seven “stages” in data analysis. These stages are not all compulsory, but give options for differing ways to analyse data depending on the researchers’ objective. The seven stages are:

1) Data reduction: reducing data collected through statistical analysis of quantitative data, or writing summaries of qualitative data.

2) Data display: reducing quantitative data to, for example, tables and reducing qualitative data to, for example, charts and rubrics.

3) Data transformation: transforming qualitative data into quantitative data.

4) Data correlation: correlating quantitative data with quantized, qualitative data.

5) Data consolidation: combining both data types to create new or consolidated variables or data sets.

6) Data comparison: comparing data from different sources.
7) Data integration: integrating all data into a coherent whole.

Several of these stages were used in the data analysis and subsequent integration in this study. Analysis and integration (following the notation of Creswell and Plano Clark (2010)) occurred at the following stages (see Figure 3.1):

The practitioner survey (QUAN->qual) informed the practitioner focus groups and interviews in two ways; firstly, survey findings on the use of multiple modalities, including those that required clarification (such as those that were in conflict with the current research), were incorporated into the interview and focus group schedule of questions; secondly, practitioners who filled in the survey had the opportunity to indicate their experience in treating menstrual health and were then invited to participate in the focus groups and interviews. This purposive sampling was used to select acupuncturists who were representative of the wider group of women’s health specialists who treat primary dysmenorrhea.
FIGURE 3.1. DATA COLLECTION AND INTEGRATION

Methods

Survey: Acupuncture practitioners in New Zealand and Australia

Focus groups and semi-structured interviews: Acupuncturists with expertise in treating dysmenorrhea

RCT: Acupuncture for the treatment of primary dysmenorrhea

Semi-structured interviews: Participants in the RCT for the treatment of primary dysmenorrhea

Data type

QUAN Data: Descriptive and Inferential statistics

QUAL Data: Focus groups and interviews transcribed and coded

QUAN Data: Descriptive and Inferential statistics

QUAL Data: Interviews transcribed and coded

Data analysis

Data Analysis using SPSS

Thematic analysis

Data Analysis using SPSS

Thematic analysis

Data integration

Survey, Focus group and SSI data used to develop protocol for RCT

RCT and SSI data combined to allow fuller understanding of experience in the trial

Meta analyses
The focus groups and interviews informed the subsequent RCT in two ways, via the transformation of transcribed data and the practitioner data sheets (QUAL+QUAN). Qualitative interview data was transformed into quantitative data based on frequency of agreement; for example, the most frequent needle retention time was 20 minutes. The quantified data and the practitioner data sheets were used to develop the manualised trial protocol for the RCT phase (more detail for this process is provided in Chapter Four).

The RCT phase provided potential participants for the post-trial interviews; purposive sampling, based on improvement scores in the RCT, was used to ensure both responders and non-responders were present in the interviews. This allowed a further examination of why these differing outcomes in symptoms may have occurred. Post-trial interview data (QUAN->qual) was used to explain the results of the quantitative RCT by further understanding the changes in health that occurred during the RCT, and what value participants put on the different components of the acupuncture treatment.

At the conclusion of all four phases, meta-inferences were explored. Meta-inferences are conclusions drawn from across the quantitative and qualitative strands of a mixed-methods study (Creswell & Plano Clark 2010). O’Cathain, Murphy and Nicoll (2010) suggest three possible methods for drawing robust meta-inferences or “meta-themes” from mixed-methods data (O’Cathain, Murphy & Nicholl 2010). This study uses one of these methods, “triangulation”. Triangulation occurs after each individual dataset has been analysed separately. Researchers then list the findings of each component or phase of the overall study in a table looking for findings that agree (convergence), offer complementary information, or contradict other findings (dissonance). Examining any dissonance between findings is an important component of this method. There may also be “silence” where some findings are not present in each phase, due to the nature of the method used for that phase. Discussion of convergence, dissonance and complementary information then allows the
generation of meta-themes and/or meta-inferences from across all study phases (Farmer et al. 2006).

### 3.7 Survey of the treatment of women’s menstrual health by acupuncturists

The aim of this research was to explore the diversity of acupuncture clinical practice in the field of women’s menstrual health⁴.

The specific research questions were:

- What was the prevalence of acupuncture treatment for menstrual health conditions amongst New Zealand and Australian acupuncturists?
- When treating women’s menstrual health conditions, what specific treatment modalities do acupuncture practitioners use?
- What were the major referral sources for acupuncture practitioners of patients with women’s menstrual health conditions?
- What other health professionals, if any, do acupuncture practitioners work with when treating women’s menstrual health conditions?
- Given the diverse background of acupuncture practitioners, where did they train, what treatment modalities do they offer in clinic and what theoretical framework informs their practice?

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⁴ This study was part of a larger study conducted to examine the practice of acupuncture in relation to reproductive health. The researcher (MA) led the methodological design and implementation.
3.7.1 Study design

A self-complete survey was administered via a web-based questionnaire and a content-identical, paper-based questionnaire to collect data from registered acupuncturists in New Zealand and Australia. The web-based component was provided via survey provider Survey Monkey (www.surveymonkey.com).

Web-based surveys, such as those provided by Survey Monkey, are becoming more popular in the field of health research as they can offer significant advantages over traditional, paper-based surveys (Kaplowitz, Hadlock & Levine 2004; Wright 2006). In this instance the ability to reach a large number of participants separated by large, geographic distances (New Zealand and Australia), along with a significant decrease in cost compared to paper surveys (due to postage, printing and other associated costs), were key factors in the choice of a web-based survey (Kroth et al. 2009). However, web-based distribution does have its drawbacks over traditional, paper-based surveys, with some research suggesting that response rates in online surveys can be lower than equivalent paper surveys, especially amongst physicians (Beebe et al. 2007; Lin & Van Ryzin 2012; Seguin et al. 2004; Shih & Xitao Fan 2008; Truell, Bartlett & Alexander 2002). This disparity may be due to a number of issues, including restricted access to computer at work or home, misfiling of the email invitation as spam, or simply overlooking the email due to the large volume of email that many health professionals receive on a daily basis (Wright 2006).

Response rates are considered to be a key factor in the generalisability and validity of survey results (Cook, Heath & Thompson 2000). Therefore maximising response rate is a key factor in survey design. Physicians’ response rates are around 10% lower than the general population (Asch, Jedrziewski & Christakis 1997), and there is evidence that response rates are declining even further (Cull et al. 2005). Analysis of paper versus email distribution amongst physicians also suggests that different demographics respond by each method.
(Beebe et al. 2007). It would be reasonable to assume that this would be similar amongst other complementary health professionals, such as acupuncturists.

A possible solution to these low response rates and preference of mode of distribution by different demographic segments is a mixed-mode of distribution, where both web and paper-based surveys are used. Dillman (2000) suggests that by using multiple modes the researchers “provide an opportunity to compensate for the weaknesses of each method” (Dillman 2000, p. 218). This mixed-mode approach has been shown to optimise response rates amongst health professionals (Beebe et al. 2007; Greenlaw & Brown-Welty 2009; Kroth et al. 2009).

Strengths of the mixed-mode approach include an increased response rate compared with either method singularly, reduction in bias by not excluding those that are not regular internet users and those that may have missed the questionnaire due to misfiling (for example, marked as spam) (Wright 2006). The most significant limitation of this approach is the approximately six-fold increase in cost of a mixed-mode survey compared with web distribution alone (Greenlaw & Brown-Welty 2009).

A variation of the mixed-mode of distribution that can provide some of the benefit at a smaller cost is the use of a postal follow-up to a web-based survey. In this variation, initially data collection is undertaken via email invitations to a web-based survey and at the end of the collection period a single postal questionnaire is distributed to those who have not responded (Kaplowitz, Hadlock & Levine 2004; Kroth et al. 2009). Kroth and colleagues (2009) suggest that this can be an optimal method, as they believe some clinicians will only respond to paper surveys, no matter how many emails they receive, and also the appearance of a paper version gives the impression that this is their last opportunity to respond, inciting a call to action. This mixed-mode method utilising email contact with postal follow-up was chosen for this study, due to its ability to improve response rate within the constraints of the research budget.
3.7.2 Self-completed questionnaire

Four topic areas were covered in the questionnaire; gynaecological health (five questions), fertility (four questions), pregnancy (four questions), referral patterns (one question) and practice / demographic information (eight questions). The survey consisted of 22 questions, with a mixture of multiple choice, as well as open questions, allowing participants to provide more detail if desired (See Appendix A2). Participants were eligible to answer the questions on gynaecological health if they had treated any gynaecological, fertility or pregnancy related conditions in the previous 12 months; this timeframe was chosen to reduce the incidence of recall bias.

Completion time for the survey was approximately 15 minutes and consisted of seven screens or pages. The web-based survey used adaptive questioning to guide respondents to appropriate sections based on their treatment patterns in the previous year. The paper-based survey contained manual instructions on which questions to answer based on treatment patterns in the previous year. Adaptive questioning was used so that those who were eligible answered all 22 questions, while those who were not answered just nine questions. A completeness check was performed on each page when submitted to Survey Monkey to assure all questions on the page were completed.

The nine questions all respondents were asked to complete covered a range of topics about the practitioner characteristics, including demographics, years of experience, location of training and current practice, theoretical basis of practice and co-interventions offered. The remaining survey questions were designed specifically for this study. Questions to describe the acupuncturists’ treatment of gynaecological health included frequency of treatment of various gynaecological health conditions in the previous year, what treatment modalities were commonly used for each condition and referral networks used (for example, word of mouth, biomedical, CAM). Gynaecological health conditions were taken from the most recent English language TCM gynaecology
textbook (Maciocia & Kaptchuk 2011). Treatment modalities were based on the scope of TCM practice in New Zealand (Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003 n.d.) and Australia (Regulation of Practitioners of Chinese Medicine in Western Australia n.d.), with the option for participants to specify other treatment modalities. The questionnaire ended with an invitation to acupuncturists to take part in future focus groups on these conditions if they considered themselves experienced practitioners in this field. The survey was anonymous, except in the cases where practitioners volunteered their information for focus group participation.

3.7.3 Participants

The population of interest was acupuncturists that treated gynaecological health as part of their practice, in a private clinic setting and who operated under a TCM framework. Acupuncturists are not classed as “registered health professionals” in New Zealand therefore all acupuncturists operate in some form of private clinical practice, rather than within the public health system.

Acupuncture can be practiced under a variety of theoretical frameworks. Based on the number of registered practitioners, TCM is the most common theoretical framework for those practicing acupuncture in New Zealand and Australia as a primary modality, rather than an adjunct to a biomedical practice. TCM is the framework in which the researcher (MA) practices. Due to the fact that most acupuncturists are generalists (Chi et al. 1996) and records of specialisation are not recorded by professional acupuncture bodies, it was not possible to pre-select practitioners who were currently engaged in this area of specialist clinical practice. All acupuncturists were eligible provided they belonged to one of the professional bodies and were in clinical practice in the previous 12 months.
3.7.4 Sampling

Due to privacy laws, direct contact with registered members of the acupuncture professional bodies was not possible therefore the professional bodies used their internal member lists to distribute the survey via email or postal mail. The survey announcement email is included in Appendix A3. This precluded the use of any probability sampling techniques and therefore a convenience sampling method was used. Convenience sampling is a form of non-probability sampling, which uses participants who are “conveniently placed” for the obtaining of data. The limitations of this method include difficulty in calculating accurate response rates, as it is unknown how many of the potential participants actually received the invitation to participate, and difficulties in determining if the sample is an accurate cross-section of the population. Therefore care must be taken in extrapolating results of convenience samples to the population as a whole.

3.7.5 Pilot

The 22-question questionnaire was piloted on three acupuncturists in New Zealand and two in Australia. Paper copies were provided to three acupuncturists with no previous research experience, and two who were currently enrolled in higher degree research. Feedback was solicited on tone, clarity of questions and suitability of answer selection, relevance to the research question, logical flow, spelling and grammar. Based on this feedback the question order was revised, grammatical changes made and additional answer options were provided. The revised version was sent for comment, however, no further changes were considered necessary.

3.7.6 Survey administration

The web-based and paper-based questionnaires were distributed and responses collected between September 2012 and March 2013. Six months was considered to be a suitable collection period within the timeframe of the overall
research project. Response rates were monitored and collection was closed after two weeks of no new responses. No responses were received by postal mail after this date.

Emails with a link to the Survey Monkey questionnaire were distributed by the four major acupuncture professional bodies in Australia and New Zealand: the New Zealand Registrar of Acupuncturists (NZRA), the Australian Acupuncture and Chinese Medicine Association (AACMA), the New Zealand Society of Acupuncture (NZSA) and the Federation of Chinese Medicine Association (FCMA). These societies comprise the bulk of actively practicing practitioners in New Zealand and Australia who would consider acupuncture their primary practice modality, rather than an addition to a primarily biomedical practice. The survey was distributed to 3406 acupuncturists: in Australia to 2083 AACMA and 623 FCMA members, and in New Zealand to 412 NZRA and 288 NZASA members. Seventy-five New Zealand members held dual registration; this data was not available from the Australian professional bodies.

Covering letters with both email and postal questionnaires advised potential participants of completion time, purpose of the survey, university sponsorship and that returning or submitting the questionnaire was considered to constitute informed consent (see Appendix A4).

Due to the importance of high response rates in survey validity, the researcher followed advice by Dillman (2006) in “Chapter 4: Five needed elements for achieving a high response rate” (Dillman 2006). In this chapter, Dillman (2006) notes that “the questionnaire is only one element of a well-done survey” and that even an easy to complete questionnaire is not the main determinant of response rate. He places high priority on multiple contacts throughout the survey period, as this has been shown to be more effective than any other single technique in improving response rate either by mail- or email-based administration. Dillman’s (2006) recommended strategy for these multiple contacts are: a brief, positive “pre-notice” letter, distributed prior to the survey
itself, a covering letter on the questionnaire explaining its importance, a “thank you postcard” sent several days to a week after the initial survey distribution, a replacement questionnaire sent several weeks after the initial questionnaire, and a final contact, preferably by a different mode of delivery than the initial approach two to four weeks after the most recent contact. A modified version of these principles was used, as cooperation from each professional body was required for each point of contact.

Prior to survey administration, the professional bodies distributed a “pre-approach” email to inform and develop a sense of anticipation. Approximately 48 hours after the pre-approach email was sent, a further email was sent via the professional bodies that included a covering letter, containing the details of the primary investigator (MA), and a link to the Survey Monkey website. Twelve to 14 days after the initial email distribution another reminder email was sent out via the professional bodies. This was to remind those who had not yet responded that the survey was still open and that their response was valuable. A final reminder and covering letter was sent approximately 28 days after the initial email. As per Dillman (2006), this reminded practitioners of the importance of participation in research, so that all practitioners’ “voices” could be heard, and a deadline of four weeks for final responses to be received.

Those practitioners who were registered with professional bodies but did not have an email address on file had copies of the survey sent by post with a stamped, addressed envelope included. Due to the low response rate in December 2012, a postal copy of the questionnaire was sent to all 412 NZRA members in New Zealand, as previous research has shown improved response rates with a postal follow-up, compared with additional email reminders (Partin et al. 2013).

A recent Cochrane review of 481 trials by Edwards and colleagues noted a number of strategies designed to improve response rate to both electronic and postal surveys (Edwards et al. 2009). Measures used in this survey to improve
response rate that were suggested by the authors were: pre-notification, follow-up contact, mentioning an obligation to respond, giving a deadline and university sponsorship.

3.7.7 **Data management and data analysis**

Data from the web-based questionnaire was exported from Survey Monkey in Excel format and data from the paper-based questionnaire was entered directly into Excel (Microsoft Corporation, 2010). Data was coded and entered into Prism (Graphpad Inc, 2013). All usable questionnaires were included and missing data reported. Statistical analyses were carried out using IBM SPSS Statistics 21.0 (the IBM Statistical Package for the Social Sciences 14419, Chicago, IL).

Univariate descriptive statistics of demographics and practice characteristics were used to report percentage and frequencies for categorical data. Cross tabulations were generated and chi square tests used to examine differences between variables related to treatment modalities based on practice location. Where appropriate, 95% confidence intervals (CI) were reported, and p values < 0.05 were considered significant.

3.7.8 **Ethical approval**

Health and Disability Ethics Committee (HDEC) approval for New Zealand was not required due to the lack of interventional component. UWS Human ethics committee approved this study, which also covered the focus group and interview data collection (H9866). See Appendix A5.

3.8 **Focus groups and semi-structured interviews**

The aim of these focus groups and interviews was to develop a clinical trial protocol based on practitioners’ understanding of the complexities of clinical practice. Our survey data showed that treatment of primary dysmenorrhea by
acupuncture practitioners included multiple modalities, including moxibustion and diet and lifestyle advice.

The specific research questions were:

1. How is acupuncture treatment for primary dysmenorrhea delivered in clinical practice in Australia and New Zealand?
2. What components of the acupuncture treatment do practitioners believe are important for treatment success?
3. What patterns of disharmony and acupuncture points are considered vital and important in treating primary dysmenorrhea?

Focus groups and semi-structured interviews (SSI) were used to gain an understanding of how experienced practitioners embody contemporary clinical practice in the field of women’s health and most specifically in treating primary dysmenorrhea. Focus groups ideally contain between four and eight participants within each group (Kitzinger 1995). Focus groups allow the collection of a large amount of interaction in a short time, and allow observation of interaction between practitioners around particular topics, with participants encouraged to “talk to one another, ask questions and exchange anecdotes and comment on each others experiences and points of view ” (Kitzinger 1995, p. 299). Where geographical circumstances permitted, focus groups were preferred over SSI due to their level of interaction, where participants helped clarify and explore themes raised by others (Kitzinger 1995). Because of this ability to explore and clarify points of view, focus groups hold an advantage over SSI in generating depth to the data when the topic may not be something that is consciously thought about or is a matter of habit (Morgan 1997), which appears to be the case with a lot of acupuncture practice (Cochrane, Smith & Possamai-Inesedy 2011). Possible disadvantages of focus groups over SSI is the presence of dominant personalities in the group, which may intimidate or prevent others expressing their views, especially if they hold a dissenting
viewpoint. However the presence of dominant personalities is not necessarily a disadvantage per se as often these participants can ‘break the ice’ for the shyer participants (Kitzinger 1995).

3.8.1 Sampling

All participants were selected for an interview or inclusion in one of the focus groups using purposeful sampling. Purposive sampling was used based on the assumption that those with significant experience in women’s health would yield significant information and provide unique perspectives based on their experience in the field (Collins 2010, p. 357). Sixty-two practitioners indicated that they considered themselves experienced women’s health practitioners and would be interested in participating in the focus groups and/or interviews.

Due to the location of the primary investigator (MA), participants in or close to the two main centres in New Zealand (Auckland and Wellington) were selected to participate in focus groups, while those outside of New Zealand were invited to participate in “face to face” Skype interviews.

In order to ensure that the treatment protocol represented the range of treatments used in clinic by TCM practitioners of varying ethnic backgrounds in both New Zealand and Australia, in addition to the New Zealand focus groups, four European-trained and five Chinese-trained acupuncturists residing in Australia were approached to participate in SSI. These SSI were carried out via Skype.

Previous literature using “experts” to generate protocols via a Delphi Method has used a variety of definitions of expert (Cotchett et al. 2011; Guangyi et al. 2009; Smith et al. 2011a), with some researchers leaving the term undefined (Alraek, Borud & White 2011). A common position is that experts are well known in the field and/or hold suitable clinical experience in the topic under discussion; however, there is no consistent definition. The practitioners participating in interviews were self-selected as “very experienced” in the field
of gynaecology, rather than as “experts”. Since this was a design based on contemporary clinical practice, the criteria for “very experienced” was based around the principle that the very experienced practitioners either had a current private practice of more than 20 hours per week with a significant gynaecological focus, defined as more than 25% of current caseload or actively involved in researching or teaching in the area of acupuncture and gynaecology at the postdoctoral level. Current clinical practice of greater than 20 hours per week was considered an important characteristic given the emphasis on “contemporary” clinical practice and was the threshold where practitioners were considered to hold a full-time, active clinical practice. The importance of having mostly active clinical practitioners as opposed to mostly academic experts is highlighted by Alaraek who found that there was less than 30% overlap between the points selected by those identified as experts versus those chosen by practitioners themselves, and cautioned against allowing protocol development to be a purely theoretical exercise (Alraek, Borud & White 2011).

Nineteen practitioners who were located in New Zealand were invited via email to participate in a focus group in either Auckland or Wellington. Seventeen practitioners indicated interest in participating, however, due to scheduling issues and other circumstances ten practitioners participated in two focus groups of five participants in Auckland and Wellington. Those practitioners participating in the focus groups had between four and 21 years experience in treating gynaecological conditions, and all of the Wellington participants were members of the Fertility and Acupuncture Childbirth Team (www.fact.net.nz)

Initially Australian participants located in or around Sydney were invited to a focus group, in a similar manner to those in Auckland and Wellington. However, due to logistical problems of the primary investigator (MA) only being available in Sydney on very limited dates and most practitioners unable to meet in a central location, this focus group was abandoned after several attempts at changing location and timing. Due to these logistical issues and difficulties in contacting many of the practitioners, potential Skype interviewees were
suggested by members of the supervisory panel (CS) and (XZ) as being very experienced in the practical field of women’s health and also holding an interest in research. Four of these participants had also indicated interest in participation via the survey in Phase One.

3.8.2 Practitioner data forms: patterns of disharmony and acupuncture point selection

In addition to the discussion on various practical and theoretical aspects of delivery of treatment in cases of primary dysmenorrhea, information on diagnosis and treatment was also necessary for protocol development. A variety of textbooks on women’s health in English and Chinese were used to provide a range of patterns of disharmony (See Appendix A1). Patterns of combined Qi / Blood stagnation were left separate as the protocol had allowances for two concurrent patterns. Patterns with different names but very similar symptoms were combined as naming conventions varied between Chinese and English textbooks. A practitioner sheet summarising these patterns and points was created from the combined textbook data (see Appendix A7).

Prior to the focus group or interview, all participants filled in the practitioner data sheet which asked participants to:

- Rank the importance of the symptoms in each pattern of disharmony from 1–5 (5 being the most important).
- Provide an indication (frequently, occasionally or never) of how often they saw that pattern of disharmony in clinic.
- Select from a list of points that were the most important points for treating each pattern of disharmony. As many points as practitioners thought necessary could be selected and space was provided to enter their own points.
- Provide information on whether moxibustion was indicated in this pattern.
3.8.3 Interview schedule for focus groups and interviews

A broad focus on acupuncture for the treatment of primary dysmenorrhea was the starting point, and subsequent sub-topics relating to this overarching idea were explored. An interview topic guide containing open-ended questions was used to ensure that all specific areas of interest were covered. Participants were encouraged to draw on their own experience in treating primary dysmenorrhea in clinical practice to answer all questions. Topics covered included barriers to treatment, ideal treatment frequency, needle retention time, use of co-interventions, importance of diet and lifestyle advice and styles of needle stimulation. Examples of specific questions included: How long would you retain needles in treating dysmenorrhea and what factors influence that decision? In your clinical experience how many treatments are usually necessary to see a significant improvement in dysmenorrhea?

All focus group questions were designed to encourage discussion and similar versions of the questions were prepared for the SSI. Focus groups lasted approximately 90 minutes and were digitally recorded. Focus group data was transcribed and analysed thematically, and any divergent viewpoints noted and incorporated into the question sheet for the SSI to provide further clarification. Appendix A8 contains the focus group and practitioner interview question sheet.

3.8.4 Data analysis

Both focus groups and SSIs were digitally recorded and transcribed by AdeptSTS (www.adepsts.co.nz) into MS Word format documents. NVivo (NVIVO 10) was then used to undertake line-by-line coding. Thematic analysis, according to Braun (2006), is “a method for identifying, analysing and reporting patterns (themes) within data” (Braun & Clarke 2006, p. 79). Thematic analysis is commonly used in qualitative research, but often not specifically named or acknowledged as such. However, unlike many other qualitative research
techniques, such as discourse analysis, thematic analysis is not “wedded” to any particular theoretical framework and therefore fits well within a pragmatic worldview. Thematic analysis was used to report themes in data after each dataset was transcribed. Reflexive memos were used and negative cases examined. Quantitative components were also extracted from the transcripts, including consensus on needle retention time, treatment frequency and consensus on diet and lifestyle advice. Data from the practitioner data sheets were entered into Excel and analysed using descriptive statistics.

After each interview, preliminary thematic analysis was carried out using the constant comparative method described by Bowen (Bowen 2008) to determine if any new codes or themes were present. Bowen (2008) notes that the process for determining saturation is “nebulous” and a lack of explicit guidelines in the literature is problematic. Guest and colleagues (2006) concur and note there is little in the way of guidelines to determine sample size for interviews using techniques like purposive sampling (Guest, Bunce & Johnson 2006). Both Bowen (2008) and Guest (2006) use similar definitions of saturation; new data being added does not add any new codes or themes to the existing data and no new insights are provided, in effect saturation reflects the point of diminishing returns. Saturation in this sample was noted after 19 participants, with no new codes being applied to the data and no new themes emerging from data at this point.

Practitioner data sheets were used to provide data on symptom importance, use of moxibustion and point selection. Symptoms were ranked using the median score given by practitioners. A 70% or greater consensus was required for moxibustion and for the selection of “compulsory” points. 70% was chosen as an appropriate level, as this was over the two-thirds agreement level and the highest level of consensus that provided the minimum number of points needed to develop the protocol. Any points that were selected by greater than 25% of

5 In some of our protocol sheets these were referred to as “vital” points.
practitioners were considered as optional points, to allow more flexibility within point choice, while still removing points that were not considered to be “commonly” used. Constraining point selection within a reasonable number of choices was important as a large number of points would have introduced considerable variation and made the effect of timing or stimulation less pronounced.

3.9 Factorial designed RCT: the effect of timing and mode of stimulation in acupuncture treatments on primary dysmenorrhea

The aim of this study was to determine the effect of changing the frequency, timing and mode of stimulation of acupuncture treatments on menstrual pain and other menstrual symptoms in women with primary dysmenorrhea.

The specific research questions included:

1. Does using a manualised protocol to deliver acupuncture treatment change self-rated menstrual pain scores?
2. What extent, if any, do differing frequencies of treatment and types of stimulation contribute to changes observed in (1)?
3. Does the manualised acupuncture intervention alter the frequency of secondary symptoms of dysmenorrhea?
4. Are more frequent acupuncture treatments an acceptable intervention for participants?
5. Is electro-acupuncture an acceptable mode of stimulation?

There were two primary hypotheses for this study:

1) High-frequency acupuncture would have the greater effect on reducing menstrual pain compared to a low-frequency acupuncture treatment, and
2) Electro-acupuncture would have the greater effect on reducing menstrual pain compared with a manual acupuncture treatment.

The secondary hypotheses were:

3) High-frequency acupuncture would have a greater reduction in medication use and increase health-related quality of life (HRQoL) compared with a low-frequency acupuncture treatment, and

4) Electro-acupuncture would have a greater reduction in medication use and increase health-related quality of life (HRQoL) compared with a manual acupuncture treatment.

### 3.9.1 Study design

The study was a 2x2 factorial study. The rationale for this design is discussed below.

### 3.9.2 Group design

The four-group factorial design was established to test the individual and combined effects of changing 1) treatment timing and 2) mode of stimulation. A factorial design was chosen as it allows testing of multiple hypotheses in one experiment, by manipulating factors between subjects. This allows testing of real world conditions, and accounts for variation in acupuncture in relation to timing and type of stimulation, rather than one or the other. In addition, it allows examination of any possible interaction between timing and mode of stimulation.

The four groups were:

- High frequency, manual acupuncture (HF–MA)
- High frequency, electro acupuncture (HF–EA)
- Low frequency, manual acupuncture (LF–MA)
- Low frequency, electro acupuncture (LF–EA)
3.9.3 Rationale for a pragmatic study

Randomised controlled trials are considered the “gold standard” in terms of determining causality, in part due to their ability to remove confounding factors, reduce selection bias and systematic error, therefore reducing threats to internal validity (Kaptchuk 2001). However, the external validity, or generalisability of the trial to the population of interest, is dependent on the approach used in the trial design, chiefly whether the trial favours an efficacy (does the intervention work?) or effectiveness (how well does the intervention work in clinical practice?) design (Zwarenstein et al. 2008). This choice of approach should be tied intimately with the research question itself; if one is interested in evaluating clinical effectiveness of a therapy then favouring effectiveness or “pragmatic” design is more appropriate (Macpherson 2004).

Zwarenstein and colleagues (2008) note that the attitude or approach to trial design is not one of a dichotomy, where either an explanatory or pragmatic attitude must be chosen, but rather trials fall upon a continuum between the two. In acupuncture research efficacy designs are often best suited to early phase trials, where biochemical or physiological changes of specific points are being tested. When evaluating a complex intervention or “package of care,” such as TCM acupuncture, a design slanted towards the pragmatic / effectiveness end of the continuum is more appropriate and increases the ecological validity of the outcome (Macpherson 2004). This emphasis on pragmatic design and a focus on comparative effectiveness (Aickin 2010), so that research is able to inform clinical practice, has been echoed in recent position papers by acupuncture (Langevin et al. 2011; Napadow et al. 2008; Wayne et al. 2009) and CAM (Fønnebø et al. 2007) researchers as well as acupuncture practitioners (Kaptchuk, Chen & Song 2010; Robinson et al. 2012).

This study uses a pragmatic design with some qualifications, including the use of a manualised acupuncture protocol designed to reduce the amount of variation between practitioners. This allows a balance between removing
excessive inter-practitioner variation and still encompassing the complex nature of TCM clinical practice.

CONSORT guidelines (www.consort-statement.org), with extensions added for pragmatic trials as detailed by Zwarenstein (Zwarenstein et al. 2008), were used for reporting trial design and flow. Acupuncture-specific reporting in this trial follows the revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (MacPherson et al. 2010)

3.9.4 Participants

Inclusion criteria

Women with suspected or confirmed primary dysmenorrhea as defined by the following:

- Age 18–45 years.
- History of period pain beginning before the age of 18, or period pain beginning after the age of 18, but gynaecological investigations by laparoscopy and / or ultrasound scan show no evidence of secondary dysmenorrhea.
- Pain greater than or equal to 3 out of 10 on a numeric rating scale during the first three days of menses for at least two of the past three menstrual cycles.
- Regular menstrual cycles (28 +/- 7 days) for the last three months.

6 The inclusion criteria went through two revisions (approved by NZ HDEC and UWS Human Ethics) to clarify the age when period pain first began. Originally this was within two years of menarche, however, many women could not remember precisely due to the time that had passed. Second revision added the exception that women with a negative laparoscopy and / or ultrasound were eligible, independent of age of first experiencing the pain.
• Understands spoken and written English.
• Able to give informed consent.

**Exclusion criteria**

• Previous diagnosis of endometriosis or secondary dysmenorrhea.
• Abdominal surgery in the previous three months.
• Injectable or implant contraceptives (Depo Provera, Jadelle, Murina) within the last three months.
• Oral contraceptive usage started less than three months prior to enrolment.
• Chronic pain conditions (>14 days per month with pain).
• Current mental health illness.
• Neuropathic pain secondary to surgery.
• Sterilisation.

**3.9.5 Recruitment**

Women with primary dysmenorrhea have two common factors which influence recruitment; they were likely to be under the age of 25 (Burnett et al. 2005; Tavallaee et al. 2011; Zahradnik, Hanjalic-Beck & Groth 2010) and were unlikely to have discussed their condition with their general practitioner or primary healthcare provider (Banikarim, Chacko & Kelder 2000; Campbell & McGrath 1997; O’Connell, Davis & Westhoff 2006; Wong 2011).

This younger population has been shown to be difficult to engage in health research due to age-related social changes, such as beginning of tertiary study, with many younger adults feeling significant time constraints (Faden et al. 2004). Previous research on other interventions with younger Australian women in a community setting noted that recruitment via “traditional” means, such as letter drops, media advertisements and letters to health professionals, resulted in poor recruitment rates (Griffin et al. 2013; Leonard et al. 2014). In contrast, Facebook and other social media have been used successfully in
Australia to recruit this younger (<25) population to health research and to do so on a limited budget (Fenner et al. 2012; Leonard et al. 2014).

Eighty percent of all households in New Zealand have access to the internet and 93–94% of 15–34-year-olds have internet access, the highest of any New Zealand demographic (*Household Use of Information and Communication Technology: 2012* n.d.). Facebook is the most popular social networking site with over 720 million active users daily (*Facebook: company information* n.d.), with approximately 75% of all internet users under 25 years of age having social network profiles (Correa, Hinsley & De Zuniga 2010). Use of social networking sites is the number one online activity for 16- to 29-year-olds (Anonymous 2010). Exact age data for New Zealand is not available, however, a 2011 report suggests 65.6% of women had a Facebook profile and spent around four hours per week on Facebook (*University of Auckland: How many people use Facebook in New Zealand?* n.d.), with 61% of users checking Facebook at least once per day (*UMR Research: Social Media in New Zealand 2012* n.d.). This suggests that the internet, and specifically social media, has a large pool of potential participants in the target demographic for primary dysmenorrhea. However, it would be imprudent to ignore other avenues that have shown previous success with younger adults such as email lists, flyers and posters (Griffin et al. 2013; Leonard et al. 2014).

**Internet and social media**

Due to the above considerations of the likelihood of the population of interest being significant consumers of social media, and internet users in general, a Facebook advertisement and Google Ad-words ad were created in conjunction with the UWS social media committee. Both of these linked the participant with
the UWS study website\textsuperscript{7} which provided more information and the contact details of the researcher (MA).

Facebook advertisements were targeted to women, aged 18–45 years living within 60 miles of Auckland and Wellington, New Zealand. Sixty miles was chosen as a suitable radius as it was considered unlikely that women outside this distance would be happy to travel in for treatment if randomised to either of the high-frequency groups. Several women from the outer regions of Auckland, who enquired about the study, did not participate due to the travel involved. Therefore this radius seems appropriate.

Google Ad-words ads were brief and linked to a list of keywords centred around searches for period pain. See Appendix A9 for a list of keywords used and an example of the ads generated.

Finally, a Facebook group\textsuperscript{8} was created to allow women to learn more about the study either before or after contacting the primary investigator (MA) and to post updates about the study. In addition to the Facebook advertisement using techniques suggested by Bhutta (Bhutta 2012), owners of other Facebook groups whose members were likely to have interest in this study were contacted via private message, in which the was study briefly explained and a request made to re-post the link to the study website on their Facebook page. Possibly due to the notion that period pain was “normal,” there were very few specialist groups for primary dysmenorrhea, in contrast to groups for secondary dysmenorrhea, which would support sufferers of polycystic ovary syndrome or endometriosis for example. Nevertheless, several groups reposted the invitation to participate included The Period Pain Guru

\textsuperscript{7}http://www.uws.edu.au/complemed/clinical_trials/acupuncture_treatment_for_period_pain_clinical_trial

\textsuperscript{8}https://www.facebook.com/groups/acuperiodpain/
Poster and flyer distribution

Many younger women in New Zealand use the services of family planning, due to their low costs, including free consultations for under-22 year olds. Family planning provides advice on contraception, sexual health and menstrual issues and was therefore a likely source of younger participants who were actively seeking advice on gynaecological problems. Posters advertising the study (see Appendix A10) were placed in family planning clinics in central Wellington and a satellite clinic in Lower Hutt. DLE sized flyers with information on the trial and the contact details of the primary investigator were distributed via administration staff and doctors to patients presenting with the symptoms of primary dysmenorrhea. Auckland family planning clinics were running a study on the treatment of primary dysmenorrhea at the time of recruitment and declined to place the posters over concerns of confusion between the studies.

Email distribution

The Faculty of Medicine and Health Science (FMHS) at the University of Auckland agreed to distribute a brief description of the study and a link to the study website via their “junk mail” list, which is distributed to all FHMS staff, including higher degree research students. This email was sent on three occasions with four-week intervals in between each distribution.

3.9.6 Screening

Upon contacting the primary investigator, women were screened by a brief interview over the telephone or in person, dependent on their preference. Screening consisted of questions related to age of menarche and subsequent age
of the onset of period pain, severity of pain, duration of menstrual cycle, prior diagnosis of secondary dysmenorrhea and contraceptive status.

Women were then instructed to fill in a menstrual pain diary during their next menstrual period and this was assessed to confirm the presence of cycle length, pain levels and pain characteristics indicative of primary dysmenorrhea.

Baseline data was collected on age of menarche, menstrual cycle length, age of appearance of dysmenorrhea, contraceptive usage, smoking status, obstetric history, usage of pain-relieving medication, other non-pharmaceutical interventions used for pain relief, current medications and previous usage of acupuncture.

Consent was given in writing and returned via post, or scanned and emailed to the researcher. Consent was obtained after initial telephone screening, but prior to completion of baseline menstrual pain diary and baseline data. Menstrual pain diary and baseline data were assessed to confirm eligibility before randomisation occurred.

Women who were not eligible for the study were advised via email or phone call and had the reason for ineligibility recorded.

3.9.7 Randomisation

Randomisation was computer generated and allocation was concealed by way of an internet-based randomisation service, Sealed Envelope (www.sealedenvelope.com). Randomisation into one of four study groups was done via web access by the primary investigator (MA).

3.9.8 Sample Size

Due to the inherent time and financial constraints within a PhD, this study was designed as an exploratory pilot study, to determine if there is any evidence for differences in timing or mode of stimulation which would warrant a full scale
RCT. Data from this pilot study would also provide vital information for power calculations and therefore sample size required for this larger study.

3.9.9 **Manualised acupuncture protocol**

Previous acupuncture research has sometimes found it difficult to achieve a balance between a “tight” and “loosely” defined intervention, so that the intervention still reflects the individualisation of treatment inherent in TCM clinical practice, while allowing enough standardisation across practitioners to protect the internal validity of the trial (MacPherson & Schroer 2007).

Schnyer and colleagues (2002) developed the idea of a manualised protocol to achieve this balance, providing a framework that allows practitioners to individualise treatments within specific guidelines. This style of manualisation has been successfully used in previous acupuncture trials to “distil” expert advice into a form that allows both individualisation and reproducibility (Macpherson et al. 2012; Schnyer & Allen 2002; Schnyer et al. 2006; Schnyer et al. 2008). Manualisation allows the exploration of individual contributions of frequency and stimulation style by reducing the variation present in the trial, while still staying faithful to the theoretical framework that underpins TCM acupuncture, an important consideration in evaluating complex interventions (Paterson & Britten 2004; Paterson & Dieppe 2005).

The researcher (MA), using data from the survey, focus groups and semi-structured interviews, developed the protocol for this study. Aspects of the protocol that were determined from this data were: frequency of treatment, needle retention time, importance of DeQi, patterns of disharmony, use of moxibustion and point selection. Aspects of the protocol that were not derived from previous phases were: use of electro-acupuncture as a comparator and the use of personalised diet and lifestyle advice. The use of electro-acupuncture and personalised diet and lifestyle advice were used to answer unresolved questions in the literature outlined in Chapter Two, this reasoning is discussed along with
protocol development based on the findings from the survey, focus groups and
interviews in Chapter Four.

Multiple patterns of disharmony are common in dysmenorrhea (Liu et al. 2012)
and this trial supports up to two concurrent patterns of disharmony, designated
as root (primary) and secondary (branch) patterns.

The overall treatment framework is presented, with specifics described in
Chapter Five. Treatment was based on TCM's eight principles and Zang Fu
diagnosis. Once a TCM diagnosis had been ascertained, the practitioners had the
flexibility with their point selection to address the diagnosed pattern of
disharmony as per the treatment handbook. Each pattern had a selection of
“compulsory” points that were identified by the experienced practitioners in
Phase Two, as being key to the treatment outcome for each pattern. If the
patient presented with one (root) pattern, then three points from the
compulsory category were selected based on the acupuncturist’s clinical
judgement. If the clinical presentation was complex, an additional, other four
acupuncture points could be selected from the compulsory or optional category.
If the patient presents with two patterns concurrently then, if possible, three
points were chosen from the compulsory category common to both patterns. If
this was not possible then two points from each pattern’s compulsory category
were chosen. If clinically warranted, an additional four points could be selected
from the compulsory or optional category from either pattern. In all cases no
more than seven acupuncture points were to be used (Figure 3.2). The protocol
contains optional points on the bladder channel that runs on the posterior
surface of the body. As all of the compulsory points are on the anterior surface
of the body, these cannot be needled simultaneously. If the practitioner wished
to use these bladder channel points, they needed to split the treatment into two
parts: one containing the points on the anterior surface, and one on the
posterior surface. Each needed to last at least ten minutes for a total time of no
less than 20 minutes.
DeQi is obtained for each acupuncture point. Acupuncture points were needled bilaterally, except those where only one side was used clinically, such as opening extraordinary vessels such as the Chong Mai (Maciocia & Kaptchuk 2011). Point location and needling depth was as specified in *A Manual of Acupuncture* (Deadman, Al-Khafaji & Baker 1998). The study practitioners maintained a case report form detailing all aspects of treatment provided, including co-interventions such as moxibustion. Single use, stainless steel needles of varying gauge (.20 x 30mm or .25 x 40mm, DongBang, Korea) were used. Needles were retained for 20–30 minutes.

Each pattern also has moxibustion as a compulsory, optional or forbidden component of the treatment. Indirect moxa was administered via smokeless moxa stick. The moxa stick was held approximately 2–3cm away from the skin over the designated acupuncture points, as per standard acupuncture texts (Maciocia 2005; Maciocia 2008). Moxibustion was used for 7–10 minutes or until the participant was no longer comfortable with the sensation of warmth.
Herbal medicine or additional supplementation was not to be provided by practitioners during the trial. Each subsequent treatment session would allow for a confirmation or update on the TCM diagnosis and therefore point selection could vary from treatment to treatment.

After the conclusion of three menstrual cycles, there was an approximately one-month follow-up period, ending on the completion of the subjects’ subsequent menstrual period.

Each patient was given a diet and lifestyle advice sheet during their first treatment session. While the importance of individualised diet and lifestyle advice was discussed in Phase Two and reported in Chapter Four, not enough information was provided by practitioners to form diet and lifestyle sheets for each specific pattern of disharmony. Therefore these sheets were compiled by the primary investigator (MA) from recent acupuncture texts on women’s health (Lewis 2008; Maciocia & Kaptchuk 2011). These were grounded in TCM theory on the nature of food, and also gave advice on lifestyle components, such as sleep recommendations and stress reduction. Each pattern of disharmony had a separate sheet, these included: Qi stagnation, Blood stasis, Stagnation due to cold, Damp-heat, Liver fire, Liver and kidney Yin deficiency, Qi and Blood deficiency and Yang and blood deficiency. These sheets are provided in Appendix A11. In the case of multiple patterns, the sheet for the primary pattern was provided, however, additional sheets could be provided in the event that the patient’s pattern of disharmony changed over the course of treatment.

The protocol manual and case report forms also conform to the guidelines set out by Smith and colleagues (2011), who discuss the importance of reporting different components of the acupuncture treatment (Smith et al. 2011a).

3.9.10 Treatment schedule

All women in the study were scheduled to receive 12 treatments over the course of three menstrual cycles.
• Women in the high frequency (HF) group received three treatments in the seven days prior to the estimated day one of the menstrual cycle.

• Women in the low frequency (LF) group received three treatments in the time between menses, approximately every seven to ten days dependent on cycle length.

Both groups received a treatment in the first two days of menses (day one or day two of the menses).

Initial consultations were allocated 60 minutes, with follow-up consultations of 45 minutes duration, including a 20–30 minute treatment intervention in each session.

3.9.11 Practitioner training and quality control

All three study practitioners (including the researcher [MA]) in the study were registered members of the New Zealand Register of Acupuncturists with a minimum of four years’ clinical experience. All complied with both ethical and skin penetration guidelines outlined by the New Zealand Register of Acupuncturists. Practitioners undertook a two-hour training course with the researcher (MA) prior to treating their first participant. This training covered appointment timing, key differential diagnosis points, needle insertion, electro-acupuncture training and the delivery of lifestyle and diet advice. All three study practitioners used electro-acupuncture on a regular basis in their normal clinical practice, with one practitioner teaching the use of electro-acupuncture to undergraduate acupuncture students. Each study practitioner was observed by the researcher (MA) treating a study participant during the treatment period to check for protocol compliance.

3.9.12 Treatment group: manual acupuncture

Sterile, single-use needles (Dongbang, Korea) in either .20x30 or .25x40 gauge were used. A minimum of three and a maximum of seven acupuncture points
were used. Needles were inserted to a depth as per standard texts (Deadman, Al-Khafaji & Baker 1998), until DeQi sensation was obtained. All needles were stimulated by hand using tonifying, reducing or even method, based on the practitioner’s clinical judgement approximately 10–15 minutes after needle insertion was completed.

3.9.13 Treatment group: electro-acupuncture

Sterile, single-use needles (Dongbang, Korea) in either 0.20x30 or 0.25x40 gauge were used. A minimum of three and a maximum of seven acupuncture points were used. Needles were inserted to a depth as per standard texts (Deadman, Al-Khafaji & Baker 1998), until DeQi sensation was obtained. Two distal points (from the previously chosen point prescription) were selected by the practitioner and a 2Hz / 100Hz square wave pulse of 200ms duration was applied between each point for 20 minutes using an ITO ES-160 electro-acupuncture machine (Ito Co. Ltd, Japan). Intensity level was based on patient feedback; noticeable sensation present, but below the threshold for discomfort.

3.9.14 Endpoints

Primary endpoints

- Reduction in peak menstrual pain (0–10) on days one, two and three of the menstrual period at one, two, three and four months from trial entry.
- Reduction in average menstrual pain (0-10) over the whole of the menstrual period at one, two, three and four months from trial entry.

Secondary endpoints

- Duration of menstrual pain (in hours) as recorded in the menstrual pain diary at one, two, three and four months from trial entry.
- Worst menstrual pain as measured on a 0–10 NRS (a postori).
• Analgesic medication intake at one, two, three and four months from trial entry.
• Days taken off work/school at one, two, three and four months from trial entry.
• Number of secondary menstrual-related symptoms, such as bloating, breast tenderness and nausea at one, two, three and four months from trial entry.
• Changes in health-related quality of life, as measured by the SF-36 at four months from trial entry.
• Self-rated symptom improvement score recorded in the post-trial exit questionnaire measured at three months post trial entry.

3.9.14 Data collection tools

Trial entry form (See Appendix A13):

This was developed by the researcher (MA), in conjunction with supervisors (CS and CF). This was used to collect baseline data on demographics, history and severity of period pain, as well as factors that are known to influence period pain. Data on weight and height was collected to allow calculation of BMI. Menstrual history questions were asked, including age of menarche, age of onset of pain, cycle length and length of menses. Data was collected on social factors, such as smoking (including number of cigarettes per day) and alcohol consumption (number of drinks per week), as well as obstetric history (number of births). Information on current medications (including supplements and herbal medicines) used on a regular basis was collected via an open question. Typical symptoms of primary dysmenorrhea experienced were collected via a tick box and included both physical (such as breast tenderness) and emotional symptoms. Participants were also asked about use of pain relieving medications and their effectiveness in reducing their period pain (pain completely gone, pain reduced or pain stays the same). If participants did not use pain relief, they were asked for reasons they chose not to use pain-relieving medications. Adjunct
non-pharmacological therapies used were also investigated, including the use of rest, exercise and herbal medicines. Finally expectation of improvement via acupuncture was measured via a five-point Likert Scale (Definitely won’t help, probably won’t help, unsure, probably will help, definitely will help).

**Menstrual pain diary (See Appendix A14)**

This was developed by the researcher (MA), in conjunction with supervisors (CS and CF). This was used to assess the changes in pain, analgesic intake, menstrual characteristics and secondary symptoms, and allowed women to self-rate the severity of their dysmenorrhea in both intensity and duration of pain, as well as the presence of secondary symptoms. The primary data endpoint used an 11-point numerical rating scale (NRS) for both “peak” and “average” pain each day, with 0 being no pain and 10 being the worst pain imaginable. NRS was used in preference to visual analogue scale (VAS). The NRS is comparable in sensitivity to the VAS (Bijur, Latimer & Gallagher 2003; Bourdel et al. 2015), but has a higher compliance rate, is easier to use, preferred by chronic pain patients and fits the compact format of a menstrual diary (Hjermstad et al. 2011).

The diary also collected information on menstrual characteristics, including flow (heavy, medium, light, spotting) and presence or absence of clots, duration of menstrual pain each day (hours or “all day”), secondary menstrual symptoms, including presence or absence of breast tenderness, nausea etc., analgesic usage (brand / pharmaceutical name, dosage and number of doses per day), non-pharmaceutical therapies used (rest, hot water bottle / wheat pack), absence from school or work and also any other notes the participant deemed important.

The diary was completed by the participant at the conclusion of the day during either the menstrual period itself or one to two days prior to the menstrual period if they were experiencing sharp, stabbing, cramping or aching pain in the lower abdomen or lower back that they would normally associate with their
period. The menstrual pain diary was chosen over other alternative measures for two reasons:

1) It was suitable to be administered in paper and web-based format. This was an important consideration as the target population of younger women prefer web-based or smartphone-based data collection to traditional, paper versions (Hutchesson et al. 2015).

2) Completion took less than two minutes each day of the menstrual cycle, so participants were not overly burdened by data collection. This was a concern expressed by many women prior to study participation.

**SF-36**

The SF-36v2 is a health-related quality of life questionnaire that examines health across eight domains: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health. The SF-36 has been shown to be valid and reliable across a broad demographic, with women being high responders (Brazier et al. 1992), and has previously shown suitability for use in dysmenorrhea (Unsal et al. 2010). Importantly, other research on the use of acupuncture to treat dysmenorrhea has used the SF-36 as a secondary outcome measure, therefore allowing comparison of outcomes with other studies (Smith et al. 2011; Witt et al. 2008). The SF-36v2 was administered at baseline, prior to the first acupuncture session, and again at one-month follow-up, post-trial completion. The participant filled in the questionnaire without assistance from the acupuncture practitioner.

**Post-trial questionnaire (see Appendix A15)**

The researcher (MA), in conjunction with a supervisor (CS), designed this questionnaire. Its purpose was to capture the experience of the participants as part of the clinical trial, and was completed within seven days of the final acupuncture treatment session. The questionnaire includes questions on
components of the trial they enjoyed and thought were beneficial, or did not enjoy and thought were detrimental, self-rated overall symptom improvement scores using a NRS, likelihood of recommendation to others, as well as free text sections to describe any symptom improvement, opinions on components of treatment, relationship with acupuncturist and overall experience in the trial. This was administered at the conclusion of the third menstrual period after the final treatment session.

3.9.15 Data management

Data analysis was undertaken by the researcher (MA), with guidance from a statistician and supervisor (CS). Baseline, menstrual pain diary and post-trial questionnaire data was captured using a Google Docs spreadsheet, exported in Excel format and entered into SPSS where necessary. In cases where these forms were filled in on paper, the researcher entered them into Google Docs before export. This provided consistency between written and digitally entered data.

SF-36 forms were coded and norm based scoring was used (Ware et al. 2008) via the QualityMetric Health Outcome Scoring Software (version 2.0). SF-36 data was checked for quality prior to analysis for out of range responses, missing items and multiple responses per item.

3.9.16 Statistical analysis

Data analysis used descriptive statistics and inferential statistics to examine the demographic and baseline characteristics. Age, BMI, age of menarche, analgesic usage, expectation, smoking and alcohol status, peak pain on day one, two, and three, average pain and SF-36 scores were compared between groups at baseline using one-way ANOVA to ensure randomisation was successful. Differences at baseline are reported as means and standard deviations or frequencies and percentages. The analyses of the endpoints used an “intention
to treat” approach. Missing data was imputed using last observation carried forward (LOCF).

On advice of a biostatistician, a mixed model repeated measures analysis of co-variance (ANCOVA) was used for pre- and post-intervention comparisons for peak, average and worst menstrual pain, changes in number of secondary symptoms, duration of pain and amount of analgesic medication consumed. ANCOVAs have been used previously for examining the outcomes of period pain (Smith et al. 2011; Witt et al. 2008). A McNemar test was used for changes in non-pharmaceutical interventions and absenteeism. Patient acceptability outcomes were compared between groups using Fishers Exact. Number of treatments per group and safety data were analysed using Mann-Whitney. All p values <.05 were considered significant.

**3.9.17 Blinding of participants and researchers**

Participants were not blinded to group allocation. Data entry was undertaken blind to the study group, and analysis was undertaken by the primary investigator (MA) blind to group allocation.

**3.9.18 Ethics approval**

Both UWS Human Ethics Committee (H10082) and the HDEC New Zealand (13/CEN/60) approved this study. Maori approval was also obtained along with locality assessments for Auckland and Wellington. Approvals attached in Appendix A16

This approval also covered the semi-structured interviews that were undertaken post-trial.
3.10 Participant semi-structured interviews

Semi-structured interviews of women who participated in the RCT phase were used to explore the experiences of women who took part in the trial. The specific research questions were:

- What were participants’ experiences of participating in the clinical trial?
- What, if any, benefits or changes in their symptoms did they experience after participating in the trial?
- Did participants in the study find the diet and lifestyle advice useful, did they implement any of the advice and what effect did they think it had?
- Where did women who participated in the study get advice on period pain prior to being in the trial?
- Did the TCM explanation of period pain change the way participants viewed their symptoms?
- Did the study participants view period pain as “normal” or “abnormal” prior to being in the trial and had that view changed?
- Did the study participants find the acupuncture treatment as acceptable intervention in terms of comfort, logistics and possible financial cost?

3.10.1 Sampling

Women from both sites (Auckland and Wellington) were offered the opportunity to participate in the interviews. Purposive sampling was then used on the sample of women who consented to interviews based on their group allocation and the self-rated effectiveness score in the exit questionnaire.

An equal proportion of women who rated the trial as having an effectiveness of >5/10 and those rating it as having an effectiveness of <=5/10 across all four groups and both sites was thought to be diverse enough to examine any differences in how the experience of the trial differed amongst women who did
or did not respond to the treatment, especially in relation to the areas of uptake and effectiveness of the diet and lifestyle advice.

Twelve women were interviewed in the order they finished the trial (four from Wellington, eight from Auckland) until saturation was achieved, defined as coding of new interviews that did not increase the number of codes and when no new themes emerged. The number of women from each site were chosen to represent the 40%/60% geographical split in participants, and to ensure each site was represented in proportion to its contribution to overall results in the RCT.

### 3.10.2 Interview guide

A written question guide was used in these interviews and asked participants to share their experience of receiving acupuncture for period pain. Participants were encouraged to explain in their own words the experience in the trial, and if it had changed their perceptions of health and wellbeing. A specific focus was placed around the uptake of diet and lifestyle advice, as previous SSI and focus groups with acupuncturists had stressed its importance in a positive treatment outcome. Specific questions included: How did you use the self-care advice you were given? Before participating in this study, whom had you talked to or got advice from about your period pain? Did your view of your period and the symptoms change between the start and end of the trial?

See Appendix A17 for the complete question list.

### 3.10.3 Interview format

The interviews were conducted via Skype by either an independent researcher with a background in acupuncture and experience in conducting qualitative interviews for those women who located in Auckland, and by the primary investigator (MA) for those women who were located in Wellington. The researcher (MA) only treated women in Auckland and did not interview any
participant where he had administered treatment. Interviews were conducted over approximately 30–45 minutes and were recorded on the interviewer’s computer before professional transcription was carried out.

3.10.4 Data analysis

The SSI were digitally recorded and transcribed by Night Owl Transcriptions (www.nightowltranscriptions.com.au) into MS Word format documents. NVivo (NVIVO 10, QSR International) was then used to undertake line-by-line coding. Thematic analysis (Braun & Clarke 2006) was used in a similar manner to the practitioner focus groups and interviews. Thematic analysis was used to report themes in the data after each dataset was transcribed. Reflexive memos were used and negative cases examined.

After each interview, preliminary thematic analysis was carried out using the constant comparative method described by Bowen (Bowen 2008) to determine if any new codes or themes were present. Saturation in this sample was noted after 12 participants, with no new codes being applied to the data and no new themes emerging from the data at this point.

3.11 Summary

This chapter outlines the methodology used in each of the four phases of this MMR PhD. The pragmatic paradigm underlies all four stages and allows for integration both at the conclusion of each phase and in the final analysis, where meta-inferences will be discussed.

Chapter Four outlines the first two of these four phases: the results of the practitioner survey and subsequent focus groups and semi-structured interviews with practitioners who are experienced in the treatment of women’s health conditions.
Chapter Four: How acupuncturists treat dysmenorrhea in clinical practice: findings from a survey, focus groups and semi-structured interviews

This chapter will present the findings from of a survey of practitioners from New Zealand and Australia, represented by two focus groups in New Zealand (comprising of ten practitioners, with five in each group) and nine semi-structured interviews with practitioners based in Australia. The methods related to this study have been described in Chapter Three.

4.1 Survey of New Zealand and Australian acupuncture practitioners

This survey data was collected as part of a larger survey on broader aspects of women’s health, which included pregnancy and fertility. Only questions on aspects of gynaecological health, which were designed by the investigator (MA), are reported here, except where comparison is data is needed.

4.1.1 Demographics and responders

A total of 377 questionnaires were returned, giving an overall response rate of 11.3%; country-specific response rates were 19% (95% CI 16.1 to 22.3) in New Zealand (119), and 6.9% (95% CI 5.6 to 7.4) in Australia (188), (p<0.05). Comparing the characteristics of our Australian and New Zealand study population with the demographic profile of practitioners held by two New Zealand associations, we found a greater proportion of female respondents from New Zealand (p=0.0007). Early and late responders were compared with no significant differences (p>0.05) in demographics.
Of all responders, 66% were women and the majority were aged over 35 years (see Table 4.1) and 60% of respondents were currently practising in Australia. Most respondents had been in practice for ten to 20 years. Traditional Chinese Medicine (TCM) was the most common theoretical framework used in clinical practice, with 90.6% of responders using it. Australia was the most common acupuncture training location (61.7%), followed by China (27.9%), and New Zealand (26%), with the majority of Australians (91.4%) and New Zealanders (67.2%) undertaking training in their own country. There was no significant difference in practitioner demographics between Australia and New Zealand.

Acupuncture was the most common modality practised and was offered by all 377 respondents. Other modalities commonly practised included moxibustion (90.6%), cupping (84.2%), Chinese herbal medicine (76.2%), and western herbal medicine (16%).

### 4.1.2 Treatment of gynaecological conditions

Of all responders, 96% (95% CI 93.4 to 97.6) of practitioners had treated women's health conditions within the previous year, with 96% (95% CI 94.3 to 98.3) of those practitioners treating a wide range of gynaecological conditions. The most commonly treated conditions were pre-menstrual syndrome (PMS) (90.1%, 95% CI 86.2 to 93.0), menopause (89.4%, 95% CI 85.4 to 92.4) and primary dysmenorrhea (89.1%, 95% CI 85.1 to 92.2) (see Table 4.2). Acupuncture was the most common modality used, with greater than 90% of acupuncturists reporting its use in the treatment of eight conditions. Other TCM modalities were commonly used, with frequency of use varying, depending on the gynaecological condition. For example, moxibustion was more commonly used to treat all conditions except menopause (35%, 95% CI 29.6 to 41.2) and menstrual headache (27.2%, 95% CI 21.7 to 33.3), while electro-acupuncture was more frequently used in the treatment of polycystic ovarian syndrome (14.7%, 95% CI 10.5 to 19.9) than for menopause (6.2%, 95% CI 3.6 to 9.8) or menorrhagia (4.5%, 95% CI 2.2 to 7.9) (p<.05). Chinese herbal medicine was
commonly used across all gynaecological conditions. Dietary and lifestyle advice was provided, particularly in relation to patients presenting with menopausal symptoms (80.5%, 95% CI 75.3 to 85.0), compared with patients presenting with menstrual-related symptoms, such as primary dysmenorrhea (69.7, 95% CI 63.8 to 75.1), menorrhagia (67.9%, 95% CI 61.6 to 73.7), irregular periods (66.4%, 95% CI 60.4 to 72.0), menstrual headache (63.6%, 95% CI 57.2 to 69.0) and secondary dysmenorrhea (68.3%, 95% CI 62.0 to 74.1) (p<.05).

**Table 4.1: Demographic and practice characteristics of acupuncturists who participated in the survey.**

<table>
<thead>
<tr>
<th></th>
<th>New Zealand (n=119)</th>
<th>Australian (n=188)</th>
<th>Combined (n=377)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% 95% CI</td>
<td>% 95% CI</td>
<td>% 95% CI</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>35 26.9 to 44</td>
<td>31.5 25.0 to 38.9</td>
<td>32.5 27.6 to 38.1</td>
</tr>
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<td>Female</td>
<td>64.9 55.9 to 73</td>
<td>68.4 61.1 to 74.3</td>
<td>66.9 61.8 to 72.3</td>
</tr>
<tr>
<td><strong>Age</strong></td>
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<td></td>
<td></td>
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<td>18-25</td>
<td>0.8 0.1 to 5.0</td>
<td>3.1 1.3 to 6.9</td>
<td>2.5 1.1 to 5.0</td>
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<tr>
<td>26-34</td>
<td>11.7 7.0 to 18.9</td>
<td>22.8 17.4 to 29.4</td>
<td>18.4 14.2 to 23.2</td>
</tr>
<tr>
<td>35-44</td>
<td>27.7 20.4 to 36.4</td>
<td>30.3 24.1 to 37.2</td>
<td>30.1 25 to 35.5</td>
</tr>
<tr>
<td>45-54</td>
<td>33.6 25.7 to 42.5</td>
<td>25.0 19.3 to 31.6</td>
<td>28.1 23.2 to 33.5</td>
</tr>
<tr>
<td>55-64</td>
<td>22.6 16.0 to 31.5</td>
<td>14.8 10.4 to 20.7</td>
<td>17.8 13.7 to 22.5</td>
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<tr>
<td>65+</td>
<td>1.6 0.8 to 6.3</td>
<td>3.7 1.6 to 7.6</td>
<td>2.9 1.3 to 5.4</td>
</tr>
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<td><strong>Practice Location</strong></td>
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<td></td>
<td></td>
</tr>
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<td>New Zealand</td>
<td>93.8 89.6 to 97.5</td>
<td>96.0 94.2 to 97.6</td>
<td>95.0 93.6 to 96.4</td>
</tr>
<tr>
<td>Australia</td>
<td>60.5 54.9 to 66.1</td>
<td>10.0 2.0 to 2.8</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1.0 0.2 to 2.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Years in Practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 1 year</td>
<td>6.7 3.2 to 12.9</td>
<td>4.2 2.0 to 9.3</td>
<td>5.2 3.0 to 8.3</td>
</tr>
<tr>
<td>1-5 years</td>
<td>21.8 15.3 to 30.1</td>
<td>22.8 17.4 to 29.4</td>
<td>22.5 18.2 to 27.9</td>
</tr>
<tr>
<td>6-9 years</td>
<td>28.5 21.2 to 37.2</td>
<td>21.8 16.4 to 28.2</td>
<td>24.4 19.7 to 29.6</td>
</tr>
<tr>
<td>10-20 years</td>
<td>22.6 16.0 to 31.0</td>
<td>30.8 24.6 to 37.7</td>
<td>28.0 23.0 to 33.3</td>
</tr>
<tr>
<td>21+ years</td>
<td>18.4 12.4 to 26.4</td>
<td>20.2 15.0 to 26.5</td>
<td>19.5 15.2 to 24.4</td>
</tr>
<tr>
<td><strong>Style of Acupuncture</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five Element</td>
<td>32.0 24.9 to 41.6</td>
<td>26.6 20.7 to 33.5</td>
<td>29.2 24.4 to 34.5</td>
</tr>
<tr>
<td>Japanese</td>
<td>13.4 8.3 to 20.8</td>
<td>19.6 14.6 to 25.9</td>
<td>17.0 13.2 to 21.6</td>
</tr>
<tr>
<td>Traditional Chinese Medicine</td>
<td>95.8 90.2 to 98.4</td>
<td>87.7 82.2 to 91.7</td>
<td>90.6 86.8 to 93.4</td>
</tr>
<tr>
<td>Western Medical acupuncture</td>
<td>6.7 3.2 to 12.8</td>
<td>7.4 4.4 to 12.2</td>
<td>7.1 4.6 to 10.5</td>
</tr>
<tr>
<td>Other style</td>
<td>10 5.7 to 16.9</td>
<td>10.1 6.4 to 15.3</td>
<td>10.0 7.0 to 13.8</td>
</tr>
<tr>
<td><strong>Other services</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acupressure (ear/scalp etc)</td>
<td>76.4 68.0 to 83.2</td>
<td>59.0 51.9 to 66.8</td>
<td>65.2 59.8 to 70.3</td>
</tr>
<tr>
<td>Chinese herbal medicine</td>
<td>68.9 60.0 to 76.5</td>
<td>82.4 76.3 to 87.2</td>
<td>76.2 71.1 to 80.6</td>
</tr>
<tr>
<td>Western herbal medicine</td>
<td>18.4 12.4 to 26.4</td>
<td>14.8 10.4 to 20.7</td>
<td>16.0 12.3 to 20.5</td>
</tr>
<tr>
<td>Tuina</td>
<td>68.0 59.2 to 75.7</td>
<td>44.1 37.2 to 51.2</td>
<td>53.7 48.1 to 59.1</td>
</tr>
<tr>
<td>Moxibustion</td>
<td>92.4 86.0 to 96.1</td>
<td>89.3 84.0 to 93.0</td>
<td>90.6 86.8 to 93.4</td>
</tr>
<tr>
<td>Dietary/Nutritional Supplements</td>
<td>62.1 53.2 to 70.4</td>
<td>62.7 55.6 to 69.3</td>
<td>62.0 56.5 to 67.2</td>
</tr>
<tr>
<td>Tai Chi / QiGong</td>
<td>26.8 19.7 to 35.5</td>
<td>13.3 9.5 to 19.5</td>
<td>18.9 14.9 to 23.7</td>
</tr>
<tr>
<td>Other</td>
<td>29.4 21.9 to 38.1</td>
<td>24.4 18.8 to 31.1</td>
<td>26.0 21.4 to 31.2</td>
</tr>
<tr>
<td><strong>Training Location</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td>67.2 58.3 to 75.0</td>
<td>0.5 0.01 to 3.2</td>
<td>26.0 21.4 to 31.2</td>
</tr>
<tr>
<td>Australia</td>
<td>15.9 10.3 to 23.6</td>
<td>91.4 86.5 to 94.7</td>
<td>61.7 56.2 to 66.9</td>
</tr>
<tr>
<td>China</td>
<td>24.3 17.5 to 32.8</td>
<td>30.3 24.1 to 37.2</td>
<td>27.9 23.2 to 33.2</td>
</tr>
<tr>
<td>Other</td>
<td>25.0 15.9 to 36.9</td>
<td>8.7 5.3 to 14.0</td>
<td>15.7 12.1 to 20.2</td>
</tr>
</tbody>
</table>
### Table 4.2: Acupuncture Treatment Modalities for Gynaecological Conditions

Data presented as % 95% CI

*Premenstrual syndrome, ** Polycystic ovarian syndrome, *** Chinese herbal medicine

<table>
<thead>
<tr>
<th>Condition treated</th>
<th>Acupuncture</th>
<th>Moxibustion</th>
<th>Electro acupuncture</th>
<th>CHM***</th>
<th>Capping</th>
<th>Micro systems</th>
<th>Taichi &amp; Qi gong</th>
<th>Used Lifestyle/diet advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menopause 89.4 to 92.4</td>
<td>99.6/97.6 to 99.9</td>
<td>35.0/29.6 to 41.2</td>
<td>6.2/3.6 to 9.8</td>
<td>75/69.8 to 80.3</td>
<td>22.4/17.6 to 27.8</td>
<td>30.1/24.7 to 35.9</td>
<td>8.8/5.7 to 12.8</td>
<td>80.5/75.5 to 85.0</td>
</tr>
<tr>
<td>Primary dysmenorrhea 89.1 to 92.2</td>
<td>93.3/89.7 to 96.0</td>
<td>61.2/55.1 to 67.0</td>
<td>9.9/6.6 to 14.1</td>
<td>66.7/60.8 to 72.3</td>
<td>23.9/19.0 to 29.5</td>
<td>23.6/18.6 to 29.1</td>
<td>7.3/4.5 to 11.1</td>
<td>69.7/63.8 to 75.1</td>
</tr>
<tr>
<td>PMS* 90.1 to 93.0</td>
<td>96.7/93.8 to 98.4</td>
<td>44.5/38.5 to 50.6</td>
<td>6.9/4.2 to 10.6</td>
<td>67.8/62.0 to 73.3</td>
<td>25.1/20.1 to 30.7</td>
<td>24.0/19.1 to 29.5</td>
<td>8.7/5.6 to 12.7</td>
<td>72.2/66.5 to 77.4</td>
</tr>
<tr>
<td>Menorrhagia 79.9 to 84.0</td>
<td>96.2/93.0 to 98.2</td>
<td>43.6/37.2 to 50.1</td>
<td>4.5/2.2 to 7.9</td>
<td>66.2/59.9 to 72.1</td>
<td>17.2/12.7 to 22.6</td>
<td>18.5/13.8 to 23.9</td>
<td>6.9/4.1 to 10.9</td>
<td>67.9/61.6 to 73.7</td>
</tr>
<tr>
<td>Irregular periods 89.1 to 92.2</td>
<td>95.9/92.8 to 97.9</td>
<td>50.9/44.8 to 57.0</td>
<td>7.7/4.8 to 11.6</td>
<td>70.1/64.2 to 75.4</td>
<td>20.6/16.0 to 25.9</td>
<td>21.0/16.3 to 26.3</td>
<td>5.5/3.1 to 8.9</td>
<td>66.4/60.4 to 72.0</td>
</tr>
<tr>
<td>PCOS** 77.9 to 82.2</td>
<td>97.0/94.0 to 98.8</td>
<td>53.1/46.5 to 59.6</td>
<td>14.7/10.5 to 19.9</td>
<td>66.4/53.0 to 65.7</td>
<td>20.6/15.7 to 26.3</td>
<td>26.1/20.6 to 32.2</td>
<td>5.9/3.2 to 9.7</td>
<td>73.8/67.7 to 79.3</td>
</tr>
<tr>
<td>Menstrual headache 79.6 to 83.7</td>
<td>97.5/94.6 to 99.0</td>
<td>27.2/21.7 to 33.3</td>
<td>9.5/6.1 to 13.9</td>
<td>59.5/53.0 to 65.7</td>
<td>26.8/21.3 to 32.9</td>
<td>21.9/16.8 to 27.6</td>
<td>8.2/5.1 to 12.4</td>
<td>63.6/57.2 to 69.0</td>
</tr>
<tr>
<td>Secondary dysmenorrhea 78.9 to 83.1</td>
<td>97.0/94.0 to 98.8</td>
<td>55.4/48.8 to 61.8</td>
<td>10.8/7.2 to 15.4</td>
<td>72.9/66.8 to 78.4</td>
<td>24.5/19.2 to 30.5</td>
<td>22.5/17.3 to 28.3</td>
<td>7.5/4.5 to 11.5</td>
<td>68.3/62.0 to 74.1</td>
</tr>
</tbody>
</table>
Table 4.3: Referral patterns for women's health conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Word of Mouth</th>
<th>Referral from CAM</th>
<th>Referral from medical practitioners</th>
<th>Advertising</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td></td>
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<td>95% CI</td>
<td>95% CI</td>
<td>95% CI</td>
<td>95% CI</td>
</tr>
<tr>
<td>Menstrual</td>
<td>87.5</td>
<td>43.7</td>
<td>29.2</td>
<td>42.4</td>
<td>24.0</td>
</tr>
<tr>
<td></td>
<td>83.2 to 90.7</td>
<td>38.2 to 49.3</td>
<td>24.4 to 34.6</td>
<td>37.0 to 48.0</td>
<td>19.5 to 29.1</td>
</tr>
<tr>
<td>Fertility</td>
<td>89.3</td>
<td>54.2</td>
<td>42.5</td>
<td>46.8</td>
<td>26.2</td>
</tr>
<tr>
<td></td>
<td>85.1 to 92.4</td>
<td>48.4 to 59.9</td>
<td>36.9 to 48.3</td>
<td>41.0 to 52.8</td>
<td>21.4 to 31.6</td>
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<tr>
<td>Pregnancy</td>
<td>90.0</td>
<td>52.6</td>
<td>47.3</td>
<td>46.9</td>
<td>25.6</td>
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<tr>
<td></td>
<td>86.3 to 93.3</td>
<td>46.8 to 58.4</td>
<td>41.5 to 53.1</td>
<td>41.2 to 52.8</td>
<td>20.8 to 31.0</td>
</tr>
</tbody>
</table>
4.1.3 Different practice characteristics between New Zealand and Australian practitioners

Differences were found in clinical practice between the Australian and New Zealand settings. Findings suggest a wider range of treatment practices were used among Australian acupuncturists compared with their New Zealand colleagues. In relation to gynaecology, Australian practitioners treated significantly more patients with menopause (p=0.0004), primary dysmenorrhea (p=0.0027), PMS (p=0.0319), heavy periods (p=0.0047) and menstrual headaches (p=0.0474) compared with their New Zealand counterparts.

4.1.4 Referral and professional networks

Acupuncturists received most of their referrals by word of mouth, irrespective of the health condition being treated (see Table 4.3). Referrals from biomedical practitioners were significantly less likely for gynaecological conditions (29.2%, 95% CI 24.4 to 34.6) compared to fertility (42.5%, 95% CI 36.9 to 48.3) (p=0.0010) and pregnancy (47.3%, 95% CI 41.5 to 53.1) (p<.0001). When treating gynaecological conditions, practitioners often worked with other CAM practitioners (40.8 95% CI 35.4 to 46.4), or with biomedical practitioners (43.4% 95% CI 37.9 to 49.0). However, a significant portion of practitioners (40.1% 95% CI 34.7 to 45.7) did not work in conjunction with any other practitioners when treating gynaecological conditions.

4.2 Thematic analysis of focus groups and interviews

The aim of these focus groups and interviews was to explore how experienced TCM practitioners, with a significant clinical focus on gynaecology, treated dysmenorrhea in clinical practice. The principal research question was “How do experienced practitioners treat primary dysmenorrhea in every day clinical practice?”
The fundamental and overarching theme that emerged from the data was that of “a complex partnership”; this captures the complexity of working within the partnership that occurs between practitioner and patient, involving delivery of experiential knowledge from the practitioner, tailoring treatment to suit a patient’s life circumstances and the personal framework used to deliver advice. Six related themes were also found.

The first major theme was “practical obstacles”; this captures the issues surrounding money, time and clinic space when it comes to treating women with dysmenorrhea on a regular basis, and how the practitioners overcome these obstacles. The second major theme was “textbooks are just part of the diagnosis”; this captures information on how practitioners use a variety of sources to inform their clinical practice and the somewhat obsolete nature of textbooks given the complex nature of period pain. The third major theme was “finding what is effective”; this theme illustrates how practitioners feel about treating period pain and their experience of the effects of acupuncture on period pain. The fourth major theme was “treating women holistically”; this captures how practitioners deliver individualised treatments and are sensitive to the needs of each patient. The fifth major theme was “a partnership in understanding patterns and connections” and illustrates how practitioners encourage women to take control of their own health by providing tools and knowledge to do so. The final, and sixth major theme was “it’s not cut and dried”, which captures how practitioners have a range of views on how to structure dosing, timing and needle retention during acupuncture treatments.

These themes and related sub-themes will be discussed in detail in this chapter. Each of the seven themes that emerged from analysis of the data presented sub-themes that are also included in Table 4.4 and Figure 4.1.
**Table 4.4: Themes and sub-themes from practitioner focus groups and interviews**

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-themes</th>
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<tr>
<td>A complex partnership</td>
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<td><strong>Practical obstacles of money, time and space</strong></td>
<td>Bridging the treatment gap</td>
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<td>Textbooks are just part of the diagnosis</td>
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<td>Finding what is effective</td>
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<td>Treating women holistically</td>
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<tr>
<td>A partnership in understanding patterns and connections</td>
<td>Lead them back to balance</td>
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<td></td>
<td>Introducing women to a new normal</td>
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<td></td>
<td>Reframing the narrative around period pain</td>
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<td>It's not cut and dried</td>
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4.3 A complex partnership

This overarching theme captures how acupuncturists dealt with providing treatment to women with period pain, providing knowledge, support and individual guidance based on the needs of the woman presenting to them:

So I look at it as like a partnership, that I’m here to guide them on their journey to get well and I normally try and say to them, some dietary advice I like to give you because you’ve got a cold uterus, right, so it’s best for you to eat warming foods and there’s these other reasons why (Wellington Practitioner 5)

This acupuncture partnership shows its complexity in several aspects; firstly practitioners raised the fundamental notion that in TCM each patient has a
particular “pattern of disharmony” and thus treatment is different for each patient as they are being treated for the pattern rather than the disease. Practitioners emphasised that patients do not simply fit checklist criteria and treatment is not just “one size fits all”, in fact the whole person needs to be taken into account and all aspects treated using a variety of modalities:

It’s TCM. It’s looking at the whole person, the lifestyle, the nutrition. You know, we’re looking at every aspect of that person, and I think a GP would tend to just look at what they’re presenting with, and the drug that fixes it. (Auckland Practitioner 5)

Chinese medicine is treating the body as a whole. So improve your period pain it will be your whole body will be benefit. You treat the whole body then you’ll feel no period pain. It’s not saying treat the period pain for period pain. (Sydney Chinese Practitioner 1)

Secondly, the balance in the partnership between where patients “are” and how the practitioner can work with the patient to get to the desired outcome. Practitioners relinquished the role of “expert” and acknowledged that the women have their own lives, with roles and responsibilities generating circumstances that may be in conflict with the practitioner’s ideal for them. Practitioners repeatedly mentioned the idea of empowering women to become their own “experts” in the field of their own health, by dispensing their accumulated knowledge over time and thereby further reducing the power imbalance in the relationship:

I guess in my clinical space I like to maximise the power of the patient and I don’t like to take an expert role, so I guess that means drip feeding it and I’m always really pleased when a patient comes back to me and tells me something as if it was new, that they’ve discovered, but I know I told them three weeks before. You know, and yeah, I’m really happy if they do that. (Sydney Practitioner 1)
Thirdly, the treatment of period pain itself adds complexity due to the common observation by practitioners that many women think that period pain is “normal” and therefore something that just needs to be accepted. Practitioners expressed the importance of educating women about period pain by explaining it in TCM terms and discussing what a “normal” period is in Chinese medicine, rather than what they may have read or heard from friends. This allowed practitioners to provide a benchmark for a normal period and set women’s expectations accordingly:

When you say to people, you don’t need to be having this kind of pain. It’s not actually normal. They kind of – it’s a bit like, oh, there’s a whole other life out there. So I think it’s part of how society views periods and that a bit of pain is – or pain is expected. So it’s educating them about that as well, and that spreads the word. (Wellington Practitioner 2)

4.4 Practical obstacles of money, time and space

This theme outlines areas of concern to practitioners in delivering treatment to women with period pain, and reveals the complexity of working in a holistic partnership model. Practitioners outlined three main areas where there was conflict between “ideal” treatment situations and what patients could manage

4.4.1 The ideal treatment approach

All practitioners felt that ongoing, regular treatment was important. Often this treatment was planned to occur at key times in the menstrual cycle and the related changes in Yin and Yang balance. In addition, timing was also based around the underlying pattern of disharmony, which was responsible for the dysmenorrhea, so as to redress the balance:

Pinpointing around the menstrual cycle, one of the areas that need work the most, if it’s Yang depletion, you bring them in at that Yang time of the cycle so you can really work with them at the right time. (Wellington Practitioner 6)
Practitioners expressed a desire to time treatments during the symptomatic phase, where pain and other bothersome symptoms were present, and also at other times in the cycle. This ideal timing was always dictated by clinical factors; when not menstruating the timing of treatments was designated by the underlying pattern of disharmony, when menstruating it was dictated by the duration of the pain:

I would really like to see someone, it depends on how long their pain exists, but I would like to see someone when they’re experiencing pain probably twice. But then, depending on their underlying condition, I would like to see them at key moments in their menstrual cycle. (Sydney Practitioner 1)

I generally treat weekly throughout the cycle and I would try to time a treatment either just before the period or even during the period if I’m trying to move the blood stasis. Ideally I treat twice weekly, but it’s often not really practical. But yeah, definitely weekly throughout the cycle and with a real emphasis of the two weeks leading — well, the week leading up to the period and during the period. (Wellington Practitioner 3)

Practitioners were asked how they preferred to structure treatment timings when treating period pain and how long they would treat for before expecting to see significant improvements. In contrast to the compromises they undertook with patients in clinical practice, practitioners were asked how they would like to treat if they had the freedom to choose. Most practitioners felt that weekly treatment for two to three menstrual cycles was a reasonable length of time to expect to see some changes. However, the complexity of the condition was also acknowledged, in that some women would respond in this time, but others would require longer, especially if they had a long history of period pain:

I’d like to see results within two cycles. I’m not saying that I’m going to cure their pain completely, but you should see some kind of difference or relief
from pain within the two months and then it should progressively get better after that (Wellington Practitioner 2)

I always do say with anything, the longer you’ve had it for, the longer it’s going to take to really make those deep changes to have the long-term results that you’re looking for. But yeah, I mean, I guess three months is what I would generally say as a starting point and that you’d want to see some progression in that time, but it might take longer. (Wellington Practitioner 4)

One practitioner used the previous use of the oral contraceptive pill as a guide for how long it would take for improvements in the menstrual cycle, with a longer duration of usage of the contraceptive pill entailing a similarly longer duration of treatment:

As a very, very vague rule of thumb, I usually say for every year they’re on the contraceptive pill I’d want one cycle. So if they’ve been on the pill for ten years, then maybe ten cycles. Three years, three cycles. But that’s not really based on anything. It’s just, yeah, to re-establish a normal cycle and natural flow. (Wellington Practitioner 3)

Practitioners who trained in China before emigrating to Australia noticed that there were significant differences in treatment frequency between the two countries; in China daily treatment was considered normal and something commonly accepted, while weekly treatment was considered more common in Australia for both social and financial reasons:

But actually when I practice in China we do treat the clients every day, but since I came to Australia, yeah, it’s really hard to do it that way. (Sydney Chinese Practitioner 2)
Chinese practitioners were again aware, based on their experience, of the difficulty of getting the desired clinical outcome with less frequent treatment:

Well, it’s very difficult. In China we do very often, but here people — because of financial problem, they couldn’t afford to come frequently, so they can’t do, like what we ask for, so most of time they just come for before the period and once a week. Yeah it’s very hard for them to be more frequent. But I think they can get better results if they treat more frequent. (Sydney Chinese Practitioner 3)

New Zealand European practitioners also noticed this difference in cultural acceptance of regular acupuncture treatment and mentioned it to their patients to help them understand how treatment would ideally be structured, and how that would shorten the time to the desired outcome:

It also helps to explain, I find — not just with the menstrual type things, but for everybody, that if they were in China, that they would be having daily treatment. That would be normal to have daily treatment, and that okay we can do it once a week, but it will take probably a whole lot longer. (Auckland Practitioner 1)

4.4.2 Money

One of the most common obstacles for regular treatment was the cost, especially as treatment was likely to continue for several months. Practitioners acknowledged that many women could not afford regular treatments over a long time scale and adapted their treatment frequency to one that was more financially comfortable, often trying to reach a compromise between the practitioner’s and patient’s desired frequency and timing of treatment:

... you might discuss, let’s try and get you in weekly just for the short term. If you can just get on top of it a little bit for, say, two cycles, and then talk about
reducing the frequency again, it eases that stress for them, because it is another big expense in the week, I think, for a lot of people now. (Wellington Practitioner 5)

I even find a lot of patients find weekly too much financially. More financially, I’d say, for mine, rather than time. I treat on a Saturday and they find that quite okay, but yeah, a lot can’t do weekly and long term. (Wellington Practitioner 4)

Yes, what I try to do is get people — for their menstrual problems — try to get them to come weekly for at least three months, and I know a lot of people can’t afford it, and they want to come every other week. A lot of people seem to be able to afford every other week. So I try to get them to do ten days. That way it’s just three times a month. (Auckland Practitioner 2)

Practitioners were conscious of the fact that cost was often an issue for women and would often offer financial discounts to enable women to come regularly, especially during the period time itself, as they felt this was important for their patient to get the best results. This negotiation between practitioner and patient allowed for the practitioner to be able to treat more in line with their desired timing and frequency, while not overburdening women with extra financial pressure:

You know, it’s usually good if you can see them once a week but, yeah, during the actual pain I would like to see them two or three times a week if that was possible. And usually I would offer them a discount in order to get them to agree to that. (Sydney Practitioner 1)

Practitioners were often mindful of the fact that if they did not accommodate their patients, and subsequently were unable to see them regularly, their desired clinical outcome may take significantly longer. This was one motivating factor in wanting to offer price reductions:
[improvement] will take probably a whole lot longer, and mostly the[y] agree to come in. Drop the price a bit if they come in really quick in succession. (Auckland Practitioner 1)

Some practitioners observed that this was possibly due to the age of the women who suffered from primary dysmenorrhea, specifically younger women who have to pay for regular treatment. This may not be seen as an economical way to spend their limited funds:

... economically it’s the main issue I think for, you know, this kind of people, group of people are mainly young girls. (Sydney Chinese Practitioner 2)

4.4.3 Time

Many practitioners mentioned that the time constraints for patients were often at least as important as cost, with many women being too busy with other commitments, such as family and work, to be able to set aside regular treatment time. Practitioners acknowledged the complexity inherent in women’s lifestyles, at times having to manage multiple roles, and again empathised with and tried to find a solution that worked for the women who often were perceived as time poor:

[I] have to be guided by whatever is the most practical, financially and time wise. And, you know, I’m dealing with a lot of either women trying to get pregnant and they’re still working full-time or women who have got kids. So once you’ve got that sort of happening it can be a bit tricky. (Sydney Practitioner 3)

[T]ime constraint because it takes a lot of time out of your day to get yourself to your acupuncturist and spend an hour lying around with needles stuck in you ... most people I see, oh, don’t have that sort of freedom. (Sydney Practitioner 1)
For practitioners, space can refer to having enough physical “space” for treatment beds for their patients, as well as having “space” in their appointment diaries to be able to treat them. Practitioners highlighted the difficulties inherent in being available for multiple treatments per week, or even daily, as is common in China. This was due to multiple factors. A shortage of beds was commonly mentioned, as most did not have a multi-room practice. This impacted on the ability to see multiple patients generally, and also prevented practitioners from being able to see multiple patients during the treatment time, which would facilitate a price reduction:

The amount of treatment rooms people have — it’s easier to bring someone in if you’ve got a couple of treatment rooms, because once you’ve treated them once in the week, the next time will be just a top up, very simple, put the needles in, walk away. But most of us haven’t got the two-room, three-room facility. So it makes it a bit more expensive. (Wellington Practitioner 3)

Most practitioners also explained they worked in small, private clinics, usually by themselves. This, in conjunction with a lack of extra treatment rooms, meant that scheduling issues with regards to daily treatment would be a significant issue:

You’ve got to be able to fit them in as well, and it’s like they pop in Monday and I go I’m booked Tuesday, Wednesday, Thursday. (Auckland practitioner 3)

All practitioners worked more than 20 hours per week in clinical practice, however most did not work more than five days per week, so fitting patients in if timing fell over their days off was also a significant barrier:

I don’t know if we all work — you might be only working part time. I do four days a week, so it’s going to be quite tricky if you’re going to get someone in
for four or five consecutive sessions, depending on when you operate your clinic. (Wellington Practitioner 5)

4.4.5 Bridging the treatment gap

Many practitioners mentioned the use and benefits of herbal medicine when treating period pain. Some practitioners used herbal medicine to overcome the issues with patients finding it difficult to be able to make regular treatments due to transport, family or finances. This emphasises how practitioners embrace the complexity of a holistic partnership; if one treatment modality does not suit the patient, the practitioner will find others that do. This also shows quite clearly that practitioners often have more than “one string to their bow” and many practitioners do not use acupuncture alone when treating period pain:

So they only have four or five sessions a month treatment so that’s why I usually suggest them taking herbs as well because once a week acupuncture, it’s really not working that well. But it kind of supports to leading the energy flowing. (Sydney Chinese Practitioner 2)

I find that’s the benefit of herbs as well, that it’s — yeah, it can help ride them through if they can only make fortnightly treatments. (Wellington Practitioner 2)

You know, people that are really busy, it’s hard to get them to come weekly, particularly where I am. I deal with — I’m on [placename] so I’ve got a commuting population, and they can’t come weekly. So that’s why I use herbs a lot with them. (Sydney Practitioner 3)

In contrast, other practitioners noted using herbal medicine for specific TCM issues related to issues with the fundamental substances rather than just an adjunct to acupuncture:
... if it’s something like Yin or blood that’s causing the problem. I use the herbs to take it up. (Wellington Practitioner 6)

One other practitioner mentioned using other modalities, such as ear points or other complementary practices like yoga, to help “tide over” patients between acupuncture sessions:

We do weekly as well at the clinic and then also my own practice. But to tie them between treatments, I always [suggest] that the students and myself use ear seeds and lifestyle advice, dietary changes, yoga exercises, or get the students to show them Qi Gong to support their diagnosis. (Wellington Practitioner 1)

4.5 Textbooks are just part of the diagnosis

This theme emerged from discussion around sources of information that practitioners drew on in every day clinical practice when faced with women presenting with dysmenorrhea. Practitioners were asked how they decided on points and treatment methods to use.

4.5.1 Textbooks as a foundation

A common refrain amongst the practitioners was the idea that textbooks were a “base” or a foundation to build from; they provided some basic, reliable knowledge during training which could be developed and built on once in practice. However, once in practice practitioners’ attitudes to textbooks varied, from feeling foundations were refined with practice, to feeling textbooks could almost be discarded as being irrelevant:

... the original [information is] from the textbooks of course. So I think that’s back in the mind, as the foundation, but it changes sometimes. (Auckland Practitioner 2)
That’s why I think, like [name] said, the textbook is the base. We read so many at school. Then you get over reading textbooks and you get into the real practice. (Wellington Practitioner 3)

... [textbooks are] most likely the foundation or the possibilities and then refined from there with practice. (Auckland Practitioner 3)

4.5.2 Limitations of textbooks

Clinical reasoning in TCM acupuncturists is based around the idea of identifying the pattern of disharmony, which incorporates changes in organ function and excess or deficiency of one or more of the fundamental substances. Often there may be multiple patterns co-existing in one woman, sometimes seeming quite contradictory, for example a pattern such as “hot above, cold below”, which makes simply selecting points based on symptoms problematic. Therefore the most important criteria for most practitioners is to determine the underlying pattern of disharmony, rather than simply select points based on a diagnosis of period pain.

Practitioners identified a few areas where textbooks were felt to “fall short” of representing clinical practice. Most commonly it was due to the fact that patients did not present with a single pattern of disharmony, or had much more complex symptoms. Several practitioners commented on how nice it would be to have a patient that the textbooks represent, but in reality patients had much more complex symptoms than textbooks could account for:

Yeah. It [reading the sheet of textbook patterns] was funny. It took me back to school really. I thought, oh, it’s just so perfect. I used to find — I thought today I used to find this so easy to diagnose and say my points and then you come into the student clinic and the person seems to fit them. Now, I look at this and it seems so foreign, because it’s not just like that. It’s often a mix of a couple of patterns and there’s lots of head stress stuff going on. Yeah. (Wellington Practitioner 5)
The patterns all overlap. No one is going to fit in such a tight box as any of those really tight diagnoses that you see in a textbook, but I think it’s important that we — if we’re teaching our students, that our students are aware that these are the patterns that can be differentiated, but then you learn to overlay them, and to inter — you know, sometimes they present like this and sometimes they present like that. So have you ever seen in clinic, an exact diagnosis? Sometimes you do, but I’d say it’s very rare. (Auckland Practitioner 1)

Others mentioned that textbooks “prescribe” certain points and that doesn’t fit with their style of practice, which is more dynamic and based on underlying imbalances of fundamental substances. Practitioners mentioned their aversion to simply “prescribing” points, that a diagnosis that takes account of the whole person is the most crucial factor and it’s not a matter of simply choosing points to treat a symptom:

I don’t go to a textbook to look up a prescription points, that’s not the way I work, I’m always looking to go first principles, what’s happening in their Yin–Yang balance, you know, what’s the quality of the Qi and blood, what is the distribution of energy amongst the five elements, the internal organs. So, yeah, that’s where I’m looking — if I’m going to a textbook it’s to look for stimulating my thinking about what’s going on in this person, rather than some prescription that I could apply, you know, for better or for worse. (Sydney Practitioner 4)

Well, I’m not really looking at points. So I’m not looking at points to fix that problem. I’m just looking at the diagnosis. If I get my diagnosis right, I can move Qi, I can move blood, I can harmonise the spleen in a number of ways. So I’m just getting my diagnosis — my pattern. (Auckland Practitioner 4)
4.5.3 The importance of multiple sources

Diagnostic and clinical decision-making showed significant complexity, incorporating blogs, online courses, textbooks, other practitioners’ shared knowledge and various other sources. Practitioners often felt that each individual source had its limitations, therefore incorporating a variety of sources overcame the limitations of each type of source. Some practitioners were quite happy to include internet-based sources, as this allowed them to obtain knowledge that they may not have otherwise had due to geographical distance:

I think it’s just a big combination ... So, it’s a combination of, yes, all those methods of learning, previous teachers. Also online, I get some of my information online, there are some — there’s a very good blog I love from a herbalist in the US, she does a lot of female — blogging about female conditions and herbs and I like her things. (Sydney Practitioner 2)

One practitioner expressed caution in terms of having to be wary of falling into a particular pattern of treatment, that “new” and “extra” knowledge was important to prevent practice from becoming stale, to keep evolving to adapt to the complexity of clinical practice:

Then there’s these courses, like today, and they’re so great attending, because you just want to, yeah, hear some new things out there. Because you do start to sometimes get into your own little pattern, so it’s great to, yeah, hear extra knowledge that isn’t in the textbook. Other people’s clinical experience, or the research stuff that’s going on. They might throw in points that you think, oh, I didn’t think of that point for that and then you try it. So it’s always got to keep evolving. (Wellington Practitioner 3)

Practitioners mentioned the importance of integrating other sources of knowledge with their own experience from clinical practice. This was especially
prevalent in practitioners who had been in clinical practice for a longer time, who emphasised that after a certain number of years in practice most cases that may have appeared complex are now “straightforward”. Practitioners often favoured experientially derived information from other “expert” or experienced practitioners who may have insights that they themselves did not:

At this point in my career I’m quite happy to rely on my experience and my familiarity with the different problems and different solutions. Earlier on I would have referred possibly to textbooks, and certainly conversed with colleagues. But after 20 years, menstrual problems are usually straightforward. I mean if I’ve come across a tricky case, and one always does, then of course I would usually refer to a colleague actually first. (Sydney Practitioner 4)

One practitioner mentioned that they relied heavily on experience, both their own and others, as there was a lack of English language textbooks when they trained and so never got into the habit of using them:

Experience and other people’s experience. Textbooks are not — they don’t play a large part for me because essentially when I trained, we didn’t have any. (Auckland Practitioner 1)

### 4.5.4 Intuition

Several practitioners mentioned how sometimes they prefer to rely on “intuition” when deciding on what points to use. This was a mechanism, conscious or unconscious, that allowed them to integrate the large number of sources of knowledge that they had with clinical experience, and use the resulting insight in clinical practice:

And sometimes it all goes out the window — what I think I’m going to do or what I’m doing, and as I’m writing in the chart what I do, I think I don’t know
why I do that, but it really feels right, and the patients usually have great results. So intuitive, and I’ve never really figured it out, or analysed it. (Auckland Practitioner 2)

I think, I think that then, what makes you then choose which one you’re going to use, is your intuition. I think, you know, you listen to what the client says, they’re fitting into some — and your experience and, and that’s fit — they’re fitting into some kind of pattern, you’re thinking “oh, I used that with somebody — well before that work” or something pops into your head, and I think “oh, I’ve not thought of that before, I’ve not done that before, maybe I’ll give it a go”. (Sydney Practitioner 2)

4.6 Finding what is effective

This theme cantered around how practitioners felt when treating period pain and reflects the confidence they felt in achieving success. All practitioners had previous positive experience with treating dysmenorrhea and were very confident in their ability to get results, often in a relatively short space of time if the patients were young. There was minimal variation in practitioners comments around its effectiveness, except some practitioners emphasised that pain was the quickest symptom to respond, often significantly reducing, if not resolving, within a single treatment:

I think it’s very effective, yeah, works very well for my clients and especially for, you know, like young girls with period pain with not very long history. (Sydney Chinese Practitioner 2)

... very, very common treatment method, and a lot of people, they also like — and it’s also very effective ... straightaway can relieve the pain, that’s for sure. (Sydney Chinese Practitioner 3)
Practitioners were very confident in achieving results across a wide range of women, not just in one or two, with one practitioner estimating over three quarters of the women they treated got “great” results:

... you end up getting probably 80 per cent great results for every woman that walks through the door. In fact, when I saw your study, I thought oh what an easy thing to research, because it gets such results and you’ll be able to get great feedback. (Auckland Practitioner 2)

None of the practitioners mentioned significant issues or barriers to success when treating period pain that was not caused by secondary dysmenorrhea. There was no discussion around their own personal experience and how that compares to the current research around period pain.

4.7 Treating women holistically

This theme illustrates how practitioners use their TCM framework to view the body in a fundamentally different way to biomedicine. This holistic framework provides guidelines for all aspects of the treatment of dysmenorrhea and allows practitioners to personalise treatment and self-care advice, based on their TCM diagnosis. Two practitioners summed up how they view the difference between TCM and biomedicine, a fundamentally different way of viewing both the person and the disease:

It’s TCM. It’s looking at the whole person, the lifestyle, the nutrition. You know, we’re looking at every aspect of that person, and I think a GP would tend to just look at what they’re presenting with, and the drug that fixes it. (Auckland Practitioner 5)

Chinese medicine is treating the body as a whole. So improve your period pain it will be your whole body will be benefit. You treat the whole body then
you’ll feel no period pain. It’s not saying treat the period pain for period pain.

(Sydney Chinese Practitioner 1)

Practitioners felt that one of the key aspects of TCM treatment was self-care advice, which incorporated diet and / or lifestyle advice based on TCM theory. All components that make up the life of the patient, including the environmental factors, need to be taken into account when treating women with period pain. This was deeply rooted in the philosophy of TCM:

Diet and lifestyle is the key. I am very much of the acupuncturist preventive medicine persuasion and acupuncture is part of the philosophy of Chinese medicine and a lifestyle philosophy, so I do a lot of diet and lifestyle advice, so I will certainly be advising people to you know, eat well, avoid foods that are not serving them and exercise, definitely exercise, especially for all pain.

(Sydney Practitioner 4)

Practitioners also were quite certain of the outcome of treatment if the self-care advice was not followed, or changes to the patient’s lifestyle were not made. This was due to the fact that practitioners felt that whatever the patients had done in the past, this was a major contributing factor to the imbalance or disharmony they were experiencing, and therefore unless this was changed it was unlikely that the disharmony would not reappear:

Oh, that’s very, very important. Because we believe that’s the main reason they have this problem. I usually tell my clients, “If you don’t change this, I can fix you this month, next month you’ll get the pain again”. (Sydney Chinese Practitioner 2)

... you’ve got some dietary and lifestyle stuff with all of them actually, it has to kind of go hand in hand and my thing is usually that if you don’t change what you’re doing you’ll be back seeing me in 12 months’ time because your
lifestyle will reproduce these patterns. So I think that’s important for lasting change. (Sydney Practitioner 3)

Practitioners felt, from their experience, that if patients did not agree to commit to taking this dietary advice then treatment results would be compromised. This put practitioners in a difficult situation, as it would affect their treatment outcome:

If they’re not committed to the diet, I feel very disappointed and not really expecting a good result at all. (Sydney Chinese Practitioner 1)

The importance laid on diet and self-care advice on the treatment outcome leads to tension between practitioners and patients. Practitioners know the importance of this advice and don’t want to compromise the treatment effect. Patients, on the other hand, may not understand the need for this advice, or simply find it overwhelming.

Practitioners acknowledged that they might have to adapt their self-care advice from the ideal, based on the circumstances of the patient, to help make it more likely that the patient will commit to at least undertaking some of the diet and lifestyle advice, rather than rejecting it all out of hand. This requires practitioners to understand the personal circumstances of their patient. This personal touch is important as it allows practitioners to tailor the advice, so that women can actually implement it in their lives. While the advice all stems from the TCM framework, it is not simply a matter of “do this”, but rather “how best can these changes be made in this woman’s life”:

... it has to be personal and it has to fit with the circumstances, so you know I don’t tell a woman with two kids to go jogging three times a week, I would suggest that she takes up either yoga or some walking or some activity that the children can join in with, and I would also suggest that she finds a way of feeding herself that suits the whole family so they are all having eggs for
breakfast or porridge for breakfast instead of a bowl of cereal with milk out of the fridge. Within the general guidelines or general therapeutic strategy it has to fit that woman’s life and has to be possible for her to implement in her circumstances. (Sydney Practitioner 4)

I really get a sense of the woman and what she is likely — what kind of changes she’s likely to be able to implement — that’s not going to overwhelm her, it’s going to be easy for her to do (Sydney Practitioner 2)

Implicit in this giving of advice was that practitioners were part of a partnership with the women they treated, and that they delivered this advice from a position of knowledge, but mindful not to not make women feel pressured to implement it. This often meant practitioners encouraged small changes over time, giving patients more information or guidance each session:

So they might be having five coffees a day and they really want to cut down. How many coffees a day now? Still five. I write that down and then, yeah, I might think, if they are starting with something, then I’ll forget about it. Well, not forget about it, but leave that for a little bit, because I don’t want to feel like a nag. (Wellington Practitioner 1)

You know, it’s — but I do very much individualise it in little steps, like if they drink three cups of coffee a day, can we go to three cups of decaffeinated coffee a day and start with that, sort of thing. (Auckland Practitioner 5)

Some practitioners mentioned that if patients were resistant to the diet and lifestyle changes, they might wait until some of the preliminary benefits of acupuncture were evident, thereby allowing women to see that their treatment has some benefit, and by proxy their advice may also hold similar potential:
Because you can’t make them. You can only do so much and you don’t want to alienate them too. So it’s sometimes helpful to just leave it for a bit. You are doing something with the acupuncture and down the track when they’re feeling other benefits, then they might be ready to tackle a new thing again.

(Wellington Practitioner 3)

4.8 A Partnership in understanding patterns and connections

This theme “a partnership in understanding patterns and connections” illustrates how practitioners saw themselves as educating women on the connection between the things they do (lifestyle and diet most commonly) and the symptoms that they are experiencing. Many practitioners felt that they were “pointing out” connections that women already knew subconsciously, and many practitioners voiced that they wanted women to take charge of their own health. This is an important component of the partnership model, that there is shared understanding and shared responsibility for these health outcomes. These are discussed in the sub-themes “lead them back to balance” and “introducing women to a new normal”.

4.8.1 Lead them back to balance

This sub-theme reflects practitioners’ views on the role of empowering women to take control of their own health. Practitioners discussed this process in terms of educating women so that they will become aware of the link between their lifestyle and the symptoms of period pain. The concept of shared understanding is vital, as women can only take control of their own health if they understand how the complex interaction of lifestyle, diet and emotions weave together and influence their period pain:

I think if you relate to their symptoms, and not only dietary stuff, but if you’re looking at the emotional side of things and you can relate it to how they’re feeling physically, that resonates quite strongly. If we’re talking about dealing about stress, for example, and you’re not dealing with stress, you’re going to
get more of this pain. Maybe there’s other things that have come up that — symptom-wise, and you relate it back. You can really see the light come on and actually they really want to make those changes. (Wellington practitioner 2)

Practitioners also discussed how the development of understanding by women of how to manage their own bodies better meant shortened treatment times and also improved outcomes for the woman:

So I look at it as like a partnership, that I’m here to guide them on their journey to get well and I normally try and say to them, these are some dietary advice I like to you give you because you’ve got a cold uterus, right, so it’s best for you to eat warming foods and there’s these other reasons why. Normally when you tell them what all the benefits are they tend to go down that track as best as they can. But the key is also that the treatment times are shortened if they take on board your lifestyle advice, because it’s all about keeping that area nice and warm and things flowing. So if they can do that on their end, then you’re going to — the healing process is going to be a lot shorter. (Wellington practitioner 5)

Acupuncturists discussed a variety of ways that diet and lifestyle advice could be framed, from general principles around hot (Yang) and cold (Yin), to the specific effect of individual foods. Again, translating these concepts into terms and examples that women could practically understand was very important:

... all of those sorts of things, I talk about on a regular basis. Climate — you know, the concordances. People love the concordances — how this relates to that, relates to that, relates to that — they love it and they take it on board. (Auckland Practitioner 1)
And Chinese medicine they, they focus on the Yin / Yang, you know the warm or, or cold — in the beginning we said, “What is cold?” They think of what is “temperature”. I say, “No, because ...” you know, for example, some people they really have a cold stomach, I said, “How do you feel after eat banana?” They said, “I feel bloated”. I said, “Do you know why?” So after, like, just ask questions and then they understand, “Okay, so bananas in nature is really cold and it can harm their stomach. (Sydney Chinese Practitioner 4)

Practitioners often emphasised the importance of understanding “hot” and “cold” in terms of Chinese medicine. The importance of avoiding “cold” was often discussed as this had a significant effect on women’s period pain:

I mean, I might do it more subtly, it depends on the person, but you know, particularly, I mean the obvious issue is warmth, cold, getting them to understand that pain is a pathogen. It’s pretty important in a lot of menstrual pain. (Sydney Practitioner 1)

... just even explaining concepts — you know, hot and cold. The effect of spicy food compared to a glass of water from the refrigerator. (Auckland Practitioner 3)

Practitioners emphasised the importance of the TCM framework, and how that framework allowed them to explain these connections, which subsequently would empower women to use these connections between lifestyle choice and symptoms to improve their own understanding of how their day-to-day choices impacted their own health, in either a positive or negative way:

Yeah, it’s the oriental medicine framework where we can paint a picture for them of cause and effect, or how things relate within the body, and give them the opportunity, and power in a way to make choices day-to-day in what foods they eat, what they wear when they go out, what they’re thinking — to
be more aware of their lifestyle and how it impacts their health. (Auckland Practitioner 3)

Practitioners commented on how, previously, women had not really been listened to by other health professionals, and that the understanding of their own body was discounted in light of health professionals' superior medical knowledge. By explaining how their symptoms are connected in TCM means that women are finally being heard rather than dismissed:

We listen. We listen to what they say. Certainly what I try to do is when you’re going through and you’re asking all the appropriate questions and all the rest of it, but I also try to explain to them why I’m asking the questions, and how this symptom relates to what’s going on for them, and how that symptom relates to that symptom, and I would expect that they would have this as well, and they go yeah. And suddenly they feel that someone’s actually hearing what they’ve got to say. Whereas they may have noticed correlations or connections between what’s going on for them — GPs discount a lot of what they actually are experiencing, and people do know what’s going on in their bodies, to a large extent. (Auckland Practitioner 1)

Several practitioners felt that educating patients in this way was important, because they might not have ever had these concepts explained to them before, and that it was the practitioners’ responsibility to point these out:

That eating a tub of ice-cream when they know they’re pre-menstrual, and actually noticing the impact that it has on their actual bleeding and the pain level, and they do start to notice, but if no-one’s ever told them before, then they’ve got no reason to notice that there’s a correlation. (Auckland Practitioner 1)
Other practitioners felt that women “already knew” that they should be making these changes; it was just up to the practitioner to remind them by explaining the linkages:

I think there’s a reason why they got there. We look back at the pathology. All those things have to be worked on, because we can do whatever we do for as long as we want, but if they don’t do the other — yeah, they don’t address the lifestyle issues, then it’s just going to come back, or you’re not going to get as far with the treatment anyway. It’s a great time to educate people as well. It’s often stuff they already know, but you’re reinforcing it again and it’s going to feed into all sorts of other health issues that are going to come up for them now or in the future as well. (Wellington Practitioner 5)

One practitioner was slightly more circumspect, acknowledging that some of the advice given by TCM was quite foreign to most patients and might be in contrast to current “popular” health advice:

Yeah, actually make these changes this time because, like someone said, they do know it anyway. They knew it before they came to us. Some things. Some, like eating warm foods and things, not just having salads, they might be surprised at, because salad’s healthy. But the whole alcohol / coffee, they kind of know. (Wellington Practitioner 2)

This idea of empowering women to be their own health experts, at the least in the area of their own lives, was voiced by several practitioners. Practitioners expressed a desire to “make themselves obsolete” by teaching women to take control of their own health, to enable them to finish the healing process themselves. The practitioner’s role would therefore be diminished, or even entirely superfluous, once women knew what to do:
... they [patients] know what they need to do for the future and they’ve made some life changes, be it small or be it large, they can then finish the rest of it themselves. (Auckland Practitioner 3)

You know, if the patient can recognise things that stimulate the pain and things that ease the pain, then you’re halfway there, if they’ve got some self-awareness then they don’t need you much anymore, which is a good thing. (Sydney practitioner 1)

This knowledge was also not solely the domain of acupuncturists, but could be spread to others once patients were educated, allowing women to pass this knowledge on to others who could in turn benefit and so on, thus “changing the world”:

Yeah, I think it’s a really important part — the whole education, and then they tell their friends, they educate them too, and we can change the world. (Auckland Practitioner 1)

Another component of this was that women could share some of the responsibility for their wellbeing, that acknowledging previous diet and lifestyle choices contributed to the current disharmony was important as this meant that it wasn’t solely the practitioners’ responsibility to “cure” them:

So I pretty much give advice to everyone, and just simply, for them to be able to see that their lifestyle and whatever they’ve been doing in their whole life, has been leading to this point, which is in some state of disharmony, and if I can just highlight even just a couple of factors, what I think is leading them to this way, and they change that, they could get better theoretically by themselves over time. (Auckland Practitioner 3)
The effect of this, according to some of the practitioners, was to remind women that they not only shared the responsibility for their health, but that they are not powerless in their own bodies and able to bring themselves back to a state of balance:

Their choices have led them to being out of balance. So they can lead them[elves] back to balance. (Auckland Practitioner 3)

4.8.2 Introducing women to a new normal

This sub-theme emerged from discussion by practitioners around women presenting to their clinics for the treatment of period pain. Despite the previous discussion on how effective acupuncture treatment was for period pain; the consensus amongst practitioners was that very few women presented with period pain as their primary complaint. Most women presented for other reasons, sometimes a menstrual-related complaint, but didn't usually specify period pain as the reason for their visit:

Even then it’s not normally that they come saying “I’m here for period pain”, it’s more that they come and say “I’m here because my cycles are whacky” or, you know, “I feel like my cycle’s not healthy”, it’s usually a little bit more vague about their cycle rather than specifically coming and saying “I’ve got really bad period pain, can you help me with that?” (Sydney Practitioner 2)

Linked to this idea is the notion that menstrual issues, especially related to period pain, are only important to deal with if they interfere with others’ lives, either in terms of day-to-day interactions, or possibly contributing to issues related to falling pregnant:

It feels like they might present when what they’re experiencing is affecting other people. So when their irritability is affecting their interactions with other people, or they’re trying to get pregnant and that’s obviously a
partnership. Whereas period pain, people kind of suffer alone in silence and just seem to think that they just get through it. (Wellington Practitioner 3)

Most practitioners felt that the reason women did not present themselves as seeking treatment for period pain, was due to women considering period pain as normal, and therefore not something that either required treatment, or that treatment was even possible for. Practitioners often felt that women had never been told what a “normal” period was, and so therefore just had to imagine, due to the physical nature of bleeding, that pain is to be expected:

Yeah, I think that’s true that a lot of women think that just goes with the territory of menstruating, that you get pain and they think of it as a very physical thing, you know, their uterine lining being ripped out of them is necessarily painful, you know. (Sydney Practitioner 1)

I think it’s part of how society views periods and that a bit of pain is — or pain is expected. So it’s educating them about that as well and that spreads the word. (Wellington Practitioner 2)

One practitioner noted that a possible reason for women not presenting for period pain is that it would be more common to seek mainstream, biomedical treatment for the problem, where many women would be placed on the pill. This would often mask the symptoms and reduce the period pain while they remained on the pill:

Nobody really just come here for period pain because they’re more likely, first off is they go to see their doctor and the doctor straightaway gives them the pills and so they think the pill will get rid of the pain but it really is not a pill to help them get rid of pain, because just the pill regulated the period and so they don’t really get those pain … nobody really just coming for period pain. (Sydney Chinese Practitioner 1)
Practitioners also often found that women would not mention painful periods unless specifically asked, with painful periods not only being considered *not* a health “condition”, but also often so accepted that painful periods were not even considered a symptom at all, but just part of the structure of a normal period:

Generally what I find is that women are so conditioned to the fact that periods are painful, that they don’t actually think of it as being a symptom, and when you ask them about it, they say oh but that’s normal for me. (Auckland Practitioner 1)

... yeah, because a lot of women think that pain’s normal for their period, so they don’t mention it, because they don’t think it’s psychological or a health problem. (Sydney Practitioner 4)

In contrast, some practitioners noted that only up to a certain level of pain was considered normal, for those women who were suffering from more severe period pain, it often was a cause for concern, especially if they were unable to control it with over-the-counter pain medication:

It depends. If it’s just a little bit of pain, and some of them they don’t pay much attention, and they just take the pain killer and then it went away, but if it’s sore, it’s very severe, they still think it’s a problem and then they ask for the treatment. If it’s not so bad that they can control it with, you know, some Panadol or some Ibuprofen, then they tend to think it’s normal, but if it’s obviously severe and affecting them, then not so much. (Sydney Chinese Practitioner 3)

One practitioner felt this might be especially evident when young women are involved, with the mother noticing the severity of the daughter’s pain, and associated symptoms as possibly being far removed from her own experience:
Some girls, if it’s not severe, they’re thinking it’s a normal part of their life. If it’s perhaps severe they do thinking that they have a problem, you know, and I have some mums they bring them, you know, they said okay, my daughter is taking Panadol always ... and then she have a period and she is pale and sweating and don’t want to eat, you know, really suffer and lay down in bed, and that’s their thinking they do have a problem. (Sydney Chinese Practitioner 4)

4.8.3 Reframing the narrative around period pain

One of the therapeutic tools practitioners used was “reframing” the period pain in terms of TCM. This included discussing what a normal period involved, as well as the concepts that period pain comes about due to a pattern of disharmony rather than it being a specific disease. This changing of the pain from something mysterious to something that is often described in terms of energetic changes was thought to help women come to a new understanding with regards to their periods:

... certainly part of the process is that reframing or developing a new narrative about that pain ... it wasn’t because the practitioner said, “You have to think about it this way”, it was because the practitioner was saying, “Oh, that’s interesting, little bit of Qi stagnation there, or there’s a little bit of blood”. It was in a way the self-talk of the practitioner that got absorbed by the patient, if that makes sense. (Sydney Practitioner 1)

Often this explanation of what a normal period was, and what could be expected after treatment, gives women a sense of hope that there was a different and less traumatic experience they could have each month:

When you say to people, you don’t need to be having this kind of pain. It’s not actually normal. They kind of — it’s a bit like, oh, there’s a whole other life out there. (Wellington Practitioner 2)
Practitioners felt this explanation of a “normal” period according to TCM was well received by their patients, and women found it exciting or were surprised that they didn’t have to necessarily have pain every period:

Well certainly they are excited by the possibility that they don’t have to have pain and that they don’t have to put up with pain and that, in fact, it’s not what we regard as normal in Chinese medicine, yes. (Sydney Practitioner 4)

... they’re quite shocked to find that it’s not actually really compulsory or necessary. (Auckland Practitioner 1)

Two practitioners shared similar experiences when talking about a “normal” period to women who suffered from period pain. Both found that women were “shocked” by the fact that pain was not considered normal and found it hard to believe:

Describe a natural period to them — what a period should be like, and they’re almost invariably quite shocked that a period can be like that, because for them it has never been like that right from the beginning. (Auckland Practitioner 1)

Yeah, they don’t even believe me actually. (Auckland Practitioner 2)

They don’t believe that a period like that’s possible. (Auckland Practitioner 1)

Yeah, they just look at you like you’re crazy. (Auckland Practitioner 2)

4.9 Its not cut and dried

This is the final, major theme that emerged and captured; how, in individualising treatments, not only was the diet and lifestyle advice and point
selection based around the patient’s traditional Chinese medicine diagnosis, but there was some inter-practitioner variation around the usage of electro-acupuncture for stimulation.

The usage and experience of electro-acupuncture in treating period pain was the most diverse area when discussed, with four separate groups of practitioners emerging.

The first group was comprised of practitioners that use electro-acupuncture on a regular basis in clinic for period pain and other conditions. These practitioners may not necessarily have used it for period pain in the past, but felt comfortable using this stimulation method on a regular basis for painful conditions, and would be happy to try it on women suffering from dysmenorrhea as they regard it as an effective and safe modality:

I use that in my clinic as well, electro-acupuncture. It really depends. Because the clients, as what I said, for the period pains mainly young girls … But I think electric needles is mainly to help the needles stimulate and make the, you know, the stimulation of the treatment of the needles and make the treatment result better. (Sydney Chinese Practitioner 2)

The second group were practitioners who don’t use electro-acupuncture because they feel they have not been adequately trained in its usage, but would be open to using it more in clinic if they felt more confident. These practitioners may use it for a limited range of conditions based on the training they have received, but feel they don’t have enough knowledge or experience to use it in the treatment of period pain:

For me, I feel I haven’t been trained in it properly. I feel a bit scared of the little machine. I use it for — I find it great for tennis elbow, de Quervain’s, yeah, but even low back pain I don’t use it too much. Yeah, I just don’t feel very confident with it probably. But if I had a good seminar on it and came
away feeling confident, I might use it a lot more in practice. (Wellington Practitioner 3)

Some of this second group were also concerned that the intensity of stimulation of electro-acupuncture was too strong for using on the abdomen, and that it would be uncomfortable for patients. One practitioner mentioned that if they could have it demonstrated on them and they found it tolerable, they would be happy to use it in clinic:

I just think that electro-acupuncture is probably a bit too mean, a bit too stimulating. But I’m happy to try it, if I could just maybe have a practice run with someone. Or actually just to have it done on me. I don’t get period pain, but just to see what it feels like around the lower abdomen. But it’s quite a sensitive spot and I feel that a lot of women with the cramping they’ve got a lot of stasis there. Yes, it does need to be shifted. I can see why electro-acupuncture could work. I just think it’s — yeah, just a little bit too intense. (Wellington Practitioner 5)

The third group included practitioners who felt that the use of electro-acupuncture was in opposition to their philosophical outlook on treatment, which took a more gentle and “traditional” approach. Practitioners felt that they didn’t need electro-acupuncture, as they already had suitable tools with traditional methods, and had made a conscious decision not use electro-acupuncture at all:

I’ve never really thought about it that much, but yes, I think that I’m a little philosophically opposed to using it … I’d rather do things gently, even if it does mean it might take a little bit longer. (Sydney Practitioner 2)

I definitely don’t. I don’t use electro on anybody for anything, and that’s a conscious choice. I don’t actually like the idea. My most common thing to say about that is that acupuncture’s been working for centuries — thousands of
years — long before electricity was ever added. We should be able to do it without. I don’t like the idea of having electrical currents put through my body, and I’m not going to do it to anyone else. (Auckland Practitioner 1)

One practitioner mentioned that they felt like a “proper” practitioner because they used their hands to attain the and propagate the Qi sensation, rather than “cheating” and using electro-acupuncture as a shortcut:

I mean maybe the theoretical things are a justification of my ignorance but, yeah, I like getting De Qi, you know, I am a proper Chinese practitioner and I like using my hand to feel the Qi and to propagate Qi. And I seem to be able to do that quite strongly and I can’t see the point really of using electro. Yeah, but maybe that’s because of my ignorance of wonders of electro-acupuncture, yeah. (Sydney Practitioner 1)

The final group of practitioners were those who had previous negative experience with electro-acupuncture when treating patients due to the intensity of the sensation that electro-acupuncture often provides. This caused some practitioners to decide that they would not use it again:

Yeah. The few times I have used it, people have been a little bit — even though I start from the bottom and come up really slowly with the electricity, the few people I’ve tried it on have freaked out on me. So I’m just like, no, I’m not doing that anymore. Sensitive. (Wellington Practitioner 2)

Not all practitioners who had previous negative experiences with electro-acupuncture had decided to avoid its usage. One practitioner mentioned that it could be uncomfortable, but they would still use it sometimes if the points needed extra simulation:
And if you’re very uncomfortable they feel very uncomfortable if you give the person very strong the feeling. But sometimes I use the electric because electric is a reason you know, is a reason and they feel a lot better. But I think it’s a good way to give them more stimulant to the points. (Sydney Chinese Practitioner 5)

Those practitioners who trained in China were more likely than their counterparts who trained in New Zealand or Australia to use electro-acupuncture. Chinese-trained practitioners felt this might be due, at least in part, to the differences in clinical practice in China. A significant difference in clinical practice between the countries mentioned by one practitioner is the number of patients being treated at once by each practitioner; the number being significantly more in China, rather than the more common 1:1 ratio in New Zealand or Australia. This may account for some of the popularity of electro-acupuncture, that it allows stimulation without needing a practitioner present:

I would say the European practitioners they don’t use that at first. I found that many of them wouldn’t like buy any equipment and one is the cost. Another thing is they think without electrical is traditional. With the electrical is not traditional, you know? And then certainly the colleges have not trained them [European practitioners] with electrical and another way in China, in clinical practice, you have one doctor looking after six tables and then you do use electrical. Otherwise you come back in 20 minutes time the patient will never come back later. (Sydney Chinese Practitioner 1)

Another practitioner felt it might be due to the difference in relative authority of an acupuncturist in China and in New Zealand or Australia. In China acupuncturists take on more of the traditional, expert role that has been filled by western medical doctors in New Zealand and Australia:

I think we used more in China, electric acupuncture. Because I think the result, it’s the reason because the system is different. In China I’m a doctor, I
tell my clients, “You need to this”. They always say, “Yes, I have to do this for you”, but here I’m a practitioner, it’s different. The clients say, “Oh, I don’t want anymore” and they just stopped and I lose my client. So it’s a bit different system. (Sydney Chinese Practitioner 2)

However, some Chinese-trained practitioners disagreed with this and mentioned that they didn’t see a lot of electro-acupuncture usage when they were in China:

Actually in China, the electric acupuncture not used a lot. Normally it used for very seriously some shoulder, back or something to keep the pain, and some spine problem. Yeah, it’s used a lot but in emergencies or gynaecology really not used, but here I use a little bit. The reason is, you know, some patients you couldn’t give them very strong stimulant. (Sydney Chinese Practitioner 5)

Electro-acupuncture has been commonly used in recent research in China when treating period pain and polycystic ovary syndrome (PCOS). Practitioners indicated that they were aware of the use of electro-acupuncture in the literature, and some had incorporated it into practice after reading successful clinical trials on the usage of electro-acupuncture to treat anovulation in PCOS patients:

... in my practice there’s a lot more electro-acupuncture in the last year than probably what I have before. And that’s probably a product of some of the research I’ve seen come out actually. (Sydney Practitioner 3)

Not for period pain, but I’ve used it for ovulation and on the abdomen and PCOS. Yeah, it’s one of those areas that I think, again with my training, we certainly touched on it, but not enough that I got really into it. The more I’ve read, the more I’m getting into it and using it more. I think it probably would work really good — well for period pain actually. (Wellington Practitioner 1)
4.10 Protocol development

As outlined in Chapter Three, a clinical trial protocol was developed from the survey and focus groups / interviews discussed in this chapter. This section discusses those sources and how they shaped the development and clinical decision making involved in the protocol.

The review of the literature in Chapter Two showed that a significant number of trials (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011) that have been undertaken in recent years in China have used electro-acupuncture as the primary intervention and have shown positive outcomes, with respect to a reduction of period pain. Many of these acupuncture trials also used daily (Bu, Du & Chen 2011; Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Ma et al. 2013; Xiong et al. 2012) or near-daily (Huang et al. 2013) treatment. However, due to the low quality of these trials, as mentioned in the recent systematic reviews (Cho & Hwang 2010b; Smith et al. 2011b), as well as evidence that publications by Chinese researchers tend to publish positive results (Vickers et al. 1998) this means that these findings must be interpreted with caution. In addition to possible methodological problems, the issue of applicability to practice in the western world must also be addressed. Data from Chinese practitioners who participated in the interviews also confirms that this daily or near-daily treatment closely replicates contemporary clinical practice in China. Usage of electro-acupuncture was more controversial, with some practitioners saying it was common in China due to the nature of the large, multi-bed clinics, however, others thought that electro-acupuncture was over-represented in research as it allowed more easy standardisation of the intervention.

4.10.1 Clinical considerations

Several important clinical considerations remain unanswered, such as when delivering acupuncture in a community setting, what is the optimal treatment approach regarding when to treat and what kind of stimulation to use?
4.10.2 High and low frequency of treatment

All Chinese-trained practitioners acknowledged that they experienced significant differences in the frequency of treatment now they lived in Australia. This was supported by other European-trained practitioners who stated that their “ideal” treatment frequency would be up to three times in one week, this being the maximum they felt they could logistically support in their clinics, as most were solo practitioners with single-room practices. All practitioners felt that patients could not undertake daily treatment due to logistics and cost. Therefore three times in the week prior to the expected start of menses was chosen as an approximation of the high frequency of treatment given in China, where treatment is often focused on the week prior to menses (Bu, Du & Chen 2011; Xiong et al. 2012), while still allowing for the realities of clinical practice in New Zealand and Australia. The low-frequency treatment chosen was based around the most common treatment frequency that practitioners used in clinical practice, once per week. This is also a similar treatment frequency to previous acupuncture trials undertaken in the west (Helms 1987; Iorno et al. 2008; Smith et al. 2011).

4.10.3 Common treatments between groups

All participants in both high and low frequency treatment groups received a treatment during the first two days of menses. The decision to treat during the menstrual period was based on a combination of previous trial design, where participants received treatment during menses themselves (Kiran et al. 2013; Liu et al. 2011; Ma et al. 2010; Shi et al. 2011; Yu et al. 2010), and practitioner data; practitioners discussed how they would like to treat during the time of pain itself, as well as during the non-painful parts of the cycle. As the peak pain for primary dysmenorrhea is commonly experienced in the first eight to 72 hours after onset of menstrual flow (Proctor & Farquhar 2006) this time was chosen to provide the most significant potential for pain relief.
4.10.4 Duration of treatment

A duration of three months for the study was based on the feedback of focus group and interview participants. Most acupuncturists were circumspect around the possibility of a “cure” within three months, but the consensus was that three months was a suitable timeframe for any significant changes in symptoms to be noticeable, and many were confident that improvement would happen within the first month of treatment. This three-month, 12-treatment timeframe also ensures the study is comparable with other trials using a similar duration / treatment number (Helms 1987; Smith et al. 2011; Witt et al. 2008).

4.10.5 Mode of stimulation

Two forms of needle stimulation were included in the trial protocol, manual acupuncture and electro-acupuncture.

4.10.5.1 Manual Acupuncture

The manual acupuncture intervention was based on standard acupuncture gynaecology texts (see Appendix A1) with additional information provided by focus group and interview participants. Consensus was that DeQi needed to be obtained on needle insertion and that most practitioners would stimulate once within a treatment session to reobtain DeQi sensation. Retention time varied amongst practitioners, with 15–30 minutes being the minimum to maximum recommended times. Twenty minutes was the most commonly suggested retention time and was chosen as the recommended minimum retention time for the study, with up to 30 minutes being allowed based on practitioner considerations.

4.10.5.2 Electro-acupuncture

When designing the electro-acupuncture intervention, two important considerations arose; firstly, practitioners in the focus groups and interviews expressed concern about long durations of electro-acupuncture being “draining” on women, and secondly, some experimental evidence suggests that
15-minute durations are sufficient to elicit significant pain relief (Leung et al. 2008). Therefore a decision was made to limit the duration of the electro-acupuncture stimulation to no more than 20 minutes. This was the same as the recommended duration for retention of manual acupuncture needles. A 2Hz / 100Hz high frequency / low frequency cycle was chosen, also on the basis of both clinical and experimental consideration; this cycle has been shown to cause maximal opioid gene expression (Guo et al. 1996), as well as being the most common frequency of electro-acupuncture treatment used for primary dysmenorrhea in other trials (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011).

4.10.6 Co-interventions

The use of co-interventions is common in acupuncture practice amongst New Zealand and Australian acupuncturists (Moore 2014; Smith, Armour & Betts 2014). Two specific co-interventions, moxibustion and self-care advice, were commonly used in the practitioner survey, and the importance of these two co-interventions was reinforced by practitioners in the focus groups and interviews.

4.10.6.1 Moxibustion

The inclusion of moxibustion in the trial protocol was based upon three sources of data: textbook (Maciocia & Kaptchuk 2011), the New Zealand and Australian practitioners’ survey (Smith, Armour & Betts 2014), which showed that almost 62% of practitioners used moxibustion as a common co-intervention when treating primary dysmenorrhea, and the data provided by the focus groups / interview participants. Practitioners emphasised the importance of moxibustion usage in women with either cold stagnation or Yang deficiency patterns, but also commented on how they commonly used moxibustion across a range of patterns when treating primary dysmenorrhea as moxibustion is also effective in moving qi and blood stagnation, an underlying cause of primary dysmenorrhea. Moxibustion was therefore made optional for all, except the “Cold stagnation in the uterus” and “Yang and blood deficiency” patterns, where
it was compulsory to use moxibustion unless the practitioner provided strong clinical reasoning why it was not appropriate, for example, if the participant was suffering from a fever.

4.10.6.2 Self-care advice

Survey data (Smith, Armour & Betts 2014) shows that almost 70% of practitioners in New Zealand and Australia use diet and lifestyle advice when treating primary dysmenorrhea. Further investigation through the focus group and interview data also confirms that acupuncturists believe that diet and lifestyle advice is critical to both initial and ongoing improvement during the course of treatment, and prevention of recurrence of symptoms at the conclusion of treatment.

Practitioners indicated that they gave individualised advice based on the pattern of disharmony. They tended to repeat similar information to different patients, but delivered the information in a way that specific patients could accommodate. Previous studies on using acupuncture for primary dysmenorrhea have not delivered standardised self-care advice, nor have they followed up with study participants on the usefulness and applicability of this advice. Advice, in the form of take-home sheets, must be at least standardised in content to ensure all participants are receiving the same amount and depth of information. Insufficient information was provided by practitioners to form diet and lifestyle sheets for each specific pattern of disharmony, therefore these sheets were compiled by the primary investigator [MA] from recent acupuncture texts on women’s health (Lewis 2008; Maciocia & Kaptchuk 2011). These were grounded in traditional Chinese medical theory on the nature of food and also gave advice on lifestyle components, such as sleep recommendations and stress reduction. Each pattern of disharmony had a separate sheet, these included: Qi stagnation, Blood stasis, Stagnation due to cold, Damp-heat, Liver fire, Liver and kidney Yin deficiency, Qi and blood deficiency and Yang and blood deficiency. These sheets are provided in Appendix A11.
In the case of multiple patterns, the sheet for the primary pattern was provided, however, additional sheets could be provided in the event that the patient’s pattern of disharmony changed over the course of treatment. Study practitioners were encouraged to expand on the written information by rephrasing or reinterpreting the advice for patients to make it more applicable to their own personal situation. The diet and lifestyle advice was broken down into points to discuss each month, as practitioners expressed concern about “information dumping”, the concept of giving too much advice at once possibly leading to participants feeling overwhelmed and therefore not taking any of it.

4.11 Summary

The survey findings show that gynaecological conditions are a common area of specialisation amongst both New Zealand and Australian acupuncturists, with primary dysmenorrhea being a commonly treated disorder. Acupuncturists use a variety of modalities to treat primary dysmenorrhea, including acupuncture, moxibustion, Chinese herbal medicine and lifestyle and diet advice.

The findings from the focus groups and in-depth interviews of practitioners support the concept that acupuncturists practice within a complex partnership with the women they care for. This central theme of “a complex partnership” incorporated ideas of holism; empowering and educating patients, helping patients overcome practical obstacles to treatment, individualising treatment and the importance of including diet and lifestyle advice as part of their treatment strategy.

These themes also captured some of the complexity of acupuncture clinical practice: the individual nature of treatment, the use of a wide range of sources when making clinical decisions, and the importance of customising advice.

The findings of the survey, focus groups and in-depth interviews were used to generate a manualised clinical trial protocol based on practitioners clinical recommendations. Chapter Five reports the findings of the randomised controlled trial that was conducted using this trial protocol to examine the
effect of treatment timing and mode of stimulation on the symptoms of primary dysmenorrhea.
Chapter Five: The effect of timing and mode of stimulation of acupuncture treatments on primary dysmenorrhea — a randomised controlled trial

5.1 Introduction

This chapter presents the findings from the exploratory randomised controlled trial (RCT) undertaken in Auckland and Wellington, New Zealand, of women with primary dysmenorrhea. The overall objective of this study was to examine the effect of changing modes of acupuncture stimulation or the treatment timing on the symptoms of women suffering from primary dysmenorrhea.

There were two primary hypotheses for this study:

5) High-frequency acupuncture would have the greater effect on reducing menstrual pain compared to a low-frequency acupuncture treatment, and
6) Electro-acupuncture would have the greater effect on reducing menstrual pain compared with a manual acupuncture treatment.

The secondary hypotheses were:

7) High-frequency acupuncture would have a greater reduction in medication use and increase health-related quality of life (HRQoL) compared with a low-frequency acupuncture treatment, and
8) Electro-acupuncture would have a greater reduction in medication use and increase health-related quality of life (HRQoL) compared with a manual acupuncture treatment.
The primary endpoints for this study were:

- reduction in peak menstrual pain score (0–10) on days one, two and three of the menstrual period at one, two, three and four months from trial entry, and
- reduction in average menstrual pain score (0–10) over the whole of the menstrual period at one, two, three and four months from trial entry.

Secondary endpoints for this study include:

- duration of menstrual pain at one, two, three and four months from trial entry,
- worst menstrual pain at one, two, three and four months from trial entry \((a \postori)\),
- analgesic intake at one, two, three and four months from trial entry,
- days taken off work / school at one, two, three and four months from trial entry,
- number of secondary menstrual-related symptoms such as bloating, breast tenderness and nausea at one, two, three and four months from trial entry,
- changes in health-related quality of life at four months from trial entry, and
- self-rated symptom improvement score at three months post-trial entry.

The hypotheses and endpoints were used to answer these secondary questions:

- does using a manualised protocol to deliver acupuncture treatment change self-rated menstrual pain scores?
- what extent, if any, do differing frequencies of treatment and types of stimulation contribute to the changes in self-rated menstrual pain scores?
- does the manualised acupuncture intervention alter the frequency of secondary symptoms of dysmenorrhea?
- are more frequent acupuncture treatments an acceptable intervention for participants?
• is electro-acupuncture an acceptable mode of stimulation?

## 5.2 Randomised Controlled Trial (RCT)

### 5.2.1 Eligibility

A total of 106 women expressed interest in the study by contacting the primary investigator via the University of Western Sydney Portal web page\(^9\) or directly via email. Ninety-six (90.5%) of these women participated in the screening interview, while ten (9.4%) did not reply to follow-up emails or phone calls. Of the women screened, 79 (82.2%) met the entry requirements on the initial screening questionnaire. See Figure 5.1 for more detail on participant flow.

Seventeen women were excluded at initial screening: 15 had a confirmed diagnosis of secondary dysmenorrhea from their general practitioner or specialist, one had pain that had started at age 36 and had not sought medical advice, and one was aged 17.

Of the 79 women who met the initial entry screening requirements, upon receipt of the baseline menstrual pain diary and prior to randomisation, five women were excluded: two had menstrual cycles exceeding 36 days in length, two could not travel to the study site in Auckland, and one had subsequently made plans to travel for an extended period of time during the study timeframe.

Based on early feedback from potential participants we found some grey areas around the eligibility criteria. Firstly, many who were now over the age of 30 could not remember precisely if their pain started within two years of menarche, and some women had pain that started after the age of 25 but had been screened by ultrasound scan and laparoscopy and cleared of secondary dysmenorrhea. An ethics amendment was submitted and approved to include

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women whose pain started prior to age 18, or after age 18 if an ultrasound scan or laparoscopy showed no signs of secondary dysmenorrhea.

5.2.2 Randomisation and participant flow

Seventy-four women were eligible to join the trial based on the results of the menstrual pain diary and were randomised to one of the four groups. Eighteen women each were randomised to the high-frequency manual acupuncture (HF–MA) group and low-frequency electro-acupuncture (LF–EA) group, 19 women each to the low frequency manual acupuncture (LF–MA) group and high frequency electro-acupuncture (HF–EA) group. One participant in the LF–EA group was excluded post-randomisation following the identification of signs of endometriosis by the treating acupuncturist and was referred to a gynaecologist who suspected endometriosis and referred for a laparoscopy.

Sixty-three women completed the treatment phase of the trial. Ten participants withdrew during the treatment phase of the trial. Withdrawal from the trial was equally distributed across groups, with none of the women citing any group-related concerns as reason for withdrawal. One participant withdrew due to moving cities for work. Two participants withdrew due to logistical issues with getting to the clinic during opening hours. Two participants withdrew due to falling pregnant. One participant withdrew due to a diagnosis of cervical cancer. One participant withdrew due to pre-existing anxiety, which became aggravated by the acupuncture. Three participants withdrew prior to their first treatment session: two due to a return to their home countries and one due to changing work commitments.
Figure 5.1: CONSORT flow diagram.

[Diagram showing the flow of participants from contacted researcher to randomised participants, with details on allocation, discontinuation, and follow-up.]
**Figure 5.2: Data collection time points during trial.**

Potential participants fill in baseline demographics and baseline menstrual pain diary

Researcher checks eligibility

First treatment session: baseline SF-36

Acupuncture treatments

First menstrual period after joining the study: Menstrual pain diary month 1

Acupuncture treatments

Second menstrual period after joining the study: Menstrual pain diary month 2

Acupuncture treatments

Third menstrual period after joining the study: Menstrual pain diary month 3 & post trial questionnaire

No treatment

First menstrual period after finishing study treatment: Menstrual pain diary followup & followup SF-36
There were four data collection points in the study: prior to entry to the trial, at each menstrual period for the three months of active treatment, and at the next menstrual period after exiting the trial (see Figure 5.2).

During the treatment phase of the trial, some data was not collected or lost. One woman returned their baseline data sheet to one of the treatment acupuncturists who misplaced it. Three women did not complete one of the three menstrual diaries during the study period: one was hospitalised and did not complete it, and two were on holiday and forgot to complete the diary. During the follow-up phase, one woman forgot to fill in the menstrual diary. One participant fell pregnant during the follow-up month and did not complete any follow-up data. Missing data was equally distributed across groups, with no group-specific reasons for missing data reported. All missing data was imputed using the last observation carried forward (LOCF) method, under the principles of an intention-to-treat analysis.

5.2.3 Characteristics of women at trial entry

The demographic and menstrual characteristics of the women in this study according to the group randomisation are shown in Table 5.1. The mean age of women entering the study was 30.4 years. According to BMI measurements 4% of women in the study were underweight, 55.4% were in the normal weight range, 24.3% overweight and 16.2% obese. The mean age at menarche was 12.7 years while the mean age of the onset of dysmenorrhea was 14.7 years. Sixteen women (21.6%) had previously given birth. Women on average had 28.3 days between menstrual periods with 5.3 days of menstrual bleeding. With regards to the menstrual symptoms themselves, all trial participants had symptoms in addition to abdominal cramping such as nausea and breast tenderness. Sixty (81%) women regularly used analgesic medication during their period. When women did use analgesic medication 10.8% attained complete pain relief, 82.4% received partial pain relief while 5.4% reported no change in the pain with analgesic usage. Seventy three (98.6%) women used other non-pharmaceutical interventions such as rest or heat to help with their period pain. There were no differences in baseline menstrual symptoms between groups.
### Table 5.1: Demographic and Menstrual Characteristics of Women at Trial Entry.

Continuous data presented as mean (SD). Categorical data as N (%).

<table>
<thead>
<tr>
<th></th>
<th>HF-MA (n=18)</th>
<th>HF-EA (n=19)</th>
<th>LF-MA (n=19)</th>
<th>LF-EA (n=18)</th>
<th>Total (N=74)</th>
<th>p-value</th>
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<tr>
<td></td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td></td>
</tr>
<tr>
<td><strong>Demographic</strong></td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>Age</td>
<td>29.9 (7.2)</td>
<td>31.2 (7.4)</td>
<td>31.1 (6.6)</td>
<td>29.3 (5.6)</td>
<td>30.4 (6.7)</td>
<td>0.800</td>
</tr>
<tr>
<td>BMI (n %)*</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>0 (0.0)</td>
<td>2 (10.5)</td>
<td>1 (5.2)</td>
<td>0 (0.0)</td>
<td>3 (4.0)</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>9 (50.0)</td>
<td>8 (42.1)</td>
<td>13 (68.4)</td>
<td>11 (61.1)</td>
<td>41 (55.4)</td>
<td>0.501</td>
</tr>
<tr>
<td>Overweight</td>
<td>4 (22.2)</td>
<td>6 (31.5)</td>
<td>4 (21.0)</td>
<td>4 (22.2)</td>
<td>18 (24.3)</td>
<td></td>
</tr>
<tr>
<td>Obese</td>
<td>5 (27.7)</td>
<td>3 (15.7)</td>
<td>1 (5.2)</td>
<td>3 (16.6)</td>
<td>12 (16.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Previously given birth</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>14 (77.7)</td>
<td>16 (84.2)</td>
<td>13 (68.4)</td>
<td>15 (83.3)</td>
<td>58 (78.4)</td>
<td>0.624</td>
</tr>
<tr>
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<td>4 (22.2)</td>
<td>3 (15.7)</td>
<td>6 (31.6)</td>
<td>3 (16.6)</td>
<td>16 (21.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Menstrual characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age of Menarche (years)</td>
<td>12.5 (1.7)</td>
<td>12.7 (1.4)</td>
<td>13.2 (1.6)</td>
<td>12.3 (0.9)</td>
<td>12.7 (1.5)</td>
<td>0.307</td>
</tr>
<tr>
<td>Age of onset of dysmenorrhea (years)</td>
<td>15.8 (6.8)</td>
<td>13.7 (1.5)</td>
<td>15.9 (5.8)</td>
<td>13.3 (1.5)</td>
<td>14.7 (4.7)</td>
<td>0.190</td>
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<tr>
<td>Length of menstrual cycle (days)</td>
<td>28.1 (1.8)</td>
<td>28.7 (2.1)</td>
<td>27.8 (2.0)</td>
<td>28.6 (2.1)</td>
<td>28.3 (2.0)</td>
<td>0.499</td>
</tr>
<tr>
<td>Length of menses (days)</td>
<td>5.3 (1.9)</td>
<td>4.9 (0.8)</td>
<td>5.4 (1.2)</td>
<td>5.6 (1.7)</td>
<td>5.3 (1.2)</td>
<td>0.487</td>
</tr>
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<td><strong>Additional Menstrual Symptoms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18 (100)</td>
<td>19 (100)</td>
<td>19 (100)</td>
<td>18 (100)</td>
<td>74 (100)</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>HF-MA (n=18)</td>
<td>HF-EA (n=19)</td>
<td>LF-MA (n=19)</td>
<td>LF-EA (n=18)</td>
<td>Total (N=74)</td>
<td>p-value</td>
</tr>
<tr>
<td>-----------------------------------</td>
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<td>--------------</td>
<td>--------------</td>
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</tr>
<tr>
<td><strong>Pain relief with analgesia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No - Pain still present</td>
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<td>2 (10.5)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (5.4)</td>
<td>0.365</td>
</tr>
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<td>Yes - Partial Relief</td>
<td>13 (72.2)</td>
<td>16 (84.2)</td>
<td>15 (78.9)</td>
<td>17 (94.4)</td>
<td>61 (82.4)</td>
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</tr>
<tr>
<td>Yes - Complete relief</td>
<td>3 (16.6)</td>
<td>1 (5.2)</td>
<td>3 (15.7)</td>
<td>1 (5.6)</td>
<td>8 (10.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Use of non-pharmaceutical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>techniques for menstrual pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0 (0.0)</td>
<td>1 (5.3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (1.4)</td>
<td>0.402</td>
</tr>
<tr>
<td>Yes</td>
<td>18 (100.0)</td>
<td>18 (94.7)</td>
<td>19 (100.0)</td>
<td>18 (100.0)</td>
<td>73 (98.6)</td>
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</table>
**Table 5.2: Lifestyle and Acupuncture Characteristics at Trial Entry.**

Categorical data presented as N (%).

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=18)</th>
<th>HF–EA (n=19)</th>
<th>LF–MA (n=19)</th>
<th>LF–EA (n=18)</th>
<th>Total (n=74)</th>
<th>p-value</th>
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<td><strong>Lifestyle</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>Current smoker</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>16 (88.9)</td>
<td>19 (100.0)</td>
<td>17 (89.4)</td>
<td>18 (100)</td>
<td>70 (94.5)</td>
<td>0.237</td>
</tr>
<tr>
<td>Yes</td>
<td>2 (11.1)</td>
<td>0 (0.0)</td>
<td>2 (10.6)</td>
<td>0 (0.0)</td>
<td>4 (5.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Currently drinking alcohol</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2 (11.1)</td>
<td>3 (15.7)</td>
<td>9 (47.3)</td>
<td>3 (16.6)</td>
<td>17 (22.9)</td>
<td>0.032*</td>
</tr>
<tr>
<td>Yes</td>
<td>16 (88.9)</td>
<td>16 (84.2)</td>
<td>10 (52.6)</td>
<td>15 (83.3)</td>
<td>57 (77.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Acupuncture related</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Previous use of acupuncture for any condition</strong></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>9 (50.0)</td>
<td>10 (52.6)</td>
<td>11 (57.8)</td>
<td>10 (55.5)</td>
<td>40 (54.0)</td>
<td>0.967</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (50.0)</td>
<td>9 (47.3)</td>
<td>8 (42.1)</td>
<td>8 (44.5)</td>
<td>34 (46.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Expectation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsure</td>
<td>9 (50.0)</td>
<td>4 (21.0)</td>
<td>10 (52.6)</td>
<td>7 (38.8)</td>
<td>30 (40.5)</td>
<td></td>
</tr>
<tr>
<td>Probably will help</td>
<td>4 (22.2)</td>
<td>14 (73.6)</td>
<td>8 (42.1)</td>
<td>8 (44.4)</td>
<td>34 (46.0)</td>
<td>0.042*</td>
</tr>
<tr>
<td>Definitely will help</td>
<td>5 (27.8)</td>
<td>1 (5.2)</td>
<td>1 (5.2)</td>
<td>3 (16.6)</td>
<td>10 (13.5)</td>
<td></td>
</tr>
</tbody>
</table>
5.2.4 Lifestyle characteristics and previous use of acupuncture

Table 5.2 outlines the lifestyle characteristics of women in the four intervention groups. Four (5.4%) women were current smokers and 57 (77%) had one or more standard alcoholic drinks each week. Fewer women in the LF-MA group were current alcohol drinkers (52.6%) than in the other three groups (p=0.032).

Thirty-four (46%) women had previously used acupuncture for primary dysmenorrhea, or any other condition. This did not differ between groups. When asked if they thought acupuncture would help their condition 30 (40.5%) were unsure, 34 (46.0%) thought it probably will help and ten (13.5%) thought it definitely will help. Women in the HF-EA group had a significantly higher expectation (p=0.042) of the effectiveness of acupuncture with 78.8% expecting it will probably or definitely help, compared with 61% of women in the LF-EA group, 50% of women in HF-MA and 47.3% of women in the LF-MA group.

5.2.5 Quality of life

Participants completed the SF-36v2 during the first acupuncture treatment session to assess health-related quality of life (HRQoL). Sixty-nine women completed a baseline SF-36 and had data for analysis, see Table 5.3. Three women withdrew prior to first treatment, one completed her first treatment but withdrew after this and did not return her baseline SF-36. One woman completed a baseline SF-36, but her treating acupuncturist misplaced it. Four women who completed the trial did not complete the follow-up SF-36. Eight women who withdrew from the trial completed the baseline, but not the follow-up SF-36. All 69 participants who completed the baseline SF-36 had any missing data at follow-up imputed by LOCF.
### TABLE 5.3: SF-36 SCORES AT BASELINE. P-VALUES FROM ONE-WAY ANALYSIS OF VARIANCE (ONE-WAY ANOVA).

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=18)</th>
<th>HF–EA (n=19)</th>
<th>LF–MA (n=17)</th>
<th>LF–EA (n=15)</th>
<th>Total (n=69)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Physical function</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>55.8 (2.9)</td>
<td>55.0 (3.9)</td>
<td>52.8 (8.4)</td>
<td>53.7 (7.4)</td>
<td>54.3 (6.1)</td>
<td>0.456</td>
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<tr>
<td>Role physical</td>
<td>54.8 (5.0)</td>
<td>46.4 (9.7)</td>
<td>50.2 (7.8)</td>
<td>47.6 (8.0)</td>
<td>49.7 (8.4)</td>
<td>0.008 *</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>49.1 (7.4)</td>
<td>43.6 (5.3)</td>
<td>44.8 (9.3)</td>
<td>43.4 (7.4)</td>
<td>44.9 (7.7)</td>
<td>0.087</td>
</tr>
<tr>
<td>General health</td>
<td>51.3 (10.6)</td>
<td>50.4 (10.4)</td>
<td>52.8 (9.9)</td>
<td>51.6 (7.7)</td>
<td>51.5 (9.6)</td>
<td>0.901</td>
</tr>
<tr>
<td>Vitality</td>
<td>48.1 (9.8)</td>
<td>45.4 (7.8)</td>
<td>48.2 (9.9)</td>
<td>48.9 (6.5)</td>
<td>47.7 (8.6)</td>
<td>0.609</td>
</tr>
<tr>
<td>Social function</td>
<td>50.7 (8.2)</td>
<td>43.9 (11.3)</td>
<td>44.9 (10.7)</td>
<td>47.6 (7.0)</td>
<td>46.7 (9.7)</td>
<td>0.146</td>
</tr>
<tr>
<td>Role emotional</td>
<td>49.6 (6.6)</td>
<td>47.6 (8.9)</td>
<td>47.6 (8.9)</td>
<td>49.0 (8.0)</td>
<td>48.4 (8.1)</td>
<td>0.828</td>
</tr>
<tr>
<td>Mental health</td>
<td>51.0 (6.3)</td>
<td>50.3 (5.8)</td>
<td>47.3 (8.1)</td>
<td>49.6 (7.2)</td>
<td>49.5 (6.9)</td>
<td>0.384</td>
</tr>
<tr>
<td>Overall mental</td>
<td>48.1 (8.1)</td>
<td>44.8 (10.0)</td>
<td>46.1 (9.4)</td>
<td>47.9 (8.7)</td>
<td>46.7 (9.0)</td>
<td>0.677</td>
</tr>
<tr>
<td>component</td>
<td>54.1 (6.6)</td>
<td>49.4 (6.7)</td>
<td>51.4 (6.3)</td>
<td>49.3 (6.9)</td>
<td>51.0 (6.8)</td>
<td>0.134</td>
</tr>
</tbody>
</table>

Mean baseline scores were: 54.3 (6.1) for physical function, 49.7 (8.4) for role physical, 44.9 (7.7) for bodily pain, 51.5 (9.6) for general health, 47.7 (8.6) for vitality, 46.7 (9.7) for social function, 48.4 (8.1) for role emotional, 49.5 (6.9) for mental health, 46.7 (9.0) for overall mental component and 51.0 (6.8) for overall physical component.

One-way ANOVA between groups at baseline showed there were no between group differences, except for role physical which was significantly lower in the HF-EA and the LF-EA groups F(3,69)=1.12, p=0.008.
5.2.6 Baseline menstrual pain diary

At trial entry the mean peak pain, measured as the mean of the worst pain (0–10) on each of the first three days, was 5.6 (2.3), 5.3 (2.6) and 3.8 (2.8) respectively. The worst pain intensity, measured as the highest peak score during each menstrual period, was 7.1 (1.4). The average pain intensity, measured as the mean of the average pain score (0–10) over the entire menstrual period, was 2.6 (1.2). The mean duration of pain each day over the menstrual period was 5.5 (5.0) hours. The mean number of additional menstrual symptoms (such as bloating or breast tenderness) per day was 2.6 (1.6). Menstrual symptoms present in women at trial entry were lower back pain (74.7%), abdominal bloating (70.9%), breast tenderness (68.4%), bowel changes (68.4%), emotional changes (67.1%), headache (51.9%), nausea (49.4%), dizziness (36.7%), thigh / leg pain (32.9%), fluid retention (32.9%) and vomiting (8.9%). The average number of doses of analgesia taken per day of menses was 0.4 (0.4). Ibuprofen (51% of medication) and paracetamol (43% of medication) were the most common analgesic medications used at trial entry. Four participants used both ibuprofen and paracetamol simultaneously. One-way ANOVA showed there were no differences between groups at baseline for any of the menstrual pain diary measures.

5.2.7 TCM patterns

The three study acupuncturists administering the study were able to choose from a list of eight TCM patterns pertaining to primary dysmenorrhea. Up to two TCM patterns could be chosen, a primary and secondary pattern to account for the complexity seen in clinical practice. Seventy-one women attended at least the first treatment and were given a diagnosis. Fourteen women (19.2%) had just one pattern of disharmony, while the remaining 57 women (80.25%) had two patterns of disharmony. Table 5.4 shows the patterns that were chosen in the first three treatments. Qi stagnation was the most common primary and secondary presentation, with 36 (50.7%) and 19 (33.3%) women respectively being diagnosed as such. Blood stasis was the primary diagnosis in 13 (18.3%) and the secondary diagnosis in eight (14%) of women, while stagnation due to
cold was the primary diagnosis in 16 (22.5%) and secondary in six (10.5%) women. Other diagnoses were less common: Qi and blood deficiency was diagnosed as the primary cause in two (2.8%) and as the secondary in seven (12.2%) women. Yang and blood deficiency was the primary cause in four (5.6%) and secondary in eight (14%) women. Damp-heat, liver and kidney Yin deficiency and liver-fire were not found as primary patterns in any of the women who participated in the study.

**TABLE 5.4: PRIMARY AND SECONDARY TCM PATTERNS IN TRIAL PARTICIPANTS.**

<table>
<thead>
<tr>
<th></th>
<th>HF–MA n=18</th>
<th>HF–EA n=18</th>
<th>LF–MA n=18</th>
<th>LF–EA n=17</th>
<th>Total n=71</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary pattern</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qi stagnation</td>
<td>10</td>
<td>8</td>
<td>9</td>
<td>9</td>
<td>36</td>
<td>50.7%</td>
</tr>
<tr>
<td>Stagnation due to cold</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>16</td>
<td>22.5%</td>
</tr>
<tr>
<td>Blood stasis</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>13</td>
<td>18.3%</td>
</tr>
<tr>
<td>Yang and blood deficiency</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>5.6%</td>
</tr>
<tr>
<td>Qi and blood deficiency</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2.8%</td>
</tr>
<tr>
<td>Damp-heat</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Liver and kidney Yin deficiency</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Liver-fire</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Secondary pattern</strong></td>
<td>n=14</td>
<td>n=14</td>
<td>n=17</td>
<td>n=12</td>
<td>n=57</td>
<td></td>
</tr>
<tr>
<td>Qi stagnation</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>19</td>
<td>33.3%</td>
</tr>
<tr>
<td>Blood stasis</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>14%</td>
</tr>
<tr>
<td>Yang and blood deficiency</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>8</td>
<td>14%</td>
</tr>
<tr>
<td>Qi and blood deficiency</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>7</td>
<td>12.2%</td>
</tr>
<tr>
<td>Stagnation due to cold</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>10.5%</td>
</tr>
<tr>
<td>Damp-heat</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>8.7%</td>
</tr>
<tr>
<td>Liver and kidney Yin deficiency</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>5.2%</td>
</tr>
<tr>
<td>Liver-fire</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

A Fisher’s exact test showed no differences between groups in the frequency of either primary (p=0.961) or secondary (p=0.508) patterns. Collapsing diagnostic data to compare a primary diagnosis of Qi stagnation versus other diagnoses using a Fisher’s exact test showed no difference between groups (p=0.642).

Due to the number of participants and the number of different TCM diagnoses, for these variables to be included as a variable in the analysis of primary and secondary outcomes, the data was categorised to “Qi stagnation” and “Other”. This was used as a covariate where stated.

**5.2.8 Addressing incomplete randomisation**

Despite randomisation, there were some statistically significant baseline imbalances between groups as outlined in the previous subsections, specifically expectation for a positive outcome, SF-36 role physical and current alcohol
consumption. These three imbalances had the potential to account for differences in outcomes and were corrected for in all primary and secondary outcome measures via inclusion as covariates. Comparison between baseline and follow-up SF-36 did not include SF-36 role physical as a covariate.

### 5.2.9 Statistical conventions

Due to the small sample size all p-values are exploratory. All post hoc tests used Bonferroni correction for multiple comparisons. Where 95% confidence intervals are displayed, standard deviations were always within those confidence intervals. Where means have been adjusted by ANCOVA, all relevant tables display adjusted means.

### 5.2.10 Practitioner group distribution

Practitioners in different geographical locations saw differing numbers of study participants. The distribution of participants by group between each practitioner is shown in Table 5.5. Practitioner 1, the primary investigator, saw the majority of study participants. Practitioner 3 was a locum for Practitioner 2 while they were on holiday and only saw three study participants. Group allocation between practitioners was not equal, with Practitioner 1 seeing more of the LF-MA and LF-EA groups than either Practitioner 2 or Practitioner 3. This was primarily due to the greater interest in Auckland, where Practitioner 1 was located, which has a much greater population (1.42 million) than Wellington (471,000), where Practitioner 2 and 3 were practicing.

There is some evidence that differences in how practitioners are perceived can influence pain reduction (White et al. 2012) therefore practitioner allocation was added as a co-variate to the ANCOVA for all pain related outcomes. There was no effect of practitioner allocation on any of the pain related outcomes, (p > .05). As there was a difference between group allocation amongst practitioners, group allocation was collapsed and practitioner allocation added as the between group factor and no significant effect was found on any pain related outcomes (p > .05). Finally group*practitioner interaction was also found to be non-
significant for any pain outcomes (p > .05). Therefore practitioner allocation was not a potential factor in any observed pain related changes in this study.
<table>
<thead>
<tr>
<th>Practitioner</th>
<th>HF-MA (n=18)</th>
<th>HF-EA (n=19)</th>
<th>LF-MA (n=19)</th>
<th>LF-EA (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% of group</td>
<td>% of each</td>
<td>% of group</td>
<td>% of each</td>
</tr>
<tr>
<td>n</td>
<td>allocation</td>
<td>practitioner</td>
<td>allocation</td>
<td>practitioner</td>
</tr>
<tr>
<td>practitioner</td>
<td>% of group</td>
<td>% of each</td>
<td>% of group</td>
<td>% of each</td>
</tr>
<tr>
<td>Practitioner 1</td>
<td>61% [38.5</td>
<td>22% [12.3 to</td>
<td>63.1% [40.9</td>
<td>24% [13.8 to</td>
</tr>
<tr>
<td>(Auckland)</td>
<td>to 79.7]</td>
<td>34.9]</td>
<td>to 80.9]</td>
<td>37.0]</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>12</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Practitioner 2</td>
<td>33% [16.1</td>
<td>30% [14.3 to</td>
<td>36.8% [19.0</td>
<td>35% [17.9 to</td>
</tr>
<tr>
<td>(Wellington)</td>
<td>to 56.4]</td>
<td>52.1]</td>
<td>to 59.0]</td>
<td>56.8]</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>7</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Practitioner 3</td>
<td>5.5% [&lt;1 to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
5.3 Primary outcome measures

5.3.1 Responder rate

The decision to calculate a responder rate was done *a posteriori*. The responder rate provides clinically meaningful information on the magnitude of pain reduction, in addition to the continuous outcome data. Responder rates were calculated for the primary outcome measures and for worst pain to allow comparison with other studies. A recent review of chronic pain has shown that the threshold of a 30% reduction in pain scores mark where patients feel a clinically important change has occurred (Dworkin et al. 2008). However, the choice of responder rate can appear arbitrary and possibly bias the results, therefore providing a range of responder rates allows a more transparent view of the data (Dworkin et al. 2009). Numeric data for responder rates is provided for 30%, 50% and 70% reductions from baseline. The style of cumulative responder analysis suggested by Farrar (Farrar, Dworkin & Max 2006) was chosen to display the range of responder rates graphically.

5.3.2 Peak pain scores

A repeated measures ANCOVA was conducted to determine if there were statistically significant changes in day one, two or three peak pain over the course of the intervention, and at the one month follow-up. There were no outliers and the data was normally distributed, as assessed by boxplot and Shapiro–Wilk test (p>.05), respectively. Means were adjusted by adding baseline values for expectation, currently drinking and SF-36 role physical values as covariates. Differential diagnosis (DDX) based on TCM pattern was added as a covariate to examine any influence on outcomes, either individually or as an interaction with group (DDX*Group). Neither DDX nor the DDX*Group interaction was a significant factor in peak pain scores at any time point. Table 5.6 contains the mean peak pain scores by group for the first three days of menses.
**Table 5.6: Peak pain for the first three days of menses by group.**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Δ Baseline [95% CI]</td>
<td>Mean (SD)</td>
<td>Δ Baseline [95% CI]</td>
</tr>
<tr>
<td><strong>Peak pain day 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>5.4 (2.5)</td>
<td>5.7 (2.0)</td>
<td>6.2 (1.9)</td>
<td>5.16 (2.8)</td>
</tr>
<tr>
<td>Month 1</td>
<td>4.6 (2.9)</td>
<td>-0.833 [-2.0 to 0.35]</td>
<td>5.1 (2.8)</td>
<td>-0.68 [-1.8 to 0.47]</td>
</tr>
<tr>
<td>Month 2</td>
<td>4.3 (2.8)</td>
<td>-1.16 [-2.35 to 0.02]</td>
<td>4.7 (2.9)</td>
<td>-1.05 [-2.2 to 0.105]</td>
</tr>
<tr>
<td>Month 3</td>
<td>4.3 (3.3)</td>
<td>-1.16 [-2.35 to 0.02]</td>
<td>4.3 (2.4)</td>
<td>-1.47 [-2.63 to -0.31]</td>
</tr>
<tr>
<td>Follow up</td>
<td>3.4 (2.7)</td>
<td>-2 [-3.2 to -0.86]</td>
<td>4.6 (3.0)</td>
<td>-1.15 [-2.31 to 0.006]</td>
</tr>
<tr>
<td><strong>Peak pain day 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.4 (2.5)</td>
<td>5.6 (2.5)</td>
<td>5.7 (2.3)</td>
<td>5.2 (2.9)</td>
</tr>
<tr>
<td>Month 1</td>
<td>3.5 (2.3)</td>
<td>-0.82 [-2.0 to 0.44]</td>
<td>4.1 (2.6)</td>
<td>-1.5 [-2.8 to -0.36]</td>
</tr>
<tr>
<td>Month 2</td>
<td>3.9 (2.1)</td>
<td>-0.5 [-1.7 to 0.74]</td>
<td>4.6 (2.7)</td>
<td>-1 [-2.2 to 0.21]</td>
</tr>
<tr>
<td>Month 3</td>
<td>4.2 (2.9)</td>
<td>-0.16 [-1.4 to 1.0]</td>
<td>3.1 (2.9)</td>
<td>-2.5 [-3.7 to -1.3]</td>
</tr>
<tr>
<td>Follow up</td>
<td>3.1 (2.6)</td>
<td>-1.33 [-2.5 to -0.08]</td>
<td>4.3 (2.8)</td>
<td>-1.3 [-2.5 to 0.10]</td>
</tr>
<tr>
<td><strong>Peak pain day 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.7 (2.6)</td>
<td>4.0 (2.4)</td>
<td>4.1 (3.2)</td>
<td>3.5 (3.0)</td>
</tr>
<tr>
<td>Month 1</td>
<td>2.4 (2.5)</td>
<td>-1.22 [-2.4 to -0.03]</td>
<td>2.8 (2.8)</td>
<td>-1.2 [-2.4 to -0.03]</td>
</tr>
<tr>
<td>Month 2</td>
<td>3.0 (2.8)</td>
<td>-0.69 [-1.8 to 0.47]</td>
<td>2.4 (2.5)</td>
<td>-1.55 [-2.7 to -3.7]</td>
</tr>
<tr>
<td>Month 3</td>
<td>1.8 (2.4)</td>
<td>-1.9 [-3.1 to -0.77]</td>
<td>2.4 (2.6)</td>
<td>-1.43 [-2.6 to -0.20]</td>
</tr>
<tr>
<td>Follow up</td>
<td>1.7 (2.1)</td>
<td>-1.97 [-3.1 to -0.79]</td>
<td>2.3 (2.6)</td>
<td>-1.6 [-2.78 to -0.42]</td>
</tr>
</tbody>
</table>
For Day One peak pain, the assumption of sphericity was met, as assessed by Mauchly's test of sphericity, $\chi^2(9) = 16.8$, $p=0.059$. The main effect of time showed a statistically significant difference on Day One peak pain at different time points, $F(4, 284) = 9.2$, $p<.0001$, partial $\eta^2 = 0.115$. There was no significant main effect of group ($p=0.833$) or group*time interaction ($p=0.861$). Post-hoc pairwise comparison showed, compared to baseline, significant reductions in Day One peak pain were seen by Month Two (mean difference (MD) $-0.95$, 95% CI $0.138$ to $1.76$, $p=0.011$), Month Three (MD $-1.3$, 95% CI $0.344$ to $2.2$, $p=0.002$), and one-month follow-up (MD $-1.7$, 95% CI $0.659$ to $2.7$, $p<0.0001$), irrespective of group. Figure 5.3 shows responder rate by group for Day One peak pain.

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for Day 1 peak pain between baseline and follow-up was 0.515 (95% CI $-0.713$ to $1.742$, $p=0.406$) for high vs. low frequency and 0.837 (95% CI $-0.391$ to $2.065$, $p=0.179$) for manual vs. electro-acupuncture.
For Day Two peak pain, the assumption of sphericity was met, as assessed by Mauchly's test of sphericity, $\chi^2(9) = 14.5$, $p=0.105$. The main effect of time showed a statistically significant difference on Day Two peak pain at different time points, $F(4, 276) = 8.1$ $p<.0001$, partial $\eta^2 = 0.105$. There was no significant main effect of group ($p=0.707$) or group*time interaction ($p=0.152$). *Post-hoc* pairwise comparison showed compared to baseline, significant reductions in Day Two peak pain were seen by Month Three (MD -1.65, 95% CI 0.67 to 2.6, $p<0.001$), and one-month follow-up (MD -1.5, 95% CI 0.45 to 2.5, $p=0.001$), irrespective of group. Figure 5.4 shows responder rate by group for Day Two peak pain.

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for Day 2 peak pain between baseline and follow-up was -0.227 (95% CI -1.46 to 1.00, $p=0.715$) for high vs. low frequency and 0.538 (95% CI -0.688 to 1.764, $p=0.385$) for manual vs. electro-acupuncture.
For Day Three peak pain the assumption of sphericity was not met, as assessed by Mauchly’s test of sphericity, $\chi^2(9) = 38.8$, p<0.0001. Epsilon (ε) was 0.804, as calculated according to Greenhouse and Geisser (1959), and was used to correct the repeated measures ANOVA. The main effect of time showed a statistically significant difference on Day Three peak pain at different time points, $F(4, 276) = 8.2$, p<0.0001, partial $\eta^2 = 0.107$. There was no significant main effect of group (p=0.707) or group*time interaction (p=0.152). Post-hoc pairwise comparison showed compared to baseline, significant reductions in Day Three peak pain were seen by Month One (MD -1.1, 95% CI 0.32 to 2.0, p=0.002), and were significant at all time points including one-month follow-up (MD -1.35, 95% CI, 0.32 to 2.3, p=0.003), irrespective of group. Figure 5.5 shows responder rate by group for Day Three peak pain.

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for Day 3 peak pain between baseline and follow-up was -0.228 (95% CI -1.42 to 0.973, p=0.706) for high vs. low frequency and 0.863 (95% CI -0.337 to 2.064, p=0.156) for manual vs. electro-acupuncture.
There was no significant difference in the proportion of responders at any time point for peak pain. Table 5.7 shows the proportion of responders at 30, 50 and 70% pain reduction at Day One, Two and Three between groups.

**Table 5.7: Proportion of responders at each pain-reduction percentage between baseline and follow-up.**

<table>
<thead>
<tr>
<th></th>
<th>Day One</th>
<th>Day Two</th>
<th>Day Three</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30%</td>
<td>50%</td>
<td>70%</td>
</tr>
<tr>
<td>HF–MA</td>
<td>55.6%</td>
<td>50.0%</td>
<td>38.9%</td>
</tr>
<tr>
<td></td>
<td>61.1%</td>
<td>44.4%</td>
<td>38.9%</td>
</tr>
<tr>
<td></td>
<td>61.1%</td>
<td>50.0%</td>
<td>38.9%</td>
</tr>
<tr>
<td>HF–EA</td>
<td>36.8%</td>
<td>26.3%</td>
<td>21.1%</td>
</tr>
<tr>
<td></td>
<td>42.1%</td>
<td>31.6%</td>
<td>26.3%</td>
</tr>
<tr>
<td></td>
<td>47.4%</td>
<td>47.4%</td>
<td>42.1%</td>
</tr>
<tr>
<td>LF–MA</td>
<td>52.6%</td>
<td>26.3%</td>
<td>15.8%</td>
</tr>
<tr>
<td></td>
<td>42.1%</td>
<td>31.6%</td>
<td>15.8%</td>
</tr>
<tr>
<td></td>
<td>52.6%</td>
<td>47.4%</td>
<td>36.8%</td>
</tr>
<tr>
<td>LF–EA</td>
<td>50.0%</td>
<td>44.4%</td>
<td>27.8%</td>
</tr>
<tr>
<td></td>
<td>38.9%</td>
<td>27.8%</td>
<td>22.2%</td>
</tr>
<tr>
<td></td>
<td>16.7%</td>
<td>11.1%</td>
<td>5.6%</td>
</tr>
</tbody>
</table>

With respect to peak pain, all groups showed significant improvements in pain from baseline to one-month follow-up across the first three days of menses. The LF–MA and HF–MA groups showed the greatest mean reduction on peak pain on Day One and Day Three, however, this was not statistically significant. The proportion of responders with clinically significant pain reduction (30%) was highest in the HF–MA group across all three days (55%, 60% and 61% respectively) and over a third of women in this group had a 70% reduction in their peak pain, but again this was not statistically significant. Therefore we have no evidence to support our hypothesis that high frequency or electroacupuncture treatment provides greater pain reduction during the first three days of menses.

**5.3.3 Average pain**

A repeated measures ANCOVA was conducted to determine if there were statistically significant changes in average pain over the course of the intervention and one-month follow-up. Average pain was calculated as the
mean of each day’s average pain value, giving a single average pain score for the entire menses for each participant. There were no outliers and the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test (p>.05) respectively. Means were adjusted by adding baseline values for expectation, currently drinking and SF-36 role physical values as covariates.

Differential diagnosis (based on TCM pattern) was added as an additional between group factor to examine any influence on outcomes, either individually or as an interaction with time (time*DDX) or time and group (DDX*time*group). Neither DDX (p=0.378) nor the time*DDX (p=0.250), or time and group (DDX*time*group) interactions (p=0.77) were significant. Differential diagnosis was not a factor in average pain.

The assumption of sphericity was not met, as assessed by Mauchly’s test of sphericity, $\chi^2(9) = 47.9$, p<0.001. Epsilon (ε) was 0.937, as calculated according to Greenhouse and Geisser (1959), and was used to correct the repeated measures ANCOVA.

The main effect of time showed a statistically significant difference on average pain at different time points, $F(4, 1392) = 21.9$ p<0.001, partial $\eta^2 = 0.059$. There was no significant main effect of group (p=0.618) or group*time interaction (p=0.325). Therefore all groups showed a reduction in average pain from baseline to one-month follow-up, and this trend was similar amongst all groups (see Figure 5.6).

*Post-hoc* pairwise comparison showed significant reductions in average pain were seen by Month One (MD -0.592, 95% CI 0.188 to 0.996, p<0.001), Month Two (MD -0.845, 95% CI 0.408 to 1.28, p<0.001), Month Three (MD -1.1, 95% CI 0.708 to 1.5, p<0.001), and one-month follow-up (MD -1.1, 95% CI 0.656 to 1.5, p<0.001), irrespective of group (see Table 5.8).

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for average pain between baseline and follow-up was 0.044 (95% CI -0.371 to 0.458, p=0.835) for high vs. low frequency and 0.293 (95% CI -0.121 to 0.708, p=0.164) for manual vs. electro-acupuncture.
The percentage of responders by group is shown in Figure 5.7. Almost three-quarters (72%) of the women in the HF-MA group had a clinically significant 30% reduction in their average pain, with 69% of the LF-MA group, 61% of the LF-EA group and the 47% of the HF-EA group achieving this reduction. Almost 60% of the LF-MA group and 55% of the HF-MA group had a 50% reduction in average pain from baseline to one-month follow-up. The electro-acupuncture groups had lower scores, with 42% and 33% of the HF-EA and LF-EA groups achieving a 50% reduction. Forty-four percent of the HF-MA group had a 70% reduction from baseline, with 31.6% of the LF-MA, 21.1% of the HF-EA and 11.1% of the LF-EA groups achieving this reduction. None of the differences between groups were statistically significant, despite their apparent magnitude.
All groups showed statistically significant reductions in pain from baseline. While the absolute changes were greater in the manual acupuncture groups, these were not significantly different to the electro-acupuncture groups. Therefore we do not have any evidence to support that either high frequency or electro-acupuncture treatment has a greater reduction on average pain scores compared with low-frequency or manual acupuncture.

5.4 Secondary outcome measures

5.4.1 Worst pain

This was assessed as the highest peak pain score for each menstrual cycle, representing the worst or most severe pain each participant felt during that menstrual period. A repeated measures ANCOVA was used to determine if there were statistically significant changes in worst pain score between baseline and one-month follow-up. Means were adjusted by adding baseline values for expectation, currently drinking and SF-36 role physical values as covariates.
Differential diagnosis (based on TCM pattern) was added as an additional between group factor to examine any influence on outcomes, either individually or as an interaction with time (time*DDX) or time and group (DDX*time*group). Neither DDX (p=0.44) nor the time*DDX (p=0.36) or time and group (DDX*time*group) interactions (p=0.83) were significant. Therefore differential diagnosis is not a factor in worst pain.

The assumption of sphericity was met, as assessed by Mauchly’s test of sphericity, \( \chi^2(9) = 7.9, p=0.540 \). The main effect of time showed a statistically significant difference in worst pain at different time points, \( F(4, 280) = 12.1, p<0.001, \) partial \( \eta^2 = 0.148 \). There was no significant main effect of group (p=0.272) or group*time interaction (p=0.147). Worst pain decreased over time and the trend was similar between groups (see Figure 5.8). Post-hoc pairwise comparison showed significant reductions in worst pain were seen by Month Two (MD -1.1, 95% CI 0.36 to 1.8, p<0.001), Month Three (MD -1.5, 95% CI 0.83 to 2.3, p<0.001), and one-month follow-up (MD -1.65, 95% CI 0.81 to 2.5, p<0.001), irrespective of group allocation (see Table 5.9).

**Table 5.9: Worst Pain Scores by Group Over Time.**

<table>
<thead>
<tr>
<th></th>
<th>HF-MA (n=18)</th>
<th>HF-EA (n=19)</th>
<th>LF-MA (n=19)</th>
<th>LF-EA (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [95% CI]</td>
<td>Mean [95% CI]</td>
<td>Mean [95% CI]</td>
<td>Mean [95% CI]</td>
<td>Mean [95% CI]</td>
</tr>
<tr>
<td>Baseline</td>
<td>6.8 [6.1 to 7.4]</td>
<td>6.8 [6.2 to 7.5]</td>
<td>7.5 [6.8 to 8.1]</td>
<td>7.2 [6.5 to 7.8]</td>
</tr>
<tr>
<td>Month One</td>
<td>5.5 [4.5 to 6.5]</td>
<td>5.8 [4.8 to 6.8]</td>
<td>6.8 [5.8 to 7.8]</td>
<td>6.4 [5.3 to 7.3]</td>
</tr>
<tr>
<td>Month Two</td>
<td>5.5 [4.5 to 6.5]</td>
<td>5.8 [4.8 to 6.8]</td>
<td>6.1 [5.1 to 7.1]</td>
<td>6.3 [5.3 to 7.3]</td>
</tr>
<tr>
<td>Month Three</td>
<td>5.7 [4.5 to 6.8]</td>
<td>4.8 [3.7 to 5.9]</td>
<td>5.5 [4.4 to 6.6]</td>
<td>5.9 [4.8 to 7.0]</td>
</tr>
<tr>
<td>Follow-up</td>
<td>4.0 [2.8 to 5.2]</td>
<td>5.8 [4.7 to 7.0]</td>
<td>5.5 [4.2 to 6.6]</td>
<td>6.2 [5.0 to 7.4]</td>
</tr>
</tbody>
</table>

Absolute reductions in worst pain between baseline and follow-up were greatest in the high (-2.8) and low frequency manual acupuncture groups (-2.0), however, this was not significantly different to the electro-acupuncture groups.

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for worst pain between baseline and follow-up was -0.683 (95% CI 0.065 to -1.431, p=0.073) for high vs. low frequency and -1.22 (95% CI -0.377 to -1.839, p=0.047) for manual vs. electro-acupuncture.

Figure 5.9 displays the responder rate by group for worst pain.
FIGURE 5.8: WORST PAIN VALUES BY GROUP AT EACH TIME POINT.

Error bars are 95% confidence intervals.

FIGURE 5.9: RESPONDERS BY GROUP FOR WORST PAIN BETWEEN BASELINE AND ONE-MONTH FOLLOW-UP.
The proportion of responders who achieved a clinically significant reduction in pain (30%) was 61% in the HF-MA group, 47% in the LF-MA group, 31% in the HF-EA group, and 28% in the LF-EA group. Similar trends were found for 50% pain reduction, with 39% of the women in the HF-MA group achieving this compared with 28% in the LF-EA, 26% in the LF-MA and 16% in the HF-EA groups. Almost a third (27.8%) of the HF-MA group achieved a 70% reduction from baseline, while only 10–12% of participants in other groups achieved this reduction. Despite this, there was no significant difference between responder rates. Therefore we have no evidence to support our hypothesis that either high frequency or electro-acupuncture improves worst pain scores compared with low-frequency or manual acupuncture.

5.4.2 Duration of pain

A repeated measures ANCOVA was conducted to determine if there were statistically significant changes in duration of pain (in hours) over the course of the intervention and one-month follow-up. Duration of pain was calculated as the mean number of hours of pain per day per participant. There were no outliers and the data was normally distributed, as assessed by boxplot and Shapiro–Wilk test (p>.05) respectively. Means were adjusted by adding baseline values for expectation, currently drinking and SF-36 role physical values as covariates. Baseline duration of pain values were added as a covariate in the ANCOVA.

Differential diagnosis (based on TCM pattern) was added as an additional between group factor to examine any influence on outcomes, either individually or as an interaction with time (time*DDX) or time and group (DDX*time*group). Neither DDX (p=0.227) nor the time*DDX (p=0.275) or time and group (DDX*time*group) interactions (p=0.874) were significant. Differential diagnosis was not a factor in duration of pain.

The assumption of sphericity was not met, as assessed by Mauchly’s test of sphericity, $\chi^2(9) = 54.8$, $p<.001$. Epsilon (ε) was 0.926, as calculated according
to Greenhouse AND Geisser (1959), and was used to correct the repeated measures ANCOVA.

The main effect of time showed a statistically significant difference in duration of pain at different time points \( F(2.7, 592) = 3.6 \ p=0.016, \ \text{partial } \eta^2 = 0.016. \) There was no significant main effect of group (\( p=0.119 \)) or group*time interaction (\( p=0.869 \)). Therefore, when taking into account baseline scores, there was a decrease in duration of pain scores over time, and there were no differences between groups at any time point (see Figure 5.10). Post-hoc pairwise comparisons showed at significant reductions in duration of pain occurred by Month Two (\( \text{MD} -1.7, 95\% \ CI 0.706 \text{ to } 2.07, p<0.001 \)), Month Three (\( \text{MD} -2.6, 95\% \ CI 1.55 \text{ to } 3.6, p<0.001 \)) and one-month follow-up (\( \text{MD} -2.4, 95\% \ CI 1.5 \text{ to } 3.5, p<0.001 \)), irrespective of group allocation (see Table 5.10).

<table>
<thead>
<tr>
<th><strong>TABLE 5.10: DURATION OF PAIN (HOURS PER DAY) BY GROUP OVER TIME.</strong></th>
<th><strong>HF–MA (n=18)</strong></th>
<th><strong>HF–EA (n=19)</strong></th>
<th><strong>LF–MA (n=19)</strong></th>
<th><strong>LF–EA (n=18)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>mean [95% CI]</td>
<td>mean [95% CI]</td>
<td>mean [95% CI]</td>
<td>mean [95% CI]</td>
</tr>
<tr>
<td>4.2 [2.6 to 5.8]</td>
<td>6.8 [5.1 to 8.4]</td>
<td>6.7 [5.1 to 8.3]</td>
<td>5.1 [3.4 to 6.8]</td>
<td></td>
</tr>
<tr>
<td>Month One</td>
<td>3.1 [1.5 to 4.7]</td>
<td>5.9 [4.3 to 7.5]</td>
<td>6.7 [5.1 to 8.3]</td>
<td>4.8 [3.1 to 6.4]</td>
</tr>
<tr>
<td>2.8 [1.4 to 4.1]</td>
<td>4.2 [2.9 to 5.6]</td>
<td>4.4 [3.0 to 5.8]</td>
<td>4.3 [2.9 to 5.7]</td>
<td></td>
</tr>
<tr>
<td>Month Three</td>
<td>2.6 [1.3 to 3.9]</td>
<td>4.1 [2.8 to 5.4]</td>
<td>4.5 [3.2 to 5.8]</td>
<td>3.9 [2.5 to 5.3]</td>
</tr>
<tr>
<td>Follow-up</td>
<td>2.4 [1.1 to 3.6]</td>
<td>3.8 [2.6 to 5.0]</td>
<td>3.7 [2.4 to 4.9]</td>
<td>3.1 [1.8 to 4.4]</td>
</tr>
</tbody>
</table>

Both absolute and percentage reductions from baseline were significant and similar amongst all groups, with most groups achieving a reduction of between 40–44% in the number of hours of menstrual pain per day. There were no significant differences between groups in the reduction of hours of menstrual pain.

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for duration of pain between baseline and follow-up was 0.119 (95% CI -0.818 to 1.055, \( p=0.803 \)) for high vs. low frequency and 0.430 (95% CI -0.506 to 1.36, \( p=0.367 \)) for manual vs. electro-acupuncture.

Therefore, with respect to duration of pain, we have no data to support our hypothesis that either electro-acupuncture or high frequency of treatment
causes a greater reduction in duration of pain compared with manual or low-frequency acupuncture.

**FIGURE 5.10: DURATION OF PAIN (IN HOURS PER DAY) OVER TIME BY GROUP.**

Error bars are 95% confidence intervals.

![Duration of Pain Graph](image)

5.4.3 Medication usage

A repeated measures ANCOVA was conducted to determine if there were statistically significant changes in the number of doses of medication taken per day over the course of the intervention and one-month follow-up. Medication usage was the mean number of doses per day per participant. There were no outliers and the data was normally distributed, as assessed by boxplot and Shapiro–Wilk test (p>.05) respectively. Means were adjusted by adding baseline values for expectation, currently drinking and SF-36 role physical values as covariates. Baseline medication usage values were added as a covariate in the ANCOVA.

Differential diagnosis (based on TCM pattern) was added as an additional between group factor to examine any influence on outcomes, either individually or as an interaction with time (time*DDX) or time and group (DDX*time*group). Neither DDX (p=0.620) nor the time*DDX (p=0.799) or time and group
(DDX*time*group) interactions (p=0.755) were significant. Therefore differential diagnosis was not a factor in changes in medication usage.

The assumption of sphericity was not met, as assessed by Mauchly’s test of sphericity, $\chi^2(5) = 12.3$ p=0.030. Epsilon ($\varepsilon$) was 0.975, as calculated according to Greenhouse and Geisser (1959), and was used to correct the repeated measures ANCOVA.

### Table 5.11: Analgesic Medication Usage (Dozes per Day) by Group Over Time.

<table>
<thead>
<tr>
<th></th>
<th>HF-MA (n=18)</th>
<th>HF-EA (n=19)</th>
<th>LF-MA (n=19)</th>
<th>LF-EA (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.348 [0.22 to 0.46]</td>
<td>0.56 [0.44 to 0.67]</td>
<td>0.365 [0.24 to 0.48]</td>
<td>0.415 [0.29 to 0.54]</td>
</tr>
<tr>
<td>Month One</td>
<td>0.225 [0.11 to 0.33]</td>
<td>0.451 [0.33 to 0.56]</td>
<td>0.247 [0.13 to 0.36]</td>
<td>0.372 [0.25 to 0.49]</td>
</tr>
<tr>
<td>Month Two</td>
<td>0.281 [0.17 to 0.39]</td>
<td>0.315 [0.20 to 0.42]</td>
<td>0.197 [0.08 to 0.30]</td>
<td>0.354 [0.23 to 0.47]</td>
</tr>
<tr>
<td>Month Three</td>
<td>0.219 [0.11 to 0.32]</td>
<td>0.299 [0.19 to 0.4]</td>
<td>0.197 [0.09 to 0.3]</td>
<td>0.311 [0.20 to 0.41]</td>
</tr>
<tr>
<td>Follow-up</td>
<td>0.169 [0.06 to 0.27]</td>
<td>0.413 [0.30 to 0.52]</td>
<td>0.185 [0.07 to 0.29]</td>
<td>0.348 [0.23 to 0.46]</td>
</tr>
</tbody>
</table>

The main effect of time showed there was significant changes in medication uses at different time points, $F(2.9, 208) = 4.5$ p =0.004, partial $\eta^2 = 0.013$. The main effect of group was statistically significant $F(3,346) = 2.7$ p=0.046. There was no time*group interaction (p=0.808). Therefore when taking into account baseline values there was a difference between groups at different time points, however the trend was similar amongst all groups (see Figure 5.11).

One-way ANCOVA showed significant differences amongst groups at one month follow-up $F(3,351) = 4.7$ p=0.003. Post-hoc tests showed both the HF–MA (MD -0.23, 95% CI -0.03 to -0.44, p=0.015) and LF–MA (MD -0.21, 95% CI -0.02 to 0.42, p=0.043) groups had significantly lower medication usage than the HF–EA group at one-month follow-up (see Table 5.11).

Three groups’ medication usage decreased over time, HF–MA, LF–MA and LF–EA, while HF–EA did not show a significant reduction from baseline. Therefore, when examining the previous pain scores it must be taken into account that to achieve those scores, the HF–MA and LF–MA groups took less analgesic medication than the HF–EA group.
When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for analgesic usage between baseline and follow-up was -0.009 (95% CI -0.116 to 0.099, p=0.876) for high vs. low frequency and 0.157 (95% CI 0.048 to 0.266 p=0.005) for manual vs. electro-acupuncture.

**Figure 5.11: Analgesic medication usage (doses per day) over time by group.**

Error bars are 95% confidence intervals.

Therefore, with respect to medication intake, we have no data to support our hypothesis that either electro-acupuncture or high frequency of treatment causes a greater reduction in the need for additional analgesic medication compared with manual or low-frequency acupuncture.

**5.4.4 Other menstrual symptoms**

A repeated measures ANCOVA was conducted to determine if there were statistically significant changes in the number of additional menstrual symptoms over the course of the intervention and one-month follow-up. The menstrual symptoms score was calculated as the mean number of symptoms per participant per day. There were no outliers and the data was normally distributed, as assessed by boxplot and Shapiro–Wilk test (p>.05) respectively. Means were adjusted by adding baseline values for expectation, currently
drinking and SF-36 role physical values as covariates. Baseline number of menstrual symptoms was added as a covariate in the ANCOVA.

Differential diagnosis (based on TCM pattern) was added as an additional between group factor to examine any influence on outcomes, either individually or as an interaction with time (time*DDX) or time and group (DDX*time*group). Neither DDX (p=0.932) nor the time*DDX (p=0.354) or time and group (DDX*time*group) interactions (p=0.061) were significant. Therefore differential diagnosis was not a factor in changes in other menstrual symptoms.

The assumption of sphericity was not met, as assessed by Mauchly’s test of sphericity, $\chi^2(5) = 13.5 p=0.019$. Epsilon ($\varepsilon$) was 0.959, as calculated according to Greenhouse and Geisser (1959), and was used to correct the repeated measures ANCOVA.

The main effect of time showed that there was a significant difference in the number of menstrual symptoms at different time points, $F(2.8, 586) = 5.54 p=0.001$ partial $\eta^2 = 0.026$. The main effect of group showed a significant difference $F(3, 204) = 3.93 p=0.009$, partial $\eta^2 = 0.055$. There was also a significant group*time interaction, $F(8.6, 586) = 2.64 p=0.006$. Therefore, when taking into account baseline values, there was a difference between groups at different time points and the trend was different between groups (see Figure 5.12).

*Post-hoc* pairwise analysis showed that the LF–EA group had significantly higher menstrual symptom count at Month Two to all groups, at Month Three compared with HF–MA (MD -0.975, 95% CI -1.7 to -0.2, p=0.005) and LF–MA (MD -0.908, 95% CI -0.14 to -1.6, p=0.011) and at one-month follow-up to HF–MA (MD -1.1, 95% CI -0.32 to -1.9, p=0.001) and LF–MA (MD -0.92, 95% CI -0.12 to -1.7, p=0.013)(see Table 5.12).

When the two factors (HF vs. LF and MA vs. EA) were examined separately the mean difference for other menstrual symptoms between baseline and follow-up was 0.278 (95% CI -0.108 to 0.664, p=0.157) for high vs. low frequency and 0.763 (95% CI 0.377 to 1.15, p<0.001) for manual vs. electro-acupuncture.
Therefore both manual acupuncture groups were superior to the LF–EA group for menstrual symptom reduction at months two, three and one-month follow-up, while the HF–EA group was only superior to LF–EA at Month Two.

**FIGURE 5.12: CHANGES IN MENSTRUAL SYMPTOMS BY GROUP OVER TIME.**

Error bars are 95% confidence intervals.

![Chart showing changes in menstrual symptoms by group over time.](chart)

**TABLE 5.12: ADDITIONAL MENSTRUAL SYMPTOMS PER DAY.**

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=18)</th>
<th>HF–EA (n=19)</th>
<th>LF–MA (n=19)</th>
<th>LF–EA (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean [95% CI]</td>
<td>mean [95% CI]</td>
<td>mean [95% CI]</td>
<td>mean [95% CI]</td>
</tr>
<tr>
<td>Baseline</td>
<td>2.3 [1.8 to 2.7]</td>
<td>3.2 [2.7 to 3.6]</td>
<td>2.9 [2.4 to 3.3]</td>
<td>2.6 [2.0 to 3.1]</td>
</tr>
<tr>
<td>Month One</td>
<td>1.9 [1.6 to 2.3]</td>
<td>2.1 [1.7 to 2.4]</td>
<td>2.3 [1.9 to 2.7]</td>
<td>2.5 [2.0 to 2.9]</td>
</tr>
<tr>
<td>Month Two</td>
<td>1.5 [1.1 to 1.8]</td>
<td>1.7 [1.3 to 2.0]</td>
<td>1.7 [1.3 to 2.0]</td>
<td>2.6 [2.2 to 2.9]</td>
</tr>
<tr>
<td>Month Three</td>
<td>1.4 [1.0 to 1.8]</td>
<td>1.8 [1.4 to 2.1]</td>
<td>1.3 [0.9 to 1.7]</td>
<td>2.3 [1.9 to 2.7]</td>
</tr>
<tr>
<td>Follow-up</td>
<td>1.4 [1.0 to 1.8]</td>
<td>2.0 [1.6 to 2.4]</td>
<td>1.6 [1.1 to 1.9]</td>
<td>2.5 [2.1 to 2.9]</td>
</tr>
</tbody>
</table>

The LF–MA, HF–MA and HF–EA groups all showed a reduction in additional menstrual symptoms from baseline to one-month follow-up. Each of these groups reduced approximately one additional menstrual symptom per day from baseline to one-month follow-up.
Therefore, with respect to additional menstrual symptoms, we have no evidence to support the hypothesis that either electro-acupuncture or high frequency of treatment provides greater additional symptom reduction than manual or low frequency acupuncture.

### 5.4.5 Absenteeism

Absenteeism was recorded as a binomial outcome, either absent from work or school or not absent. The number of absences overall was low, with only one or two women per group being absent at any time point (see Table 5.13).

**Table 5.13: Total number of women recording one or more days absent per month**

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=18)</th>
<th>HF–EA (n=19)</th>
<th>LF–MA (n=19)</th>
<th>LF–EA (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Month One</td>
<td>1 (5.5%)</td>
<td>1 (5.2%)</td>
<td>1 (5.2%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Month Two</td>
<td>1 (5.5%)</td>
<td>2 (10.5%)</td>
<td>2 (10.5%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Month Three</td>
<td>1 (5.5%)</td>
<td>1 (5.2%)</td>
<td>2 (10.5%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>1 (5.5%)</td>
<td>1 (5.2%)</td>
<td>1 (5.2%)</td>
<td>2 (11%)</td>
</tr>
</tbody>
</table>

The total number of days absent per menstrual cycle was also calculated (see Table 5.14). A McNemar test was used to determine if there was any significant difference in the number of absences between baseline and one-month follow-up. This test was not statistically significant (p=0.791) for overall data independent of group, or when examining each group individually (p>.05 for all groups). The number of absences each month was small, therefore any possible between group differences are unlikely to be visible at this sample size.

**Table 5.14: Total number of days absent per month**

n is total number of days absent and % is the percentage of days absent out of the number of days recorded for that cycle.

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=18)</th>
<th>HF–EA (n=19)</th>
<th>LF–MA (n=19)</th>
<th>LF–EA (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Month One</td>
<td>2 (3.5%)</td>
<td>3 (5.3%)</td>
<td>2 (3.5%)</td>
<td>3 (4.5%)</td>
</tr>
<tr>
<td>Month Two</td>
<td>2 (3.5%)</td>
<td>7 (12.3%)</td>
<td>4 (7.0%)</td>
<td>3 (5.8%)</td>
</tr>
<tr>
<td>Month Three</td>
<td>2 (3.5%)</td>
<td>2 (3.5%)</td>
<td>5 (8.8%)</td>
<td>4 (7.7%)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>3 (5.3%)</td>
<td>1 (1.8%)</td>
<td>2 (3.5%)</td>
<td>3 (5.8%)</td>
</tr>
</tbody>
</table>
There was no change in the number of days absent between baseline and one-month follow-up in any of the groups. Therefore we have no data to support our hypothesis that either electro-acupuncture or high frequency of treatment causes a greater reduction in absenteeism compared to manual or low-frequency acupuncture.
5.4.6 Health-related quality of life (SF-36)

**Table 5.15: SF-36 scores at one-month follow-up by group.**

Reported as Mean + / - SD. Between time point p-values from paired t-test, * = p<.05. Between group p-values from one-way ANCOVA.

<table>
<thead>
<tr>
<th></th>
<th>HF-MA (n=18)</th>
<th>HF-EA (n=19)</th>
<th>LF-MA (n=17)</th>
<th>LF-EA (n=15)</th>
<th>Total (n=69)</th>
<th>Total (n=69)</th>
<th>Total (n=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td>mean (SD)</td>
<td>Δ mean (baseline follow-up)</td>
<td>p-value (baseline follow-up)</td>
<td>p-value (between groups at follow-up)</td>
</tr>
<tr>
<td><strong>Physical function</strong></td>
<td>55.6 (2.6)</td>
<td>56.2 (1.2)</td>
<td>53.3 (5.1)</td>
<td>55.6 (3.5)</td>
<td>55.2 (3.5)</td>
<td>0.933</td>
<td>0.207</td>
</tr>
<tr>
<td><strong>Role physical</strong></td>
<td>54.2 (5.0)</td>
<td>50.7 (6.7)*</td>
<td>52.1 (4.4)</td>
<td>49.9 (6.8)</td>
<td>51.8 (5.9)</td>
<td>2.24</td>
<td>0.0029*</td>
</tr>
<tr>
<td><strong>Bodily pain</strong></td>
<td>50.7 (6.4)</td>
<td>48.7 (9.0)*</td>
<td>48.0 (7.4)*</td>
<td>47.2 (6.7)</td>
<td>48.7 (7.4)</td>
<td>3.83</td>
<td>0.0002*</td>
</tr>
<tr>
<td><strong>General health</strong></td>
<td>52.8 (11.2)</td>
<td>51.7 (9.1)</td>
<td>52.99 (7.9)</td>
<td>53.4 (7.9)</td>
<td>53.0 (9.0)</td>
<td>1</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Vitality</strong></td>
<td>52.7 (8.3)*</td>
<td>47.6 (8.9)</td>
<td>49.8 (10.8)</td>
<td>47.4 (9.5)</td>
<td>49.5 (9.4)</td>
<td>1.9</td>
<td>0.028*</td>
</tr>
<tr>
<td><strong>Social function</strong></td>
<td>53.9 (7.0)*</td>
<td>48.6 (10.0)*</td>
<td>47.3 (9.2)</td>
<td>46.6 (6.7)</td>
<td>49.2 (8.7)</td>
<td>2.6</td>
<td>0.0067*</td>
</tr>
<tr>
<td><strong>Role emotional</strong></td>
<td>50.7 (7.2)</td>
<td>47.9 (7.8)</td>
<td>48.6 (9.9)</td>
<td>47.5 (8.4)</td>
<td>48.75 (8.4)</td>
<td>0.9</td>
<td>0.209</td>
</tr>
<tr>
<td><strong>Mental health</strong></td>
<td>51.3 (7.6)</td>
<td>51.2 (7.2)</td>
<td>48.8 (10.7)</td>
<td>49.2 (8.6)</td>
<td>50.2 (8.5)</td>
<td>0.88</td>
<td>0.267</td>
</tr>
<tr>
<td><strong>Overall mental component</strong></td>
<td>50.6 (9.6)*</td>
<td>47.3 (9.5)</td>
<td>47.1 (12.2)</td>
<td>46.0 (9.3)</td>
<td>47.89 (10.1)</td>
<td>1.2</td>
<td>0.142</td>
</tr>
<tr>
<td><strong>Overall physical component</strong></td>
<td>54.5 (5.8)</td>
<td>53.1 (5.2)*</td>
<td>52.8 (6.7)</td>
<td>52.9 (6.8)*</td>
<td>53.3 (6.0)</td>
<td>2.3</td>
<td>0.001*</td>
</tr>
</tbody>
</table>
Between baseline and one-month follow-up paired t-tests showed improvements in role physical (p=0.0029), bodily pain (p=0.0002), vitality (p=0.028), social function (p=0.0067) and overall physical component (p=0.001) (see Table 5.15).

Improvements in individual group scores were observed between baseline and one-month follow-up. For role physical, only the HF–EA group showed improvement (MD 4.01, 95% CI 0.82 to 7.2, p=0.016). Bodily pain improved in both the HF–EA (MD 5.1, 95% CI 1.35 to 8.9, p=0.0106) and LF–MA (MD 4.34, 95% CI 0.17 to 8.5, p = 0.042). Vitality improved in the HF–MA group (MD 4.6, 95% CI 1.17 to 8.0, p=0.011). Social function improved in both the HF–MA (MD 3.3, 95% CI 0.5 to 6.1, p=0.023) and HF–EA (MD 4.7, 95% CI 0.76 to 8.7, p=0.022) groups. Overall mental component improved in the HF–MA group (MD 2.5, 95% CI 0.024 to 5.0, p=0.048). Overall physical component improved in both the HF–EA group (MD 3.0, 95% CI 0.058 to 6.0, p = 0.046) and the LF–EA group (MD 3.5, 95% CI 0.87 to 6.2, p=0.0131). When looking at only the post-treatment SF-36 scores there were no differences between groups.

Overall, both the high-frequency groups showed a greater number of improvements in the SF-36 domains (six domains) compared to the low-frequency groups (two domains). Therefore we find data to support our hypothesis that higher frequency of treatment will result in greater improvements in health-related quality of life (HRQoL). Both electro-acupuncture and manual acupuncture showed improvement in four domains. Therefore we do not find data to support the hypothesis that electro-acupuncture provides a greater improvement in HRQoL.

**5.4.7 Self-rated improvement score and symptom changes**

The median (IQR) 0–10 self-rated improvement score by group was HF–MA 8 (1), HF–EA 7.5 (5.5), LF–MA 8 (1) and LF–EA 7 (2). Overall self-rated improvement score, independent of group was 8 (2). A Kruskal–Wallis test showed that there was no significant difference in the self-rated improvement score by group ($\chi^2(3) = 1.539$ p=0.673). Collapsing groups by HF versus LF
(χ²(1) = 0.193 p=0.661) and by MA versus EA (χ²(1) = 1.21 p=0.271) also showed no significant difference in self-rated improvement score. Comparison between a differential diagnosis of Qi stagnation and all other diagnosis on self-rated improvement score showed no significant difference by diagnostic pattern (χ²(1) = 1.23 p=0.725).

Participants were asked to list the symptoms, if any, that they thought improved the most during the trial. Women were asked to list up to three symptoms in this section. An early version of the post-trial questionnaire was given to ten of the Wellington participants by mistake, which did not contain this section, therefore not all women filled in this section of the post-trial questionnaire so caution must be taken into extrapolating these findings. This data was converted into categorical data by group as shown in Table 5.16.

<table>
<thead>
<tr>
<th>Table 5.16 Improvements in individual symptoms by group.</th>
</tr>
</thead>
<tbody>
<tr>
<td>n is the number of women reporting each symptom. p-values from Fisher's exact test.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom</th>
<th>HF-MA (n=12)</th>
<th>HF-EA (n=14)</th>
<th>LF-MA (n=13)</th>
<th>LF-EA (n=13)</th>
<th>Total (n=52)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional changes</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>1 (8%)</td>
<td>4 (29%)</td>
<td>2 (15%)</td>
<td>1 (8%)</td>
<td>13 (25%)</td>
<td>0.427</td>
</tr>
<tr>
<td>Abdominal cramps</td>
<td>10 (83%)</td>
<td>7 (50%)</td>
<td>11 (85%)</td>
<td>8 (62%)</td>
<td>36 (69%)</td>
<td>0.563</td>
</tr>
<tr>
<td>Cravings</td>
<td>2 (17%)</td>
<td>1 (7%)</td>
<td>0 (0%)</td>
<td>2 (15%)</td>
<td>5 (10%)</td>
<td>0.381</td>
</tr>
<tr>
<td>Breast tenderness</td>
<td>1 (8%)</td>
<td>3 (21%)</td>
<td>2 (15%)</td>
<td>1 (8%)</td>
<td>7 (13%)</td>
<td>0.789</td>
</tr>
<tr>
<td>Back and leg pain</td>
<td>4 (33%)</td>
<td>3 (21%)</td>
<td>6 (46%)</td>
<td>2 (15%)</td>
<td>15 (29%)</td>
<td>0.583</td>
</tr>
<tr>
<td>PMS symptoms</td>
<td>1 (8%)</td>
<td>4 (29%)</td>
<td>4 (31%)</td>
<td>1 (8%)</td>
<td>10 (19%)</td>
<td>0.332</td>
</tr>
<tr>
<td>Nausea</td>
<td>0 (0%)</td>
<td>3 (21%)</td>
<td>3 (23%)</td>
<td>1 (8%)</td>
<td>7 (13%)</td>
<td>0.327</td>
</tr>
<tr>
<td>Bowel changes</td>
<td>1 (8%)</td>
<td>0 (0%)</td>
<td>3 (23%)</td>
<td>0 (0%)</td>
<td>4 (8%)</td>
<td>0.180</td>
</tr>
<tr>
<td>Menstrual flow</td>
<td>1 (8%)</td>
<td>1 (7%)</td>
<td>4 (31%)</td>
<td>2 (15%)</td>
<td>8 (15%)</td>
<td>0.494</td>
</tr>
</tbody>
</table>

Women reported that abdominal cramps were the most common symptom to improve, with 36 women indicating abdominal pain or cramping showed significant improvement. Emotional changes (13 women) and back and leg pain (15 women) were also commonly reported improvements.

A Fisher's exact test showed that there were no statistically significant differences between groups in terms of what symptoms women self-rated as the most improved after the trial. A series of Fisher’s exact tests collapsed by frequency (HF versus LF) or by mode of stimulation (MA versus EA) showed no significant differences between group (p> .05) on any of the self-selected, commonly reported improvements.
5.5 Acupuncture related considerations

5.5.1 Safety

Three study acupuncturists delivered a total of 702 acupuncture treatments. All practitioners recorded adverse events, if they occurred during the treatment session, and participants were questioned at the beginning of each treatment session on any events they believed were related to their previous acupuncture treatment. Practitioners were given a list of possible adverse events related to acupuncture and any reported events that matched these were noted (see Appendix A19).

Fifty-two adverse events (AE) occurred over these 702 sessions, giving an overall adverse event rate of 7.4% (95% CI 5.6 to 9.6). Most of the events were minor and self-limiting (see Table 5.17). Bruising (haematoma) was the most common adverse event (50% of all AE or 3.7% of treatments), the most common sites of bruising were Spleen 10 and Ren 4. One participant felt that the acupuncture caused loose bowels after treatment, one participant felt itchiness around the site of needle insertion. There was one incidence of minor burns after moxibustion when a piece of moxa stick broke off during treatment. This resolved after application of cold compress and did not require any further treatment.

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>% of total treatments (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td>3.7% [2.5 to 5.3]</td>
</tr>
<tr>
<td>Post-treatment soreness</td>
<td>1.4% [0.74 to 2.6]</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.1% [0.54 to 2.2]</td>
</tr>
<tr>
<td>Feeling faint</td>
<td>0.28% [0.1 to 1.1]</td>
</tr>
<tr>
<td>Itching</td>
<td>0.14% [0.1 to 0.89]</td>
</tr>
<tr>
<td>Bowel changes</td>
<td>0.14% [0.1 to 0.89]</td>
</tr>
<tr>
<td>Burns</td>
<td>0.14% [0.1 to 0.89]</td>
</tr>
</tbody>
</table>

Two serious adverse events (SAE) occurred during the trial, both by participants on the Wellington site, who were in the low frequency, manual acupuncture group. Both incidents were reported to the supervisory panel and the UWS ethics committee.
One participant experienced a rupturing of an ovarian cyst after six study treatments. This required minor medical care at Wellington Accident and Urgent Medical Centre where she was given an injection of diclofenac. This resolved the discomfort and the participant continued in the study. This was rated by the panel as a SAE of moderate severity and unlikely to be related to the study intervention.

One participant experienced an early pregnancy miscarriage. She had eight treatments prior to the miscarriage. Participant was on progesterone-only contraceptive pill for almost six months prior to commencing the study, but forgot to take one day of contraceptive during her previous menstrual cycle. Participant presented at the emergency room with vaginal bleeding, ultrasound scan confirmed natural miscarriage at five weeks. No treatment was required and participant continued in the study for the following cycles. This was rated by the panel as a SAE of moderate severity and unlikely to be related to the intervention.

A Fisher's exact test showed that there was no difference in adverse event rate per group (p=0.519).

### 5.5.2 Acceptability

Patient acceptability of the intervention was measured in several ways:

1) Participants were given a checklist, which allowed them to select what they did and did not enjoy in relation to the acupuncture treatments.

2) Participants were asked if they would participate or recommend to friends and family a similar acupuncture trial.

Overall women found the intervention to be acceptable, with 62 (98%) women recommending or participating in a similar study (Table 5.18). Table 5.19 outlines the responses participants gave on trial exit: most women (67%) said there was nothing they did not enjoy. One (5.8%) of the 63 women participating indicated she did not enjoy participating in the trial. Factors that participants
enjoyed the most in the trial were having the therapeutic relationship with the practitioner (95%), having an alternative way of looking at their health (84%), having extra attention paid to their health and wellbeing (78%) and having “time out” for themselves (78%). The least helpful or enjoyable factor identified by participants was the diet and lifestyle advice given, with only 34% of participants finding this helpful. The most common factor that participants did not enjoy was having to spend extra time thinking about their period pain (14%). Ten percent of participants found that, at least once, the acupuncture was unpleasant or uncomfortable. None of the participants in the trial found that their symptoms worsened. There were no statistically significant differences amongst groups for any of the satisfaction and acceptability measures as tested by Fisher’s exact test.

**Table 5.18 Responses to the question “Would you be interested in participating in another similar trial or would you recommend it to family or friends?”**

Data is provided as n (%).

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=15)</th>
<th>HF–EA (n=17)</th>
<th>LF–MA (n=17)</th>
<th>LF–EA (n=14)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely would not</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (7)</td>
<td>0.526</td>
</tr>
<tr>
<td>Probably would</td>
<td>3 (20)</td>
<td>3 (18)</td>
<td>1 (6)</td>
<td>1 (7)</td>
<td></td>
</tr>
<tr>
<td>Definitely would</td>
<td>12 (80)</td>
<td>14 (82)</td>
<td>16 (94)</td>
<td>12 (86)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 5.19: Acceptability outcome measures between groups**

Data is provided as n (%).

<table>
<thead>
<tr>
<th></th>
<th>HF–MA (n=15)</th>
<th>HF–EA (n=17)</th>
<th>LF–MA (n=17)</th>
<th>LF–EA (n=14)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not enjoy the trial</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Enjoyed the extra attention</td>
<td>12 (80)</td>
<td>13 (76)</td>
<td>12 (71)</td>
<td>12 (85)</td>
<td>0.825</td>
</tr>
<tr>
<td>Enjoyed the relationship with practitioner</td>
<td>13 (86)</td>
<td>16 (94)</td>
<td>17 (100)</td>
<td>14 (100)</td>
<td>0.104</td>
</tr>
<tr>
<td>Enjoyed having “time out”</td>
<td>11 (73)</td>
<td>15 (88)</td>
<td>13 (76)</td>
<td>10 (71)</td>
<td>0.378</td>
</tr>
<tr>
<td>Enjoyed alternative way of looking at health</td>
<td>14 (93)</td>
<td>13 (76)</td>
<td>15 (88)</td>
<td>11 (79)</td>
<td>0.694</td>
</tr>
<tr>
<td>Found lifestyle and diet helpful</td>
<td>12 (80)</td>
<td>9 (52)</td>
<td>13 (76)</td>
<td>8 (57)</td>
<td>0.360</td>
</tr>
<tr>
<td>Liked helping others via research</td>
<td>13 (86)</td>
<td>10 (58)</td>
<td>14 (82)</td>
<td>10 (71)</td>
<td>0.416</td>
</tr>
<tr>
<td>Nothing I didn’t enjoy</td>
<td>9 (60)</td>
<td>12 (71)</td>
<td>12 (71)</td>
<td>9 (64)</td>
<td>0.849</td>
</tr>
<tr>
<td>I spent more time thinking about my period pain</td>
<td>3 (20)</td>
<td>5 (12)</td>
<td>1 (6)</td>
<td>3 (21)</td>
<td>0.543</td>
</tr>
<tr>
<td>Didn’t like having to fill in the pain diary</td>
<td>2 (13)</td>
<td>2 (12)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.264</td>
</tr>
<tr>
<td>I found the acupuncture unpleasant or uncomfortable</td>
<td>0 (0)</td>
<td>1 (6)</td>
<td>3 (18)</td>
<td>2 (14)</td>
<td>0.368</td>
</tr>
<tr>
<td>Appointments took up too much time or were hard to schedule</td>
<td>2 (13)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.298</td>
</tr>
<tr>
<td>My symptoms got worse</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1.000</td>
</tr>
</tbody>
</table>
5.5.3 Number of treatments by group

All women were scheduled to have 12 treatments regardless of group allocation. A total of 702 study treatments were delivered. However, not all women received all 12 treatments, mostly due to logistical issues around timing of treatments with regards to the start of menses. Twenty-five participants (35.2%) received the full 12 study treatments. The median number of treatments was 11 (IQR=2) for all women who had at least one study treatment. The median number of treatments for women who withdrew from the study was 4.5 (IQR =3.25). Table 5.20 shows the median number of treatments per group. A Kruskal–Wallis test showed that there was no significant difference in the number of treatments by group ($\chi^2(3) = 6.533, p=0.0884$).

<table>
<thead>
<tr>
<th>Table 5.20: Number of treatments by group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Minimum</td>
</tr>
<tr>
<td>Maximum</td>
</tr>
</tbody>
</table>

5.5.4 Point selection:

Point selection was based upon pattern discrimination and practitioner discretion within the framework outlined by the treatment protocol. All practitioners were required to select at least three compulsory points in the case of one pattern of disharmony, with up to four compulsory points (two from each pattern) allowed in the case of two patterns of disharmony. Up to seven points in total were allowed during each session. From 702 study treatment sessions performed, data on point selection was available for 700 (99.7%) of these sessions. The median number of acupuncture points per session was six (IQR=2). The frequency of each point used is shown in Table 5.21.
TABLE 5.21: POINTS USED AS PART OF THE INTERVENTION

<table>
<thead>
<tr>
<th>Point name</th>
<th># of treatment sessions used</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spleen 6 (Sp6)</td>
<td>690</td>
<td>98.5</td>
</tr>
<tr>
<td>Liver 3 (Liv3)</td>
<td>604</td>
<td>86.2</td>
</tr>
<tr>
<td>Stomach 29 (St29)</td>
<td>583</td>
<td>83.2</td>
</tr>
<tr>
<td>Gallbladder 34 (GB34)</td>
<td>575</td>
<td>82.1</td>
</tr>
<tr>
<td>Ren 4 (Ren 4)</td>
<td>561</td>
<td>80.1</td>
</tr>
<tr>
<td>Ren 6 (Ren 6)</td>
<td>559</td>
<td>79.8</td>
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<tr>
<td>Spleen 10 (Sp10)</td>
<td>490</td>
<td>70.0</td>
</tr>
<tr>
<td>Spleen 8 (Sp8)</td>
<td>385</td>
<td>55.0</td>
</tr>
<tr>
<td>Sp4+PC6 (open Chong Mai)</td>
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<td>26.5</td>
</tr>
<tr>
<td>Bladder 23 (Bi23)</td>
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<tr>
<td>Large Intestine 4 (LI4)</td>
<td>109</td>
<td>15.5</td>
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<tr>
<td>Kidney 14 (Kid14)</td>
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<tr>
<td>Lu7+Kid6 (Open Ren Mai)</td>
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<td>Liver 2 (Liv2)</td>
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<td>.71</td>
</tr>
<tr>
<td>Stomach 28 (St28)</td>
<td>4</td>
<td>.6</td>
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</table>

5.6 Summary of trial findings

We did not find any evidence to support either of our primary hypotheses: neither electro-acupuncture or high frequency of treatment showed superior pain reduction to manual acupuncture or low frequency of treatment.

We did find some evidence to support our hypothesis that high frequency of treatment would show greater improvements in the HRQoL compared to low frequency of treatment, with six domains improving from baseline in the HF groups, with only two improving from baseline in the LF groups. There was no difference between manual and electro-acupuncture in terms of domains improved. There was no evidence to support that either high frequency of treatment or electro-acupuncture resulted in a greater reduction in analgesic medication.

Acupuncture treatment, as delivered in this trial via a manualised acupuncture protocol, showed significant clinical improvements in all three menstrual pain scores recorded; peak pain over the first three days of the menstrual period, average pain over the entire menstrual period and the worst pain during the
menstrual period. There were no between group differences in these pain outcome measures, despite large differences in responder rates between groups. This is most likely due to the exploratory nature of the study, which was not powered to detect small between group differences. Absolute percentage reductions from baseline support this observation. The use of last observation carried forward in a small sample such as this also can contribute to possible bias. Another confounding factor was that analgesic medication usage was lower amongst the HF–MA and LF–MA groups. As analgesic usage was allowed ab libitum women may have used analgesic medication to achieve an acceptable level of pain. Therefore the lower usage of analgesic medication amongst these two groups suggests that without analgesic usage there may have been more pronounced differences between these two groups. The implications of these issues will be discussed further in Chapter Eight.

The effect of differential diagnosis based on TCM pattern was also examined and found that differential diagnosis did not have any effect on the outcomes measured.

The manualised protocol did show improvements in the secondary symptoms of dysmenorrhea, with the HF–EA, HF–MA and LF–MA groups all showing significant reductions in the number of secondary symptoms from baseline. The manual acupuncture groups, irrespective of frequency, showed significantly greater reduction than the electro-acupuncture groups.

High frequency of treatment appeared to be acceptable to participants, however, three participants in the HF groups did note on the exit questionnaire that they found these appointments hard to schedule, while none of the LF participants indicated this as an issue. It must be noted that this was not a statistically significant difference and may be an artefact of the small sample size. There were no differences in dropouts between HF and LF groups for scheduling reasons. Electro-acupuncture was well tolerated by trial participants, with no differences between manual and electro-acupuncture groups in regards to discomfort during the treatment sessions and no dropouts related to type of stimulation.
Overall we found evidence for the effectiveness of manualised acupuncture for reduction of pain and secondary symptoms in primary dysmenorrhea, with clinically and statistically significant reductions in all pain scores. These reductions in pain scores were correlated with reductions in other corroborating measures with duration of pain, analgesic usage and secondary symptoms all showing significant improvements. Full discussion of these results is presented in Chapter Seven and Eight.

Chapter Six presents the results of post trial interviews undertaken with participants from the RCT and examines their experiences as part of the clinical trial.
Chapter Six: Post-trial interviews

The findings from 12 semi-structured interviews with participants in the randomised controlled trial (RCT) are presented in this chapter. The methods related to this study have been described in Chapter Three.

The aim of these interviews was to explore the experiences of women who had recently participated in a clinical trial on using Traditional Chinese Medicine (TCM) acupuncture to treat primary dysmenorrhea. The research question explored is “if and how has participating in this trial changed their perception and experience of the physical and emotional experience of dysmenorrhea?”

6.1 Participants

Using the purposive sampling described in Chapter Three, 12 participants were selected: four from Wellington and eight from Auckland. All participants were aged between 19 and 43. Group allocation is detailed in Table 6.1.

Four participants were considered non-responders: Vanessa, Trudy, Teresa and Leslie. The eight remaining participants were considered to be responders: Betty, Sally, Hannah, Vicki, Kate, Elizabeth, Sarah and Michelle.

A participant was considered a responder if they provided a self-rated improvement score at trial exit of \( \geq 5/10 \). Conversely they were considered a non-responder if they provided a self-rated improvement score of \(< 5/10\).

Seven participants were from the low-frequency treatment groups. These women received one treatment session per week, plus one treatment session within the first 48 hours of the menstrual period each cycle for three cycles.

Five participants were from the high-frequency treatment groups. These women received three treatments in the seven days prior to the onset of
menses, plus one treatment session within the first 48 hours of the menstrual period each cycle for three cycles.

**Table 6.1. Group Allocation of Interview Participants.**

Responders are marked with an asterisk (*).

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Betty</td>
<td>Vicki</td>
<td>Elizabeth</td>
<td>Leslie</td>
<td></td>
</tr>
<tr>
<td>Sally</td>
<td>Vanessa</td>
<td>Teresa</td>
<td>Sarah</td>
<td></td>
</tr>
<tr>
<td>Michelle</td>
<td>Trudy</td>
<td>Sarah*</td>
<td>Hannah*</td>
<td></td>
</tr>
<tr>
<td>Kate</td>
<td></td>
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**6.2 Findings**

The overarching theme that emerged from these interviews was “a change of perspective: becoming more in tune with my body”. This theme captured the participants’ experience, that they changed their perspective on health and wellbeing after being in the trial, both in general and more specifically related to period pain. Five major related themes were found. The first major theme was “treating more than just cramps”: this captured how participants felt that the acupuncture treated them holistically, rather than only targeting their period pain. The second major theme was “period pain, a normal part of being a woman”: this theme discusses how participants viewed the normality of period pain and related symptoms. The third major theme was “making sense of my menstrual cycle”: this captured how, after taking part in the trial, participants often changed their perspective on their menstrual cycle. The fourth major theme was “someone you can trust”: this captured how participants valued the ability to open up with, and get credible explanations from, their practitioners,
and how this was often different to previous treatments they had undertaken. The final major theme was “practical obstacles of time and money”: this captured the financial difficulties participants would potentially have if they continued on with treatment when the trial concluded. Table 6.2 and Figure 6.1 shows the major themes and their related sub-themes.

### Table 6.2: Themes and sub-themes present in the post-trial interviews

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-themes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A change of perspective: becoming more in tune with my body</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Treating more than just cramps</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Period pain, a normal part of being a woman</strong></td>
<td>You’ve just got to live with it</td>
</tr>
<tr>
<td></td>
<td>Can’t let a period stop you</td>
</tr>
<tr>
<td></td>
<td>Thinking differently</td>
</tr>
<tr>
<td><strong>Making sense of my menstrual cycle</strong></td>
<td>Gaining awareness and making connections</td>
</tr>
<tr>
<td></td>
<td>Prescribing common sense</td>
</tr>
<tr>
<td></td>
<td>Continuing to take care of myself</td>
</tr>
<tr>
<td><strong>Someone you can trust</strong></td>
<td>Not all practitioners are the same</td>
</tr>
<tr>
<td><strong>Practical obstacles of time and money</strong></td>
<td></td>
</tr>
</tbody>
</table>
6.3 A change of perspective: becoming more in tune

The overarching theme of “a change of perspective: becoming more in tune with my body” incorporates how the women felt about the explanations about period pain that were delivered to them during the trial. Participation in the trial resulted in women feeling more “in tune” with their body, and increased their understanding of what was happening to their body during the menstrual cycle. Often these explanations were different from what they had been given by other biomedical or complementary medicine practitioners, or those previously discovered in their own research, and offered quite a unique perspective:

I think I found that interesting to learn more about it and how the periods work, especially given that I had so many issues and I even had done my own research over the years but it was all very interesting to get a different perspective, just from the acupuncture perspective. (Sally)
Often what was most surprising to women was that TCM saw period pain, along with related symptoms, as part of a problem in the overall health of the body. Rather than just treating period pain, TCM acupuncturists aimed to treat the whole body, which in turn would relieve the period pain symptoms:

I understood more, well, from what he was saying about the channel and the energy and just of the theory not that I am saying I know anything about acupuncture, but just that I understand the, you know, how it all affects together and how, you know, how my leg affects my neck and how that affects my back and my period, and how it seems to be putting stress on my liver and the spleen and, you know, the links between everything like that was quite interesting for me. (Kate)

The explanations were often tied to explaining what different acupuncture points were doing or why they were chosen. Because of the flexibility in the trial protocol, points were added and subtracted at different times depending on the presenting pattern of disharmony. This allowed practitioners to explain why there were using different points at different times and link them to changes that were occurring in the women's symptoms:

It was just interesting that there are different points, what they mean and when they become more serious in the cycle. I guess learning about cycle itself was really nice, tuning into my body and tuning into my cycle and yeah kind of felt womanly in a way. (Betty)

Implicit in being in the trial was an expectation to fill in the menstrual pain diary. This required women to pay more attention to their period. Often women were taught to ignore their symptoms and “get on with it”, so the idea of paying attention and observing the changes in the body were positive experiences:

I think I became more in tune with my body because I had to pay attention, more attention to it being aware actually of how much pain I was in because I
guess I talked about it with Mike quite a bit where we are so brought up to

crack on and when we are female we have periods and everyone has to grin
and bear it sort of thing, and also really simple things like training and going to
the gym and I always thought you had to just do it, get it done even if you
were suffering and being told “no, actually your body really needs to take
time out and relax once a month and your energy is going elsewhere’’ that
was pretty cool for me to hear, yeah. (Hannah)

6.4 Treating more than just cramps

This theme captured comments made by participants that they were surprised
that the acupuncture treatment did not only improve their period pain, but also
that they often noticed improvements in other symptoms, some of which were
actually more bothersome than the abdominal pain itself.

Participants felt that not only did their period and menstrual related symptoms
improve, but their overall health and wellbeing, unrelated to the menstrual
cycle, changed for the better. This was often due to participants feeling they had
more understanding about what good habits and behaviours were:

I loved it. I felt like I was taking time out for self-care and learning about some
lifestyle changes that are good for my overall health and I was kind of
surprised with that. I didn’t expect it initially. You know, maybe that would
just help the period pain, but I felt like sort of helped my overall health and
wellness and establishing some good habits, some better habits with myself.
(Betty)

Women often commented that their “pre-period” symptoms improved,
sometimes reducing the dull ache prior to the period that sometimes occurred,
but most often the improvements were in emotional changes, nausea or
headaches:
I think that the pre-period pain or the symptoms leading actually to the period were lessened and non-existent, like my nausea-ness. I think from the second period on within the trial, I did not — I think it was the first time — I do not think I threw up, so that was a big thing for me because I always throw up with my period and not having that during the trial, that was a big thing for me. (Sally)

The reduction in these non pain-related symptoms often helped women cope with the abdominal discomfort associated with their period, as they felt like they were less vulnerable and more resilient:

If you get up and you throw up the whole day, it is so exhausting, whereas if you can at least keep your insides in [laughs], it makes it a little bit easier to deal with the pain. (Sally)

One participant felt that the reduction in her premenstrual syndrome (PMS) and premenstrual tension (PMT) symptoms were “life changing”. For this participant it wasn’t simply that during her period she was in pain, but that half of her life was so significantly affected by the symptoms she suffered and caused such distress she thought of that time as “written off”:

Well it’s been slightly life changing for me actually because I have suffered from PMS and PMT all my life so pretty much half of every month is [laughs] has been written off and in one way or another. (Hannah)

Another participant commented that while her pain was almost gone, which meant she could reduce her analgesic intake, the reduction in her “blue” days was also very important. This shows that while primary dysmenorrhea is characterised by pain, it is often not the only, or even the most important, symptom for many women, even when the pain is severe:
I suffer massively with pain before I started this study. I started on the first day of my period and also the week before I got my period, I had these days where I felt very blue and sad and down and everything is grey and nothing is happy. And these are the true changes that are the most obvious ones so I don’t have ... you can say I don’t have pain anymore — I don’t need painkillers. And just the depressive days are gone as well and this is worth a lot. (Vicki)

One of the participants felt that her both her abdominal pain and PMS reduced, and that the acupuncture made her more fertile. She fell pregnant during her second month of acupuncture treatment. She unfortunately suffered an early miscarriage, but continued on with participation in the study:

Yep, yeah. And it [the pain] did reduce. Previously, sometimes I would be bedridden for a week so I did not have that any more so that was great. Possibly it made me more fertile [and] maybe I was a bit less anxious. It is hard to say because I had so many changes going in my life at that point but yeah, I think it did reduce some of the mental effects of the PMS. (Michelle)

For those participants who experienced changes in other parts of the body, improvements in neck pain and headaches were the most common. Several participants mentioned that the headaches they normally had, either just prior to, or during the period, had significantly reduced:

Yes, for me it helped my lower abdomen pain but what was more impressive I thought, very happy about was the fact that it helped my neck pain and my headaches, I get really nasty pre-menstrual headaches if you like. So that was a really good help for me. (Elizabeth)

Oh I found to be quite positive actually and when I first started I was bothered by neck pain before my period and during my period I have lower back pain
and it definitely diminished by doing this therapy. I am cool with that really.

(Kate)

One participant got only minor relief from the abdominal cramping, but significant reduction in the severity of headaches she experienced during the period, however, this improvement seemed to be diminishing since the conclusion of treatment:

Yeah they didn’t go away completely but it changed from migraine to just headaches … I could still do stuff with headache rather than migraine … like during the study the pain wasn’t so bad and I didn’t get headaches like the one after that was like a dream come true and then it’s just getting sort of getting worse again. So I’m not sure, maybe that’s because going like reverting back to before I had acupuncture kind of thing. (Leslie)

6.5 Period pain, a normal part of being a woman

This theme discusses the common experience of participants in the study of what they perceived as a “normal” period prior to entry to the trial. Most women felt that period pain was part of a “normal” period and that it was an integral part of being a woman.

One of the participants captured a common refrain that occurred, that prior to entry to the trial she thought it was normal to have pain because she knew others that had similar symptoms and that there wasn’t anything you could do, apart from take analgesic medication and rest:

Well before the trial and before I really sort of started to think about it and compare it to other women’s experiences, I thought it was normal because it was something that my mum has always had to deal with and so naturally I saw that as just a normal part of having your period, you know you get the cramps and stuff … It’s not something that people really talk about that much
I mean, I suppose my girlfriends bring it up every so often if we’re having a bad day or whatever, but yeah it just seems to be accepted that yeah that’s just part of it and you can’t do anything about it apart from take some Panadol and go to bed. (Teresa)

Other participants commented that period pain, in their mind, was just part of “being a woman” and it was something that women had to put up with as an integral part of womanhood, that if you are a woman then you get period pain:

Yeah it’s kind of just … I don’t know … it sounds weird … a reminder or right of passage, it’s just like you know … because you are a woman, this is what you get. (Sarah)

One participant commented on how, since dysmenorrhea is so commonly experienced, that in a way it can be thought of as normal but not necessarily “okay” if and when it impacts on a woman’s daily activities and quality of life:

I guess it’s something that a lot of people experience. So, I kind of think it’s normal, but I think that would make it not okay and something I should deal with this if it’s just an impede all of my life and I think it is in general getting slowly worse and impeding all my life more and a few, like the past few months, I have had times at work where I had to take a break because I feel so awful and I think that that’s not really normal. (Vanessa)

### 6.5.1 You’ve just got to live with it

This sub-theme deals with the idea that many women noted, that since they perceived period pain as normal they had not sought out treatment because they didn’t believe it was something that needed treatment, as it was not something pathological, but rather an inevitable feature of each monthly period. This line of belief was reinforced by conversations that participants had with medical professionals, family and friends around period pain.
Most women felt that their attitude around seeking treatment for period pain was formed by the dominant narrative, that it was normal to have this pain, therefore there is no point in trying to treat something when it's normal:

I’m not really sure, I suspect part of it was the whole attitude; well it’s not something that needs treating because it’s normal. So because of that idea of being normal it’s in my head, it didn’t occur to me that ... therefore it’s normal and therefore you don’t need to do anything about it I guess. (Elizabeth)

Pain was not the only symptom that women considered normal, other symptoms like pre-menstrual symptoms were also considered something that was inextricably linked to the monthly menstrual cycle:

Well I was reading on PMS quite a bit so I knew it has to be associated since it was ... I can make an appointment in my calendar and know that it would come a week before I get my period. The same as with the pain, I just accepted it as it was. (Vicki)

Many women felt that because they were told that it was normal to have this pain, they gave up trying to have it treated. The feedback from their medical practitioners was that any further efforts outside of pain killers was a waste of time and that acceptance was the best strategy:

And my doctor just told me to try it [a German herbal extract], if this doesn’t help nothing will help and you will have to stick to pain killers and so I kind of accepted that if I have my period I have to take some pain killers — that’s the normal way. I never looked into any alternative treatments until I got this email advertising the study. (Vicki)

My other GP just told me it’s okay if you take lots of Nurofen and Panadol. It’s normal. We all do it. (Vanessa)
Quite a few of the participants had discussed their period pain with friends and family, but had been given the impression that it was something that was just normal and wasn’t really a medical problem because there was nothing that could be done. When other close family members had period pain, especially if severe, this appeared to reinforce the belief that it was inevitable that they too would have pain:

No, don’t see the doctor very often. Yeah I just sort of talked to mom and she gets them quite bad as well, so I just thought it must be normal. (Leslie)

I suppose I had talked about it to my mum before but I mean not in any sort of gory details or anything like that. But she would just be like oh take some Panadol, go in later to work or something like that. It wasn’t really … I didn’t bring it up with my doctor or anything like that because I thought there’s no use, what can they really do for it so … (Teresa)

I wasn’t the only one that got it [period pain], you know so amongst my peers it was the same thing, so I didn’t know any different and I never thought to think any differently. (Kate)

One participant had a sister who suffered from endometriosis, which brought about a discussion about getting tested for the same condition. The participant ended up getting multiple tests for both the pain and the accompanying breast tenderness, but because “they say that’s a normal thing” she just accepted it and didn’t talk about it:

Not about the period pain … Oh yeah I had a chat to my sister about it once because my sister had those … what is it called … endometriosis. She had to get I think one of her ovaries cut out because of it and I used to talk to her about how bad my period pains were and she wanted me to go get tested and stuff but I never did. My biggest problem is the breast tenderness, it’s so bad like if you accidently bump it, I’m like crying out in pain and I’ve talked to
people about that and I’ve had even some x-rays or ultrasounds, whatever, but they just say that’s a normal thing, you’ve got to live with it, so most of the time it’s like a normal thing you’ve got to live with it so you just don’t talk about it — it’s just what it is. (Sarah)

6.5.2 Can’t let a period stop you

This sub-theme reflects how women often felt pressure from friends, family or society in general to just keep on going during their period time, that it was to be treated the same as every other day and why would you let something like a period stop you:

No I think generally it’s just a case of you know friendships, family, everything, society, culture drum that into you and especially when I grew up in the 90s when it was all about women having everything, then a little thing like a period is not going to stop you. (Hannah)

Tampon advertisements showing women doing all kinds of activities like “roller blading” and implying that women should just continue with all their normal activities during the period time, and that they should be full of energy, was very different to the experience many women had of their own periods and one participant felt like society didn’t really understand how they suffered:

I think it comes from society to be honest as a whole ... you know you should be roller blading when you got your period and you should have this much energy and all of this sort of stuff. So I think it’s societal and cultural and you know there is the fact that the periods, oh the period before you actually start and you know for me anyway the first day of my period, they’re actually debilitating. (Hannah)

This same participant felt that she didn’t get a lot of support in the past from a friend, who presumably suffered from more mild dysmenorrhea than she did,
and that made her feel guilty that she was somehow overreacting or over-representing her symptoms:

A friend of mine used to say and you know because I would say or I am not feeling very well so I wasn’t able to do something and she would get very impatient and say “Oh god we all have our period, you know, you are not unique” and it used to frustrate her that I wouldn’t be able to do things like dragon boat or whatever because I wasn’t feeling very well and I used to feel quite guilty and, you know, like I was making a bigger deal of it than perhaps it was, but I actually was feeling ill. (Hannah)

One participant discussed this with her friends and found that they didn’t suffer as badly as she did and this made her feel like this was “bad luck”, that she suffered like this while others were okay, that they were able to continue on with life as normal while she was badly affected:

  I just thought — well it’s bad luck because when you talk to your friends and others and they say “well I don’t have any problems at all or my period is not as strong or as long or as painful” and you just think “Oh why me? Why did I have that luck?” (Vicki)

**6.5.3 Thinking Differently**

This sub-theme encapsulates the idea that women appreciated that the acupuncturist treating them changed the way they viewed their period time; this was often linked with hope that they did not have to simply “put up” with this pain any more, and that it was okay to treat the period time differently than other times during the cycle.

Women often found that when discussing their period pain with their acupuncturist it was quite a surprise to them that TCM did not consider period pain normal or inevitable, and that they could have periods with less or no pain.
One participant had a health-related background, but despite this she never thought of her pain as abnormal until discussing the trial with the researcher:

Yeah it was and as I say, because I’m a health professional myself and it was only when Mike and I started discussing this and whether I would be eligible for the trial and just him saying “well actually it’s not necessarily something that should be normal or normalised” and it really kind of turned my head around if you like “Huh? I really hadn’t thought about that but actually you’re right!” (Elizabeth)

Most of the women in the trial had period pain from, or beginning soon after, menarche and so felt that there was no reason to believe that a pain-free period was possible; in their experience menstruation and pain were always linked, so the possibility of a pain-free, or less painful period, was “eye opening”:

Mike had said that you don’t have to have pain with your period like it’s not a given you know what, but I had always assumed that it was. That was an eye opener for me and that was, you know, I couldn’t remember when I first got the pain compared to when I have got my periods you know that always quite symbiotic to me. (Kate)

Several of the women made mention of how once they knew it wasn’t normal, it gave them hope that they didn’t need to “settle” for the same kind of pain each month, and that there might be a new way of experiencing menstruation that didn’t involve such an impact on their life:

I think when I had my first session with Kate, she said quite a lot of women don’t get any pain at all or just very gentle pains, she’s like this isn’t something that you have to live with if you can treat it, so it kind of made me realise that maybe that wasn’t normal and I shouldn’t be settling for it and I should be trying to improve it. (Teresa)
I thought it was something I had to live with and every month it was just be like a huge hassle and I used to sort of plan and I had in plan everything around it so that I had a day off where I could just sleep, but during and after the trial I kind of realised that I do not actually have to live with it and it can be kind of fixed or dealt with better. (Rebecca)

One participant said she felt like previously she just had to keep going and just “ignore” her symptoms, because that was what was expected by others. While in the trial, hearing that it was “okay” to relax was an important change in the way she treated herself during the period:

I am really done in, so rather than just keep accepting that I suppose or accepting and ignoring and getting on anyway doing everything that I always normally do and to hear it was actually okay just put my feet up and relax rather than keep going was quite fundamental. (Hannah)

Another participant commented on how for the first time she felt that someone had listened to her and she felt validated that her previous suspicions, that this wasn’t a “normal” thing to have happen was correct:

I think it validated what I suspected, you know, the things weren’t right and you know my energy levels weren’t right, what I thought I needed to do I did need to do and I didn’t have to buy in to this idea that it’s fine. I don’t know yeah those ideas that you just got to keep going all the time. (Kate)

This same participant felt like she was already taking steps to try and deal with the pain and fatigue prior to being in the trial, but that no one had ever told her that it was okay to listen to her body and just rest. So rather than needing more advice, this participant felt like she needed acknowledgement that what she was doing was best for her body:
Yeah it’s hard to say that I had more because it’d been quite a long time, but after I had the acupuncture I would always be asleep like I’d have it at one and I’d be asleep by three. So yeah it kind of helped me to sleep but I don’t know if it was more because I mean I already did rest later in the afternoon you know it’s been going on and off quite a long time now, but I think it what most matters to me, was that I felt validated by Mike that yeah that I could actually do the things right that would work out for me and I just felt heard really. (Kate)

6.6 Making sense of my menstrual cycle

This theme illustrates how often the practitioner’s explanations helped women make sense of both the menstrual cycle and their symptoms, often changing their perspective significantly from the way they viewed the menstrual cycle prior to starting the acupuncture treatments. Several women felt that they had “eureka” moments, where these explanations made things fall into place for them in terms of how they viewed their periods. How the period and menstrual cycle was explained by the acupuncturists, in the context of a TCM framework, gave participants a different “reality” or context in which to understand their period pain:

Maybe it was partially the TCM, but there were some things I have read and really joined the dots together, that once Mike started explaining it, I would go “Oh of course” so it was more Mike’s talking around and about some of these things that happen, so that made things fall into place for me. (Elizabeth)

It was like a light bulb going on, you know, a new reality, and I quite like it when you know you are into something that kind of challenges your preconceptions or your idea for a while and it’s in a positive way ... so yeah it was pretty instantaneous. (Kate)
One participant remembered the TCM explanation of how the menstrual cycle is viewed quite vividly. This participant had a biomedical background, so the practitioner provided historical context for this different view and explained how TCM was its own “self-contained” view of the body that is separate from, and different to, that of biomedicine:

He explained it very clearly to me and all this historical thinking the Chinese had about all this energy and Qi and blood coming from the liver down onto the uterus — so he explained it to me, it was understandable, but they think in a totally different mindset. I just accepted it as ... yes ... but he did a good job explaining it as simple as possible. (Vicki)

Not all the women remembered the TCM explanations specifically, some remembered practical examples they were given by practitioners who tried to help them understand what was happening to their bodies. Practitioners often tailored these examples to some prior experience or educational background that participants could relate to, translating the abstract ideas of TCM into “what it really means” for the women; the practical examples being more important than explaining the precise theoretical framework behind it:

Because I studied physio so he was like relating it to it to my physio and explaining all the different energy channels and yeah I just found it really interesting to learn about it while it was being done. (Rebecca)

She did use acupuncture jargon or Chinese medicine jargon, but it doesn’t stick with me so it was more the ... just the act of talking. I’m not good with facts or figures or recollection of terms. But she did talk about it and we just translated that into what it really means. (Sarah)

However, not all participants felt convinced by the TCM explanations, even if they were understood clearly. Several participants had a background in biomedical science and didn’t feel totally comfortable with the TCM
explanations given, as they were in significant contrast to the way they had been taught to view the body:

Well the only thing that made sense to me is the idea of there’s energy and there’s a block and it can’t quite flow in the system. I could grasp this ... just having that image in my head that blood is towards in the liver and then it’s released a couple of days before my period — that’s so contrary to what I learned. (Vicki)

In spite of this, it did not impede the women’s ability to enjoy the acupuncture treatment or prevent them from perceiving benefit from the acupuncture itself. They were able to separate the TCM view of the body from their previous learning and look at it as a self-contained “package” that was different from what they had previously understood. They simply accepted it as a useful and alternative way of looking at the body:

So that I just decided okay, it’s something they think and it’s how they explained it. Mike always explained to me that they weren’t allowed too many anatomy studies in ancient China, so they just tried to make up their images, how the body works, not knowing what’s really going on under the skin. So the whole package was simply okay. (Vicki)

Yeah, the, I don’t know quite if I sort of believed that all the Qi stuff is sort of true, but, you know, I think like a lot of eastern ideas are really good and especially because my area of psychology and I know a lot of philosophy and so I was kind of open to it, but I think you might have seen sort of physiological thing which I found was when we put points in my belly and it kinda felt like it was replicating that period pain feeling and it kinda what made me think, “Oh, yeah, that is kind of, I can see how this might work”. (Vanessa)
Even participants who did not get total relief from their pain symptoms during the trial still found that the explanations given to them about their periods and period pain to be useful, as it provided them with a different explanation of what was causing their symptoms. In tandem with the lifestyle and diet advice they received, these explanations often made them feel empowered, as they felt like they had some agency over their bodies:

It does, yeah it does make sense. Although I am not so sure, I didn’t find acupuncture helped with the period pain very much, but like his explanations helped me understand more what I was experiencing kind of thing ... Yeah. Almost feel more empowered and on top of things. (Rebecca)

Well yeah I mean now I feel like I am empowered to be able to do something about it that’s more natural rather than taking any drugs and so yeah I feel like its separate from the pain in a way and I don’t have to put up with the pain which before I would have. (Kate)

6.6.1 Gaining awareness and making connections

This sub-theme represents the idea that an important part of the acupuncture sessions were helping women create links between activities and behaviours and the signs and symptoms of dysmenorrhea that they experienced. This was based around the TCM framework and its concepts, such as pathogenic cold.

Diet and lifestyle advice, grounded in TCM theory and often intertwined with the explanations given on how TCM views the body and the cause of disease, was given as part of the trial. Each woman in the trial was provided with at least one sheet that included semi-personalised advice that pertained to her particular pattern of disharmony. Most women were surprised that changing their diet, or choosing to go to bed earlier, would have an impact on something like period pain:
Yes. Something I found surprising. For example, I guess I didn’t realise that period pain was so holistic and so in relation to a whole lot of different things, for example, like sleep or like reduction of caffeine. I mean these, you know, these sort of general common-sense things in there. I guess learning about period pain is as a response to not looking after yourself totally in certain areas. So, yeah just you know little things like certain diet changes, the way I eat and gentle exercises. (Betty)

I think because we talked about things like diet and exercise as well, I think if your body is healthy and you’re putting the right things into it and keeping moving and active and things like that, you’re probably going to get better results in kind of every corner of your health. So I think if you’re healthy and fit, you’ll probably have less pain in general so yeah. (Teresa)

One participant felt that the acupuncture treatment actually encompassed not just the needles but also the “whole environment”; diet, lifestyle and external factors were all part of the treatment:

I think it is all connected with your body, like in your diet and the whole environment was in fact part of acupuncture, I believe. (Sally)

Many women commented that the explanations of diet and lifestyle choices and how they affected their symptoms gave them an increased awareness of what was happening in their bodies and how they could use those choices to influence their symptoms:

Just awareness of what was going on to influence those kinds of things so ... But yeah just having awareness and understanding what’s going on. (Sarah)

However, for other women, the awareness was an integral component of being in the trial itself, rather than the TCM explanations; that having to monitor their
symptoms for the menstrual pain diaries and planning treatments meant that they had to become more aware of what was going on in their bodies, even though they were often busy and in the past had just ignored them. Now that they had to pay attention, it was more obvious to them what was happening to their bodies during the period and peri-period times:

I have a bit more of an awareness of it now because spending the three months or how long thinking about it and analysing it every day and writing it down on a diary, you do start to sort of understand it a bit more in detail, whereas normally I wouldn’t pay that much attention to it, it would just be there. Probably, I think I’m sort of more aware of maybe the different stages it goes through, sort of like, what I can expect on day one, what I can expect on day three sort of thing. Just a bit more of an awareness overall. (Teresa)

No, but I think it increased my awareness of what actually happens for me because I guess it’s something that I’m really busy. So, I sort of just ignore, but I couldn’t because I was grading the pain and everything. So, yeah, it got me to think about it more, but I don’t know that it changed my perception a lot. (Vanessa)

One of the benefits of the explanations of the TCM understanding of cause and effect was that women were more aware of the impact that their lifestyle and diet choices were having on their symptoms. Women often felt that once they knew what to look for, they could more easily see the impact their choices made:

Yeah for sure, you know like the cold thing, like that was in my mind when I was getting sick of my cold coconut water that kind of stuff so I understood that there was an impact on what I was doing and how I would actually feel as a result so that was quite cool, yeah. (Hannah)
How participants emotional state affected their period pain, either directly or indirectly, through making different diet choices was something that participants felt was useful, and something that perhaps they had not linked previously, that they were perhaps emotionally eating things like ice-cream just prior to, or during the first few days of the period:

Yes. I mean it sounds stupid, but yes I didn’t realise it that it was those changes would directly impact something like period pain, it just has a whole lot more to it, it’s an emotional thing. (Betty)

We’d have a chat about what was going on at work and how that was stressing me and then she would talk about it and how that was impacting how I was eating perhaps and stuff like that so it was more of a holistic approach to everything. (Sarah)

The linkages were not just limited to diet and lifestyle choices, but also included connecting the choice of acupuncture points with the condition being treated, for example, how points on the feet might affect the woman’s headache, which involved an understanding of the acupuncture meridians:

Yeah, yeah well the way he described it, he would sort of say like this is the channel and this is where it joins up and this is what it does and they were kind of like giving examples of physio ... And it was real helpful and easy to link things. (Leslie)

He has explained everything that linked together and if a point goes in there it will affect this. (Trudy)

One participant noticed that even though she normally used heat in the past prior to participating in the trial she had never consciously made the link between the warmth and the relief of pain that she felt:
Okay. And when you used the heat before did you notice the difference? (Interviewer)

Not really, well I did but I didn’t relate it if that makes sense? I was just told that heat was good was good for us — okay, heat then, but I never actually noticed that it was definitely helping. (Leslie)

### 6.6.2 Prescribing common sense

This sub-theme details how participants found that the diet and lifestyle advice that was delivered to them in the trial was often something they felt was “common sense” and allowed them to make small, incremental changes in their behaviour.

Most participants felt that the advice they were given was often delivered in small, manageable pieces that allowed them to implement some, or all, of the advice given, without feeling overwhelmed:

Yes, definitely. It [the diet and lifestyle advice] is a gradual thing. I guess you cannot make too many changes at once ... But, yeah, it was useful and it was not too much. It was, yeah, a few tips. (Michelle)

Perhaps unexpectedly, given that the lifestyle advice incorporated avoiding ice-cream, cold water and salad for many women, a shared comment was that a lot of the advice was “common sense“:

[Practitioner] gave me the list of things to look out for. But they are things I do anyway, like I don’t ... apart from walnuts, I’m not big on walnuts. But I drink a lot of water, I don’t eat a lot of cold foods or drink cold water or anything like that so ... and that’s all pretty much common sense I think. (Sarah)
I think a lot of the advice on the sheet I was already doing so just sort of advice about eating healthy and making sure you get enough exercise and things like that. I already lead a pretty healthy lifestyle so I was kind of like “Oh, that was common knowledge” and so there wasn’t really too much that I could change or sort of focus on because I was already doing it. (Teresa)

Possibly related to the fact that many participants felt that much of the advice was “common sense”, many participants were already doing many of the things suggested by the advice sheets, though they often tried to add in any extras which they hadn’t tried previously:

I feel like most of the things I was already doing and then so, I guess I kind of just didn’t make a lot of changes because I was already doing lots of it except for yoga and I had thought about doing, starting some yoga which I haven’t done. (Vanessa)

I don’t think there was too much different to what I had already being doing in terms of doing the exercise, stress management and I already had a record of spiritual way which, you know, meditation and things and some of the things recommended. Well I don’t think there was too much difference in what I was already doing and it didn’t seem to be particularly different to what we hear about general lifestyle advice, which I think can desensitise you to it and say “Yeah, yeah, I have heard that before”. (Kate)

One participant felt like she almost instinctively knew what she should do, that she was avoiding certain things as she didn’t really enjoy them or had felt in the past they might be detrimental. However, this participant had some previous experience with TCM so that may have influenced her, in terms of her understanding of her body:
It made sense to me almost all of it I was following anyway, I don’t know if it was either instinctively or just ... I mean I practice yoga, I have a reasonably sensible diet, I don’t like cold things generally like ice-cream or ice or that sort of thing. Which I had to avoid for one of the weeks leading into my period. I think that the only thing I found hard to comply with, and again that’s more my personality, was the sitting quietly, taking some deep breaths — which was probably most what I needed to do to be improving but all of that made sense to me, but I don’t know whether that’s partly sort of having that little bit of TCM knowledge which was a bit light, but still I had a little bit of knowledge about that so I could make sense of it — I don’t know if that makes a difference ... (Elizabeth)

Several participants commented that they felt the advice was similar to that which they had received before, despite it possibly being quite different. This suggests that women are often given so much differing advice that it all seems to be the same, despite some of it perhaps being unique. This particular participant had been to see a naturopath in the past for her period pain and said she thought that the advice was similar between the two modalities, despite the fact that the advice she mentions in this quote is different to that given by the trial advice sheet:

Well, they gave me advice like no caffeine, no dairy, no sugar, no animal fat, take magnesium, which I have but I but I’m a bit slack with it [laughs] and fish oils, reduce sugar and alcohol and stress because stress worsens the problem. (Michelle)

Another participant felt that the advice given wasn’t very different from what she had read in women’s magazines like Cosmopolitan or Women’s Weekly, and that there was always something people were telling you to do to make your period better:
Yeah, oh this out there in the world about, you know, what you got of Cosmopolitan magazine or Women’s Weekly, you know it’s just what everyone tells you to do. (Kate)

However, several participants found at least some of the advice to be difficult to understand and weren’t sure how some of it might affect their period-related symptoms. These women still followed the advice, despite being skeptical or not completely understanding the possible link between the individual pieces of advice and their period pain:

I understood that it’s part of this Chinese medicine package. What pepper and spinach has to do with period pain ... so the link I couldn’t really make, but it’s the same ... it’s just pushing you to a certain point. I didn’t really understand what’s going on, it’s not like classical western medicine where you have an agent and then the effect. But I definitely accepted and embraced these advisors for nutrition and then included a couple more things into my diet regularly. (Vicki)

Oh yes, there was one about not eating or drinking cold things before your period so that I was like “Oh okay”. That I really didn’t understand, how that would make such a difference to any of the symptoms or things like that. But I mean I did stick to it and I just drank tap water and not filtered water so it wasn’t cold or anything like that and I didn’t have ice-cream and things. It was fine, it wasn’t particularly hard to do. (Teresa)

Most participants did not find it hard to follow, but one participant felt that some of the advice was difficult to follow as she enjoyed very cold water and didn’t enjoy having to drink warm instead:
Yeah, I thought that not cold water was interesting because I love cold water and that makes me feel fresh and yeah, so, I found it quite hard to follow, but I did try to follow it. (Vanessa)

One participant did not want to adopt the lifestyle and diet advice because she felt she already made so many concessions to her period time, to the point that she just didn’t feel like making any further modifications:

But it was the other lifestyles while I totally respect where she was coming from, I personally find I already have to change my life quite a bit for my period so at least I wanted to eat what I want and when I want. I know certain foods I should not have, like curry because oh, my Lord. (Sally)

Part of the reasoning for this participant was that she was friends with another study participant who had, even prior to the study, adopted a stringent diet but was still suffering from period pain:

No, because then I compare myself to other people like [name] who trains and exercises but she still gets hit [with pain] as hard as I do, whereas I do not train and maybe I eat different food than she does but still, at the end of the day, we get both hit hard. (Sally)

### 6.6.3 Continuing to take care of myself

This sub-theme captures what women talked about with regards to continuing with the diet and lifestyle advice after the trial was over. Of the participants who implemented the lifestyle and diet advice during the study, most had kept up with at least some of the diet and lifestyle advice in the post-trial period:

I mean I still don’t have cold food a lot or cold drinks a lot you know, and that’s nice, I just feel like it’s taking care of myself for some reason. (Betty)
One participant kept some of the advice in place but was not quite so strict with herself all the time:

To drinking cold water? Yeah probably, I don’t eat much ice-cream anyway because I can’t really have dairy so I suppose I would try to I think but I wouldn’t consciously go out of my way to make sure that the water was room temperature or something like that. (Teresa)

Those participants who did not find the explanations or advice particularly convincing during the trial were much less likely to continue with it when the trial was over, regardless of the magnitude of their improvements during the trial:

I didn’t pay too much attention to it so I’m still sticking to my diet ... so I can’t really answer this with a yes or no — I don’t know if it has influenced the outcome. (Vicki)

Several women who participated in the trial and didn’t feel much of a change in their period pain still found the diet and lifestyle advice useful, and still used it even when the trial had finished as they felt it was a way to help control, if not remove, the pain:

Yes I have actually, yes. Although I still get really bad period pain so I am not so sure it [acupuncture] helps that much but it was like something I learned during the trial that pain killers don’t really work and but if I use wheat packet it goes pretty much instantly and that kind of helps and that backed up that whole stagnation and drink warm stuff and stay warm. (Rebecca)

Well unfortunately it [acupuncture] didn’t actually change the period pain itself, but I found that it was worth it for the information [on] things that I can do to try and help the pains before they come up. (Trudy)
One of the reasons that participants gave for this was that, despite the lack of a significant change in their period pain, they felt like the diet and lifestyle advice empowered them to be able to make some changes in their life and that those changes would be able to alter their pain, and overall health, in the future:

It was overall a good experience, I hadn’t done acupuncture before so I was a bit nervous, you know what it would entail, but the person who was doing the acupuncture was absolutely lovely, completely put me at ease and it was just a generally pleasant experience, probably didn’t have the outcome that I was hoping for but I don’t regret doing it and I’m glad I tried doing acupuncture and I think it just helped me to look at my health holistically and understand different things that could be contributing to the period pain and things like that and just the general overall health. (Teresa)

6.7 Someone you can trust

This theme captured participant’s experiences with their acupuncture practitioner and how the therapeutic alliance was an importance component of the treatment process for them.

Trust was a very important concept to participants. Participants commented on how they felt like they could be open with their practitioners, trust them and discuss issues with them:

It’s alright so part of that was being feeling open to it and I don’t think you can get that if you haven’t got a feeling of trust and openness of the person who is practicing on you and yeah. (Hannah)

Yeah, yeah. Somehow I felt so comfortable, I could express myself freely and feel supported whenever I said whatever was going on, whatever I just be honest and open and yeah ... (Betty)
Participants mentioned that they felt “safe” with their practitioners, and this safe environment was an important part of being able to trust them, since talking about periods was often a private topic and made them feel exposed:

I think this combination has to be a good match — so between ... in this case Mike and me ... if you are on this table and being treated ... it’s a kind of exposed situation and if you can’t trust the practitioner then it feels awkward or it would feel awkward. So I was very happy that I could totally accept the way Mike treated me and also his personal way was absolutely appropriate and very professional. (Vicki)

I just felt I could go and speak openly and that was two-way as well. So he would talk to me about a thing and it wasn’t inappropriate and feel inappropriate or uncomfortable. Just felt safe and supportive and nurturing and just funny, just light hearted you know instead of just feel better afterwards for just sort of talking to someone who seem to be supportive and not judgmental and just kind of relate to what I would say as well and you know you can get that with different people in your life but he seemed to be the one for the time. (Betty)

Several participants made specific mention of the fact that they were able to ask questions and get credible explanations, or that explanations were given in terms they could understand, which was an important part of feeling like the practitioner knew what they were doing:

Yeah, I don’t think it would have been as good an experience if we didn’t build a relationship like that, I think that’s a really important part of the process and having someone you trust to talk to and you know ask stupid questions and like why are you sticking that there and, just realised how that sounded! Yeah if we didn’t have that connection, you know, I would be less likely to go. Just I think that was a big part of it. It feels really good and good at explaining things and didn’t leave any needles in me accidently so ... (Sarah)
I actually really loved Mike and I think the way he is very eloquent and he is very descriptive and he is easy to talk to, he is very approachable. So if I had questions, sometimes he would say something and I would ask him what he meant then he would go into more of a simplified explanation or whatever and I really admire that way of practicing. (Hannah)

Many participants had not experienced acupuncture previously and were not sure what to expect. The fact that the acupuncture took place in a more “western” context, rather than somewhere with music and incense was important to one participant:

I didn’t really have any expectations other than that I thought it would be more sort of like, you know, music in the background that with incense. So, I kind of expected that ...Yeah. I think that because I talked to Mike about his background and stuff and I knew that he had done all that physiology stuff and we’re in a physio building ... I know I said I expected that to bit to be different, but I think that stuff made me quite, feel quite safe that he knew what he was doing. (Vanessa)

Two-way communication and explanations of what was going to be done were another important component in gaining and retaining participants’ trust. Participants felt that this gave them some control and they could feedback to their practitioners how it felt:

Yes definitely. And I know that can be a hard thing to get straight away when somebody approaches you with needles and says I’m going to stick these in you with some electricity and put them in parts ... I’m not good with needles in my calves, like it just hurts, but she explained it and didn’t ... just kept asking if I was okay and wasn’t too sore or wasn’t too deep or anything so that was good. (Sarah)
As the primary investigator was a male, several participants commented on the importance, or lack of, of his gender. Some participants felt like it might have been uncomfortable discussing or getting treatment for gynecological issues from a man, especially in a one-on-one environment:

I think that if I had felt that he was in any way sort of dodgy or not really know what he was doing I would have felt very uncomfortable and I probably wouldn’t have gone back. So, I think because it’s so one-on-one, you know, in a room with a man that if I hadn’t felt comfortable and trusted him, I just wouldn’t have done it. (Vanessa)

I won’t go into too much but it helps to have guys that I can trust you know and somebody that’s a practitioner that you and yeah that you cannot feel intimidated or threatened by or uncomfortable with you know somebody is quite seem quite safe. (Kate)

However, it seems that for all the women participants involved, the primary investigator’s gender was not an issue once the therapeutic alliance was developed. One participant felt like that was because he did not minimise or explain away her experience as a woman:

[He] didn’t necessarily meet gender stereotype and give you back responses that you felt minimised your experience so I mean not saying he is a girl or woman [laughs] I won’t say he’s even like a woman! I am just saying that he yeah he actually reflected some of the better qualities ... (Kate)

6.7.1 Not all practitioners are the same

This sub-theme captures the differences in experiences between interactions with the study practitioners and interactions with previous therapists, both biomedical and TCM. Participants who had acupuncture previously often compared their interactions with the study practitioners in a more favourable
light. This appeared to be linked to two components; study practitioners gave better explanations of what they were doing during treatment and they generated a feeling of trust and safety amongst the participants.

Communication of what practitioners were doing, and engaging in dialogue with the patients to explain the reasons for treatment were very important to participants:

I did [have acupuncture before]. When I was struggling with acne after I went off the pill about two and a half years ago — two years ago — and yeah so I had it probably every week or two for two or three months. And it was from a Chinese guy and the communication wasn’t like myself and Mike, you know, it was quite hard to communicate with this man so I guess I got a lot more from Mike. [I] felt like the communication lines were more open and he understood, you know, what was going on for me and gave me some good feedback in terms of how the Chinese medicine stuff applies. (Betty)

One participant explained the difference between her previous treatment for shoulder pain and her treatment during the trial. Her involvement via questions and answers and participation in the treatment appears to be much greater in the trial compared to her previous experience:

... the way Mike decided to use this point or that point ... the way ... the decision making and the questions he asked, the things he looked at — my tongue, the pulse ... so it was different the way he gets to the final points and then puts the needle in and also how he inserted it, well it might be because in the previous experience in my shoulders, I didn’t see anything — it could have been. But with Mike it looked different, different angles, different depth he used — so the needling itself was a different experience as well. (Vicki)
For this participant, the lack of trust in that first treatment session was sufficient for her to not return for any more treatments, as she didn’t feel safe during treatment:

I’ve had one other acupuncturist and that was just a one-off session because he couldn’t give me this safe and secure feeling during treatment and didn’t really get my trust. I think it’s absolutely crucial. (Vicki)

One participant had spoken to two doctors in recent years about her pain, but had been told it was simply to do with her weight. She felt like that didn’t really help her, as she didn’t believe that was the problem:

Yeah. And I’ve spoken to two doctors previously about it and they both had a negative approach to it and said it was because I was overweight but I couldn’t understand how that could be because I hadn’t put on any weight in the past six years. (Trudy)

However, once she had participated in the trial, despite not responding to the acupuncture treatment, she felt that she had more, rather than less, options and therefore felt much more positively about possible solutions:

Yeah because it gave me different options instead of like before when the doctors shut me down and leaving it at that. Mike gave me options and also referred to a gynecologist and things like that so it was positive. (Trudy)

6.8 Practical obstacles of time and money

This theme captures the participant’s discussion around their interest in continuing with acupuncture when the trial had finished, and the associated issues that raised around cost and time.
6.8.1 Time

Participants were equally divided amongst groups that had treatment once per week (low frequency) or three times in the week prior to the period (high frequency). There did not seem to be any differences between the groups in terms of scheduling complaints, in fact several of the women in the high-frequency group commented on how this fitted well into their busy schedule, that they could just get it all done in a short space of time:

... three times in the week, it wasn’t really the frequency that was really a problem at all. I actually found it better because then I could sort of get it all over and done with in sort of one week rather than having to go back every single week. So it worked out better. (Teresa)

I think I was quite lucky, it really did. I don’t think I could’ve committed to the other group maybe, just being able to do a quick succession sessions and get it done was cool. I also really like the electric therapy or whatever it is. And that was mostly through my legs so there was one near the ankle and one higher up on the calf. Although one time she did it in my hands, but that was after a discussion about a lot of stress going on. (Sarah)

Women with childcare commitments, regardless of group, found it more difficult to find time to fit in the treatments, as they sometimes needed to bring the child or children with them to treatments:

Umm ... it wasn’t a real problem, it was just as I said ... a bit of a struggle with my daughter as I didn’t have anyone to pick her up and to care for her during that time. So from the personal side — it was a bit inconvenient to have it once a weekly due to my personal situation. If I just blank that out, it was actually okay ... if I didn’t have the obligation to look after her and take her with me it would have been ... yeah less inconvenient. (Vicki)
Yes so three times [in the week prior to the period] and then once within that two-day period — I think that was actually rather than the ... the frequency itself I could manage, but because I work quite long hours and I’ve got three kids and I guess that most women are busy, but trying to often slot it in and thinking “Oh my period is going to arrive on this date, okay that’s where I can fit it in this day” and it could be one day later or something and I’d be going “Oh how am I going to fit it in this time?” (Elizabeth)

As they were participants in the trial, the acupuncturists were more available time-wise than they might have otherwise been, opening on weekends and late in the evenings to allow participants to come at times that suited them:

I went on a weekend for the most of the time that made it easy but if he wasn’t working on the weekend there would have been no way that I could reasonably get to him because where I am based and where he is based you know if he was only working week days it wouldn’t have worked in terms of busyness. (Kate)

Several participants made note of the fact that it was a catch-22 situation with regards to time; they were busy and so it was sometimes difficult to find time to fit in appointments, but that the ability to have enforced “time out” was a significant part of what they enjoyed about the treatment:

I guess like it’s hard to make time for things like, you know, around work and I quite often work long hours and it’s sometimes just hard to give it, but then I think this also what I liked about it is they actually make the time which was good ... It was like an hour a week that I took to just relax which was really nice and also like it feels good to help someone else out with the study as well and also because I had little bit of well, I will do in the future, a bit of research myself and that it isn’t easy to get participants. (Vanessa)
I really enjoyed — I don’t know if this is part of the trial, but just having the time to talk about the things and during the session I thought it was a nice side effect of it but no ... I liked having the time off work, like I was forcing myself to have an hour doing nothing, just relaxing. I enjoy acupuncture and yeah I just had a good time. (Sarah)

6.8.2 Money

Money, more so than time, appeared to be a significant factor in women’s ability to carry on with treatment once they had to pay for it. Perhaps unsurprisingly, those women who were classified as “responders”, with a greater than 5/10 score on the self-rated improvement scale, were more likely to continue having acupuncture treatment than those who felt like they did not get any significant pain reduction during the treatments:

Yes. [I would continue] and I actually just went yesterday for acupuncture. (Michelle)

I would still like to go and if it had a quite positive effect on me then absolutely I would keep going at times. (Hannah)

Several participants commented on how they felt that the results they got in the trial wouldn’t justify continuing on with treatment, but they felt that if they had experienced more positive results then it was something they felt like they would have continued with:

I think for me if I wasn’t getting the results then I would probably discontinue going so I think for me it was results based. Like if I was getting a really positive result then I would have kept going and kept paying myself. (Teresa)

Oh I would be happy to pay but after the trial has finished and it hasn’t made any difference, so I didn’t see any point in continuing ... (Trudy)
However, regardless of treatment outcome or group, all participants commented on the financial burden that continuing treatment would impose, whether they were students or professionally employed:

Yeah it would have been a barrier because if you sort of add that up, that’s $240 per month, yeah that’s quite a significant amount of money I guess … I’m not devaluing the acupuncture itself, in terms of out of the family budget it would have been reasonably significant. (Elizabeth)

I think I wouldn’t have been able to afford it considering how much it is, that’s $160–$200 a fortnight … it was in a pay period so no I couldn’t have afforded it — perhaps one within the two weeks. (Vicki)

Several participants commented on the fact that because they could take pain-relieving medications and get some relief from them, it was harder to justify the costs, regardless of the benefits:

Yeah that would be a huge barrier for me because I am a studying student, so I wouldn’t have been able to … there is no way I would have been able to pay for it. I think I would have got some Panadol or something and lived through it. (Leslie)

This participant rated her improvement 9/10 and would like to continue with acupuncture, but still felt like she had to prioritise money to other, more pressing health issues at present:

… having to pay for it … the only reason I wouldn’t is I’m keen to go back and get my calves done quite regularly so I can do [cross country race], so that takes priority over … I can handle pain and treat it with Panadol over getting my calves sorted out, so once they’re back in session I’m going to do a quite intensive calf session with the girls there, but if I didn’t have that issue — yeah
I totally would be doing it all the time. Just for the time out, just for a bit of relaxation and if it’s dropping the frequency and intensity of the pain totally, I’m all for it. (Sarah)

One participant noted that if she hadn’t had such a positive experience in the trial she wouldn’t have tried acupuncture because of the cost, she felt like she couldn’t have used that money on something with such an uncertain outcome:

When you start that kind of treatment, you don’t know … is it really worth it and so you have to weigh up $200 within the pay period against something you don’t know, an uncertain outcome. So I think without this experience I have now, I would have considered it not affordable and not really would have been made this decision to take that risk. (Vicki)

A common point raised by participants was that if there was a discount, or “loyalty” program they could participate in that would allow a reduced price, that this may remove or reduce the barrier to treatment on a regular basis:

I guess maybe if they had some sort of like a loyalty program or something like that so that if you committed to an ongoing schedule and there was some sort of discount for that, which might make it more an attractive option. (Teresa)

The frequency I got together, you know, I could make that happen, but the cost — probably about half that, about $30 a session? (Elizabeth)

Other participants felt like if they just had treatment once a month, at the right time, they could afford that treatment:

Not weekly no — once a month yes, yeah before the period yeah. (Kate)
6.9 Summary

Women who participated in the RCT on using acupuncture to treat period pain felt that there were numerous benefits to participating in the trial, including a reduction in period pain, as well as a reduction in other peri-period symptoms, such as emotional changes, neck pain and headaches.

The participants were often surprised that they didn’t have to think of period pain as normal and the explanations given by their acupuncturists as part of the trial helped them re-evaluate what a normal period would be; this often gave them hope that they didn’t need to “put up with” the pain. The participants also felt that they could finally treat their period time differently rather than just having to “get on with it”.

The participants appreciated the diet and lifestyle advice, even if they didn’t always understand it completely, and most felt it was helpful and would continue using at least some of it once the trial ended.

The participants emphasised the importance of the relationship they had with their practitioner in the trial; they felt safe and heard, were listened to and given credible explanations for what was happening to them during their period. Often this was different to what they had experienced before, with either complementary medicine or biomedical practitioners.

Finally, the participants did find that the ongoing cost of treatment would be an issue, especially since the cost of analgesic medication was so low and convenient compared with the time and financial commitment for acupuncture.

Chapter Seven presents the findings of the integration that occurred at the conclusion of data collection, and the discusses the themes that emerged across three or more data sets.
Chapter Seven: Integration

Integration occurred in two phases of the thesis: at the conclusion of each of the four individual study phases, providing data for the subsequent phase(s); and again at the conclusion of data collection, where integration occurred across all four study phases.

7.1 Integration at the conclusion of each phase

The methodological approach to integration at each phase has been outlined in detail in Chapter Three. Practitioners who participated in the New Zealand and Australian survey and indicated substantial experience with menstrual disorders were invited to participate in focus groups and interviews. Focus groups were held for New Zealand practitioners, while interviews via Skype were undertaken with Australian practitioners.

The prevalence of the use of multiple modalities in treating primary dysmenorrhea was evident from the practitioner survey, especially the use of self-care advice and the low usage of electro-acupuncture. The reasoning behind the choice to use these modalities was discussed in these focus groups and interviews. The resulting practitioner discussions around stimulation modes, treatment timing and duration, use of moxibustion, individualisation of self-care, TCM diagnostics and point selection were incorporated to develop the trial protocol for the randomised controlled trial (RCT).

This manualised trial protocol was used to examine the effect of changing treatment timing and mode of stimulation of acupuncture on the outcomes of primary dysmenorrhea. A cross-section of trial participants with different responses to treatment were invited to participate in post-trial interviews to discuss their experiences with period pain, effectiveness of the acupuncture intervention and the TCM self-care advice.
7.2 Integration at the conclusion of data collection

This chapter discusses how the four individual study phases have been integrated, with the key findings presented in Table 7.1. The four study phases were:

1) a practitioner survey,
2) practitioner focus groups and interviews,
3) a RCT, and
4) follow-up interviews with participants.

The results of each separate study have been reported in Chapter Four, Chapter Five and Chapter Six.

Only themes that spanned three or more phases are discussed in this chapter, whilst those that occurred in only one or two phases are discussed in Chapter Eight.

Firstly, the research question on the effect of modes of stimulation and treatment timing on primary dysmenorrhea was examined by integrating the quantitative survey and RCT results, with both the practitioner and participant qualitative interviews and focus groups, to help better understand how these results can translate into optimal clinical practice.

Secondly, an overarching theme emerged across all phases. This was “more than needles”, which examined how multiple components of the acupuncture treatment, not just the insertion of needles themselves, were found to play a role in the therapeutic outcome.
### TABLE 7.1: INTEGRATION OF THEMES FROM THE FOUR STUDY PHASES

<table>
<thead>
<tr>
<th>Stages of data collection</th>
<th>Practitioner survey</th>
<th>Practitioner interviews / focus groups</th>
<th>Randomised controlled trial</th>
<th>Post-trial interviews</th>
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<tr>
<td></td>
<td>Method</td>
<td>Quantitative</td>
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<td></td>
<td>The effectiveness of modes of stimulation and timing to treat primary dysmenorrhea</td>
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<td>Low usage of electro-acupuncture for primary dysmenorrhea.</td>
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<td></td>
<td>“Practical obstacles of money, time and space” and “Finding what is effective” and “It’s not cut and dried”</td>
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<tr>
<td></td>
<td>No difference was found between manual and electro-acupuncture for pain outcomes. Manual acupuncture produced greater reductions in medication usage and secondary symptoms. Treatment frequency did not significantly affect primary outcomes.</td>
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<td></td>
<td>“Treating more than just cramps” and “Practical obstacles of time and money”</td>
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<td>Guiding women back to health: the importance of the partnership in TCM</td>
<td>“A complex partnership” and “Treating women holistically” and “A partnership in understanding patterns and connections”</td>
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<tr>
<td></td>
<td>The relationship with their practitioner was the highest rated component of the trial by participants.</td>
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<td></td>
<td>“Someone you can trust”</td>
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<td>Holistic understandings: a new way of thinking about period pain</td>
<td>“A complex partnership” and “Treating women holistically” and “A partnership in understanding patterns and connections”</td>
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<td></td>
<td>Explanations of TCM, understanding of the menstrual cycle and what a normal period should be in TCM delivered during RCT.</td>
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<td>“A change of perspective” and “Making sense of my menstrual cycle” and “Period pain, a normal part of being a woman”</td>
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<td>Taking back control: self-care for period pain</td>
<td>Diet and lifestyle advice and moxibustion used as common co-interventions for primary dysmenorrhea.</td>
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<td></td>
<td>“A complex partnership” and “Treating women holistically” and “Finding what is effective”</td>
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<td></td>
<td>Self-care advice was delivered based on women’s underlying TCM diagnostic pattern during the trial.</td>
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<td></td>
<td>“A change of perspective” and “Treating more than just cramps” and “Period pain, a normal part of being a woman” and “Making sense of my menstrual cycle”</td>
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7.3 The effectiveness of acupuncture in the treatment of primary dysmenorrhea

7.3.1 Prevalence in clinical practice

Practitioners in New Zealand and Australia very commonly treated primary dysmenorrhea. Almost 90% of survey respondents who treated women’s health conditions in the previous year saw women with primary dysmenorrhea. Practitioners in our focus groups described how they did not often see women come for treatment with primary dysmenorrhea as their primary complaint but it was often something they treated as part of their holistic approach to health, especially when women were coming in for fertility issues. None of the post-trial interview participants had tried using acupuncture as a treatment for period pain, because they did not know that it was an option, although almost half had used acupuncture previously for other conditions. None of the women had been told by their GP that acupuncture was a possible option. This may be explained by the low referral rates (29%) from biomedical practitioners in our practitioner survey.

7.3.2 Predicted and observed changes in abdominal pain

Practitioners in our focus groups were unanimous in their belief in the ability and efficacy of acupuncture to treat primary dysmenorrhea. All practitioners commented on how they found that the results were predictably effective, as long as there was no secondary dysmenorrhea involved, and that they would expect significant improvements in pain, secondary symptoms and general health within three menstrual cycles. Some practitioners felt that in terms of improvements, significant reduction in pain would be achieved within as little as one treatment, but treating the underlying pattern of disharmony would take longer.

Clinical improvements in primary dysmenorrhea are similar to the threshold for other chronic pain conditions, where patients consider a 30% or greater reduction in pain, or a two-point reduction on the numeric rating scale (NRS), to
be clinically meaningful, while a 10–20% reduction, or an one-point reduction on the NRS, is the minimally important change in pain (Dworkin et al. 2008). All groups showed clinically significant reductions in all pain scores at the one-month follow-up. While there were statistically significant reductions in pain at Month One, none of the scores became clinically significant until Month Two, and these changes were sustained one-month after trial exit. The HF–MA group showed the largest proportion of responders, with over 60% of women having a 30% or greater reduction in their worst pain, approximately half the women having a 50% reduction in their peak pain scores, and almost 60% having a reduction of 50% in their average pain scores. However, these differences were not significantly different between groups, reasons for which will be discussed in detail in Chapter Eight. The reductions in the pain scores were corroborated in the interviews, with women commenting on the noticeable reduction in pain they experienced and how this translated into less restriction on activities, both social and academic / professional, during their menses. For some women this improvement was marked, with a significant change in the amount of time they spent bedridden during menses. In the interviews, women from the responder groups mentioned significant reductions in abdominal pain and a reduced reliance on analgesic medication to control their menstrual cramps. Women from the non-responder groups noted that while some secondary symptoms improved (e.g. nausea), their abdominal pain did not improve to a significant degree. It appears from these comments that reductions in abdominal pain or “cramps” was a strong predictor in the overall self-rated improvement score as they are the fundamental characteristic of period pain for most women.

Our RCT and interview data support some of the views expressed in the practitioner focus groups, that acupuncture is clinically effective for pain within three menstrual cycles, however, contrary to the experience of some practitioners, we did not find that significant pain relief was achieved in a single treatment session or even within the first month of treatment. The differences in our findings compared with the dramatic improvements suggested by our practitioner focus groups may be due to the fact that acupuncture practitioners often remember specific cases of improvement, where the results were
“miraculous” (Jackson & Scambler 2007), while our data looked at a larger sample, in which individual variation would be less pronounced.

7.3.3 Predicted and observed changes in secondary symptoms and quality of life

Women with primary dysmenorrhea often have a number of secondary symptoms such as headaches, diarrhoea, nausea (French 2008) and back / thigh pain (Proctor & Farquhar 2006). While pain is the worst part of the menstrual period for most women with primary dysmenorrhea, mood changes can also be very bothersome (Hillen et al. 1999; Scambler & Scambler 1985). Participants in the RCT had a variety of secondary symptoms at trial entry, including lower back pain (74.7%), abdominal bloating (70.9%), breast tenderness (68.4%), bowel changes (68.4%), emotional changes (67.1%), headache (51.9%), nausea (49.4%), dizziness (36.7%), thigh / leg pain (32.9%), fluid retention (32.9%) and vomiting (8.9%).

Practitioners in the focus groups viewed these symptoms as part of the pattern of disharmony underlying primary dysmenorrhea and predicted that treating the underlying pattern would resolve or reduce these symptoms. The menstrual diaries showed that secondary menstrual symptoms decreased over time during the treatment period. Abdominal cramps were the most commonly improved symptom (57% of women). Back and thigh pain (24% of women) and emotional / mood changes (21% of women) were also improved amongst participants. Women in the post-trial interviews confirmed this variety of improvements and were pleasantly surprised that they experienced positive changes in their other menstrual symptoms, not solely in abdominal pain. Some interview participants felt that the mood changes were actually the most troublesome symptom and were glad that these changes had lessened or disappeared altogether. Other interview participants discussed improvements in nausea, fatigue, headaches, neck pain and back pain reinforcing the wide-ranging improvements that were collected in the exit questionnaire and also the extent of changes that practitioners in the focus groups predicted would occur when treating via the TCM model.
Interview participants also discussed improvements not just in terms of menstrual pain, but improvements in overall health and wellbeing. Some of these improvements were due to the reduced secondary menstrual symptoms, however, women discussed improvements outside the menstrual period and feeling healthier in general. This was reflected in the SF-36 scores collected at the one-month follow-up. There were significant improvements between baseline and one-month follow-up in the role physical (p=0.0029), bodily pain (p=0.0002), vitality (p =0.028), social function (p=0.0067) and overall physical component (p=0.001). These changes in SF-36 scores may suggest that after the course of acupuncture treatment, participants had less problems with work or daily activities as a result of their physical health, less pain and subsequent limitations due to pain, more energy, and less interference from physical and emotional problems in social activities (Ware, Kosinski & Keller 1994). Therefore a short, three-month course of acupuncture reduces menstrual pain both in severity and duration, as well as reducing other bothersome menstrual symptoms and improving overall health and wellbeing.

7.3.4 Use of electro-acupuncture

The use of electro-acupuncture by New Zealand and Australian acupuncture practitioners for the treatment of primary dysmenorrhea was relatively uncommon, with just under 10% of practitioners using it as a treatment modality (Smith, Armour & Betts 2014), despite electro-acupuncture appearing frequently in the literature as a treatment for primary dysmenorrhea (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Miao et al. 2014; Shi et al. 2011). TCM practitioners often base their treatment on traditional knowledge and their own experiences, rather than clinical trials (Jackson & Scambler 2007).

In our focus groups, several practitioners had used electro-acupuncture for primary dysmenorrhea, however, most practitioners had not. Chinese-trained practitioners were more likely to use electro-acupuncture than their western-trained counterparts, despite some survey evidence that use of electro-acupuncture is low in clinical practice in China (Robinson et al. 2012). Practitioners in our focus groups provided various reasons for their low usage;
some practitioners felt that they had not received adequate training, while others felt the treatment was too strong and uncomfortable for patients, and some felt that it went against the nature of their practice, which was to work with Qi and that did not require such a modern approach.

Participants at trial exit indicated that there was no difference in their perception of the discomfort of acupuncture between the manual and electro-acupuncture groups. As part of the trial protocol, electro-acupuncture was not to be of greater intensity than the level women felt comfortable with, which may differ between clinical settings. Women who participated in the follow-up interviews did not find the electro-acupuncture uncomfortable, however, they did appreciate explanations by their study practitioners as some were concerned about having “electricity” run through the needles.

While participants found electro-acupuncture an acceptable intervention and fears of discomfort voiced by practitioners did not seem to be of concern to participants, there was no additional benefit in the treatment of primary dysmenorrhea from electro-acupuncture compared to traditional manual acupuncture.

### 7.3.5 The role of cold in treatment for primary dysmenorrhea

The importance of treating cold first appears in our practitioner survey, with the prevalence of moxibustion as a co-intervention, and again in the practitioner interviews, where the prevention of cold by external means (e.g. wearing thick socks) and internal means (e.g. avoiding cold water and salad) is discussed. The concept of “hot” or “cold” as it pertained to food was something unknown to women in our trial, as was the idea of avoiding environmental cold outside the menstrual period itself. All but two (Liver-fire and Damp-heat) of our differential diagnosis patterns, based on our data from the practitioner focus groups and interviews, had moxibustion as either an optional or compulsory component. Self-care sheets given out during the RCT included advice on avoiding cold or increasing warmth for all patterns, except those where it would
be inappropriate due to the thermal nature of the disharmony (Liver and kidney Yin deficiency, Liver-fire and Damp-heat).

The use of self-applied heat to treat period pain during painful menses is a commonly reported self-care activity (Banikarim, Chacko & Kelder 2000; Chen et al. 2006; O’Connell, Davis & Westhoff 2006), however, the importance of the hot / cold balance outside menses, and avoidance of “cold” food and an increased intake of hot water only appears in populations where there is a cultural tradition of TCM, such as Hong Kong (Chia et al. 2013), Taiwan (Chen et al. 2006) and China (Zhu et al. 2009). At trial entry, women used heat in almost a quarter (23.5%) of all days when menses was present. Self-applied heat usage decreased in all groups over the course of the RCT and appeared to follow a similar trend to medication usage, with heat usage decreasing as pain scores decreased. While previous trial quality is low, with heterogeneous outcome measures and concerns with randomisation, a recent review showed positive outcomes for the usage of moxibustion in primary dysmenorrhea (Xu et al. 2014a). Continuous low-level heat, similar to that delivered by moxibustion, is a non-pharmacological analgesic that acts by increasing blood circulation in the uterus, relieving ischemia and decreasing pain (Akin et al. 2004).

This clinical experience of the importance of treating cold in primary dysmenorrhea is supported by both textbook theory (Maciocia 1998), TCM dietary therapy (Liu 1995), and by previous studies using TCM pattern differentiation, which demonstrated that patterns involving cold were the most common cause of primary dysmenorrhea in both Australian and Chinese populations (Liu et al. 2012; Zhu et al. 2009). Practitioner emphasis in the interviews and focus groups on the prevalence and importance of treating cold in primary dysmenorrhea appears justified from our RCT, where 34 women (47.8%) had a primary or secondary diagnosis that related directly to cold; either stagnation due to cold or Yang and blood deficiency. The application of moxibustion during treatment sessions was valued by women, with four women noting that this was one of their favourite parts of the treatment. Women commented that the use of moxibustion caused a rapid and substantial pain reduction when used during menses. One woman tried to purchase a
moxibustion stick via the internet to use at home during her period after the trial finished. Therefore, with a plausible mechanism of action, strong underlying theoretical support from the TCM framework, and positive feedback from trial participants, it is important to include moxibustion as a therapeutic co-intervention when treating primary dysmenorrhea.

7.3.6 Practical obstacles to achieving optimal outcomes

Interviewed practitioners and participants commented on the practical obstacles they faced as part of ongoing treatment for chronic conditions such as primary dysmenorrhea. Practitioners in the focus groups all found that the women they treated in clinical practice had significant financial and often social and domestic commitments that impacted on their ability to have weekly, or even bi-weekly treatment. Study participants echoed similar views, often discussing the demands that were placed on their time, including child-care and work that made finding time for their own health needs difficult. This was sometimes viewed as a catch-22 after advice from their study practitioners to try and reduce stress. Women wanted to reduce stress and have the acupuncture treatment, but sometimes found it stressful to try and make time to fit the treatment in. However, this “time out” was enjoyed by over three-quarters of women at trial exit and our interview participants commented that they felt the enforced relaxation was something they really came to value. So while it was sometimes difficult to make the time, participants felt that once they were having the treatment it was worth the effort.

Practitioners discussed in focus groups and interviews how they often engaged in negotiations with their patients to try and get them to commit to regular treatment, and to find a treatment frequency that would fit into their patients’ busy lives. Practitioners commented that they would love to treat more frequently, most wanting to treat at least weekly or more frequently if they could find space in their clinics to do so. Study participants did not appear to find the high-frequency, three times a week treatments, given in the week prior to menses, to be problematic, with only three participants in the exit questionnaire finding that the appointments took up too much time or were
hard to schedule. It should be noted that each of these three participants were from the high-frequency groups, but this was not a statistically significant difference between groups. Interview participants tended to find that different treatment schedules suited their own individual lifestyles, with two participants commenting on how the high-frequency treatments allowed them to get all the treatments done in one week and so ensured they did not have to worry about fitting them in for the rest of the month. Given the results of the trial, which showed no significant differences in outcomes between the high- and low-frequency groups, it appears that practitioners can schedule treatments around patients social, work and home life commitments without concern that they are delivering sub-optimal treatment. However, it is unknown if the high-frequency, three times a week treatments would still provide the same results if delivered during other times of the menstrual cycle.

Interview participants confirmed our focus group practitioners’ views that it was usually money that was a limiting factor in the ability to commit to ongoing treatment. This was a concern independent to the extent of improvement reported by participants. Those who were classified as non-responders were the least likely to want to continue on with treatment post-trial, however, even participants who rated their symptoms as much improved at trial exit still expressed concern about the ongoing cost. This was related to the relative expense compared with taking analgesic medication, with some interview participants expressing that they would just have to take analgesic medication and endure the discomfort. Despite the incomplete relief give by analgesics they felt that they did not have any other options due to lack of funds. Other interview participants simply felt that the cost was too great to be able to bear, with participants own estimates of continuing treatment ranging from $160 per fortnight to $240 per month. Concerns were raised, especially by women with families, around using money if they felt the family needed it. Interview participants often came up with similar solutions to those mentioned by practitioners in the focus groups, that they would either reduce their frequency of treatment to an affordable level, or hope for a discounted price and continue at their usual frequency.
7.3.7 Summary of the effectiveness of acupuncture for treating primary dysmenorrhea

Practitioners in our focus groups predicted significant improvements in menstrual pain, secondary menstrual symptoms and general health and wellbeing after three months of regular acupuncture treatment. TCM acupuncture, as delivered in the RCT, resulted in clinically significant reductions in peak pain, worst pain and average pain, as well as the duration of pain each day. Trial participants also had a reduction in secondary menstrual symptoms and analgesic intake. Self-rated improvement scores at trial exit showed that most women rated their overall symptomatic improvement as significant. Post-trial interviews showed that women valued the pain reduction, but often regarded the reduction in secondary symptoms, especially mood changes and headaches, as just as important, as these had a significant impact on their daily activities each month. Women found that moxibustion had analgesic effects and enjoyed its usage in the trial. Participants did not find the electro-acupuncture uncomfortable and treatment timing appeared to be a matter of personal choice, dependent on their work and social commitments. Cost of treatment was an issue highlighted by both practitioners and participants, with a reduction in treatment cost suggested to enable more frequent treatment.

7.4 “More than needles”

A key, overarching theme that was identified and ran throughout all four study phases was “more than needles”. The concept that effective treatment for primary dysmenorrhea entailed more than just the insertion of acupuncture needles was first identified in the practitioner survey, which was undertaken prior to practitioner interviews. The survey highlighted that practitioners used a variety of modalities in treating primary dysmenorrhea, including acupuncture, moxibustion and self-care advice.

Acupuncture practitioners in the focus groups emphasised the unique nature of the TCM theoretical framework that allowed them to practice from such a
holistic outlook. Acupuncturists were very clear that an acupuncture treatment encompassed much more than just the insertion of needles, and that other components of treatment, such as TCM explanations of health and disease, moxibustion and self-care advice, were also very important contributors to the therapeutic outcome and were intrinsic components of their treatment. This is similar to the findings of Hughes and colleagues (2007), where TCM-trained acupuncturists emphasised that benefits from acupuncture were not solely due to needling, while biomedically-trained acupuncturists felt any non-needling components were incidental to the treatment (Hughes et al. 2007). Acupuncturists explained the importance of self-care advice tailored to each patient’s pattern of disharmony, and the importance this advice had on the treatment outcomes. Practitioners also discussed the importance of explaining the menstrual cycle in terms of TCM physiology, and how this opened up the possibilities of painless periods or reduced pain during the period. Additionally, practitioners were also concerned about the treatment and prevention of various forms of “cold” and discussed the importance of moxibustion. These guiding principles were used to develop the protocol for the RCT, where acupuncture, moxibustion and TCM self-care advice were given to participants.

Women confirmed the importance of the TCM explanations of menstrual physiology, and specifically self-care advice, as key to increasing their self-efficacy. Women also spoke positively about the pain-relieving effect that many found from the usage of moxibustion.

Participants discussed how the context in which these explanations and advice were delivered, in a non-judgemental and supportive environment, was different to their previous experiences with general practitioners, and how this relationship with their acupuncture practitioners impacted their ability to understand their menstrual cycle better and implement the self-care advice given.
7.4.1 Guiding women back to health: the importance of a partnership in TCM

This theme discusses the relationship that participants had in the study with their practitioner, and how it was this relationship that provided the foundation of trust and mutual understanding that enabled women to gain new understandings and better implement self-care advice. Practitioners first discussed the importance of the partnership in the focus groups and interviews, discussing its fundamental importance to their practice and contrasting it to how they felt medical professionals treated their patients with primary dysmenorrhea. While women only specifically discussed the importance of the relationship they had with their practitioners in the theme “someone you can trust”, the importance of the partnership was emphasised through constant comparison with previous, less enjoyable experiences they had previously had with medical professionals and was woven throughout all the interviews. At trial exit their relationship with their practitioner was the highest rated aspect of the trial, with 95% of women stating this relationship was enjoyable, emphasising the crucial, underlying importance of this partnership.

7.4.1.1 Differences in therapeutic outlook

A key component of this relationship between practitioner and participant was the theoretical framework within which the acupuncture was delivered. TCM theory views the body, mind and emotions as one entity, necessarily connected and inseparable in contrast to the more Cartesian thinking amongst biomedicine, which tends to view the body as a collection of mechanistic interactions and emphasises mind–body duality (Lewith & Birch 2007). TCM practitioners often consider there to be a conflict between these two theoretical frameworks, with TCM being “largely incompatible” with the scientific framework behind biomedicine (Jackson & Scambler 2007). Beinfield and Korngold (1991) describe this difference in therapeutic outlook as doctor as mechanic versus doctor as gardener (Beinfield & Korngold 1991).
In western medicine, the doctor tends to view the body as a collection of standardised parts working together, with each part being separate and distinct. All parts are standard and disease develops from standard causes. When something goes wrong, the parts are replaced with another identical part.

In the TCM view, the doctor views the body like a garden, which is a microcosm of the larger universe and of nature. Similar to nature, there is a rhythm, a balance and a pattern that connects all things to one another. Everything is connected and always in flux, there are no independent, discreet entities. Therefore the role of the TCM doctor is to maintain these balances and patterns and thus promote life.

7.4.1.2 The partnership in acupuncture consultations

Practitioners in our focus groups and interviews viewed the TCM consultation process as a partnership between the practitioner and patient. Paterson (2012) found that recordings of acupuncture consultations in the community supported the concept of a partnership based on “continuity, mutuality and trust” (Paterson et al. 2012). Pairman (2010) discusses the partnership model of care in midwifery as one of the practitioner relinquishing the role of “expert” and instead reframing the discourse in terms of a relationship between the two parties involving trust, shared control and responsibility (Pairman et al. 2010). By giving up the role of “expert” this relationship is subject to constant renegotiation and encompasses a more compassionate, personal relationship. Practitioners in our focus groups discussed giving up their position as “experts” and instead often took on the role of a guide, explaining concepts of health in a new way and “pointing out” patterns and connections to help women understand how lifestyle choices impacted their health, thus empowering them to make better choices in the future. Practitioners talked of the role of negotiation, between their ideals of health and the patients’ practical realities, and how they needed to work together to find a solution that worked for patients, often using self-care or other TCM modalities, to bridge the gap between acupuncture treatments.
Women in the study highly valued the partnership approach that their study practitioners used. In the interviews women often highlighted the differences between their previous experiences, often with their general practitioner, in positive ways. Women discussed how they trusted their study practitioner, could be open about their menstrual issues, and felt "safe" discussing what was, to them, a very personal topic.

Participants specifically discussed how the supportive, non-judgmental aspects of the consultation provided by their study practitioner were key to engendering trust. This sense of trust and safety enabled them to be open and honest about their condition, and engage in two-way dialogue with their practitioner. The gender of the practitioner appears to be an issue for many women when consulting a general practitioner (Cronjé & Kritzinger 1991), but did not appear to be an issue for women in our study, despite the primary investigator being male.

An important issue acupuncture practitioners highlighted in the focus groups was that they listened to their patients; practitioners thought that women hadn't really been listened to and that their menstrual experience was discounted due to the superior medical knowledge of doctors. Women in the interviews confirmed this, explaining how they felt like their symptoms were being taken seriously by study practitioners, rather than disregarding the impact that pain had on their menstrual experience, as often happens in consultations with their general practitioner (Warner et al. 2001). Women commented that they finally felt “heard” by their study practitioners, who did not downplay their experiences, and that they felt “understood” by their practitioner. Being heard and understood is an important component of what Engel (1988) terms the patients “double need”: one to know and understand and one to be known and understood (Engel 1988). Acupuncture practitioners, by listening to participants and not discounting their experience, fulfil the need to be known and understood.
7.4.1.3 The contrast to previous experience

The most common contrast to the partnership that they had with their study practitioners was women’s previous experience with their general practitioner, who was often the only medical professional to whom they had spoken about menstruation.

Menstruation has been noted as a process that has been subject to medicalisation. Medicalisation in this case is the reframing of menstruation as an illness with physical and psychological symptoms, rather than a natural, physiological process (Fingerson 2006). The consequence of this is that menstruation is now within the doctor’s purview, that they are considered experts on the disorders of the body and therefore know more about the workings of the body than the women who menstruate (Bransen 1992). Young women are often exposed to the medicalisation of menstruation; advice columns in magazines aimed at teenage women often suggest to “go and see a doctor” for all kinds of menstrual questions, as the doctor is the expert on health and it’s the doctors job to know the body (Oinas 1998). This encourages women to rely on medical professionals to rule what is normal and what is pathological. This fits with the “doctor as mechanic” view, that the body is a complex machine, one that requires an expert to be able to fix it, rather than encouraging a “do-it-yourself” approach.

Women commented that when they did discuss their period pain with their general practitioner, they were almost universally dissatisfied with the outcome. General practitioner consultations tend to be “persistently asymmetrical,” with medical practitioners claiming the role of expert and exerting control over the dialogue that occurs, shutting down or blocking patients’ explanations and involvements in the consultation process (Pilnick & Dingwall 2011). Women mentioned that this was their experience with their general practitioners, that they didn’t feel that it was an environment that supported or encouraged two-way communication. Women often felt they couldn’t really discuss these problems with their general practitioner, which is a concern as unvoiced health needs such as these are often linked to poor health
outcomes (Barry et al. 2000). Despite the importance of involving women with primary dysmenorrhea in decision making and dialogue (Ballagh & Heyl 2008), most women interviewed didn’t feel that they were active participants in their healthcare and didn’t feel that doctors listened to what they were really saying. Overall, when women in our study engaged with the doctor as “expert,” they didn’t feel satisfied with the treatment they received; doctors did not validate their experiences, even though they were reporting bothersome symptoms. This left them feeling that doctors didn’t understand them and with a feeling of disillusionment about their general practitioner, a common feeling for many women with dysmenorrhea (Scambler & Scambler 1985).

7.4.1.4 The impact of the partnership model

The partnership model of treatment was the underlying support that the rest of the acupuncture intervention was built on. Practitioners in our focus groups emphasised the importance of listening to, understanding and educating the patient. TCM acupuncturists tend to “co-construct” their advice and explanations, which involves the practitioner and patient shaping explanations and advice given by both, and initiating and interacting in various kinds of “talk” (Paterson et al. 2012). This allows practitioners to understand the “life-world” of the patient and deliver explanations, advice and treatment that were appropriate and achievable for each individual.

Consultations also included social talk, which helps practitioners build rapport and empathy with patients (Evans et al. 2011; Paterson et al. 2012). Empathy from practitioners has been shown to increase enablement, and is linked to positive treatment outcomes through the improvement of patient self-efficacy (Bensing & Verheul 2010; MacPherson et al. 2003). Improved self-efficacy is also linked to increased optimism of future improvements (Stewart-Williams & Podd 2004). Increased self-efficacy and increased optimism were both expressed by women who participated in the trial and are discussed under the relevant sub-themes.

Self-care advice, which will be discussed later in this chapter, was an important part of the treatment for both practitioners and participants. Practitioners
discussed how self-care advice would empower patients to take more responsibility for their own health and be able to, in the words of one practitioner “get themselves better over time,” rather than having to be passive consumers of health care that a practitioner must “fix”. Similar themes around increasing agency via self-care advice and thus allowing patients to "look after themselves" appear regularly in interviews with acupuncture practitioners treating a variety of disorders (Hughes et al. 2007; MacPherson & Thomas 2008; MacPherson et al. 2014; MacPherson, Thorpe & Thomas 2006), suggesting that this empowerment of patients via self-care is a common element of acupuncture treatment.

The partnership model was important for self-care in several ways; for self-care advice to be helpful, mutual interaction between health providers and patients must engender a sense of wellbeing (Mahmud et al. 2013) and provide sufficient support to implement changes (Barter-Godfrey, Taket & Rowlands 2007). The partnership model provided this supportive, empowering, non-judgemental environment. In contrast to this, women had not taken up much, if any, self-care advice delivered by their general practitioner. This lack of uptake is a frequent occurrence in general practitioner consultations (MacKichan et al. 2011). Women explained they didn’t feel that the advice delivered by their general practitioners was delivered in a way that empowered them, which is an important factor in implementation of self-care (Sorjonen et al. 2006).

Acupuncturists in the focus groups discussed the importance of educating women, so that women could better understand their menstrual cycles from a TCM perspective. Women would then be able to view their symptoms in terms of a temporary, if sometimes prolonged, imbalance rather than a medical illness. An imbalance could be brought back into balance by a combination of acupuncture and lifestyle changes, as opposed to a disease requiring medical intervention. This education was seen as part of the practitioner’s responsibility; without this holistic understanding there could be no shared control, as women would not understand the importance of the lifestyle choices they make every day. This concept of encouraging new understandings of illness is an important part of acupuncture’s holistic model of treatment (Paterson &
If the gardener knows the patterns and linkages between all things, and understands how to maintain balance, then this knowledge can be passed on to others. While they are expert at tending the garden, they can guide others to become their own experts, allowing them to tend their own gardens without needing to rely on others.

The central importance of the partnership with the “doctor as gardener” was evident from our findings. Practitioners felt this was the way they practised in clinic, and the manualised acupuncture treatment delivered this same experience to participants during the trial. Women valued this partnership, felt heard and understood, and this enabled them to adopt self-care and take on new, holistic understandings around their menstrual cycle.

### 7.4.2 Holistic understandings: a new way of thinking about period pain

This theme examines the transformation in women’s understanding of period pain, from something “normal” and almost symbiotic with the period, to an understanding of period pain as being a holistic condition, that can be understood and managed by women themselves.

This transformation was shown in the comments from both practitioners and participants in their interviews, that prior to acupuncture treatment women often felt period pain was a normal and unavoidable part of life. This concept of normality of menstrual discomfort was often reinforced by their interactions with their family, friends and general practitioners.

After participating in the trial, women found that they had a new understanding of their menstrual cycle, one where pain was not implicit, and this new “normal” gave them hope about reducing their own period pain and taking more control over their menstrual cycle.
7.4.2.1 The normality of period pain

Practitioners who participated in the interviews and focus groups emphasised the fact that they often found women did not reveal or list period pain as a symptom when presenting in their private clinics because it was thought of as “normal”. A possible reason put forward by our acupuncturists for this is the historical belief that it was at least partially psychological and just “part of being a woman” (Dawood 1988; Johnson 1988; Wilson & Keye 1989).

Practitioners in our focus groups commented on how they often noticed that women were surprised by the concept of having reduced pain or a painless period, that this was a concept they either did not believe was possible or had never considered. This is not uncommon in women who have had dysmenorrhea onset soon after menarche (McPherson & Korfine 2004), as was the case with our participants, where most had dysmenorrhea onset approximately two years after menarche. Women in our interviews confirmed the practitioners’ observation, with women commenting that periods and pain were almost symbiotic, and so the idea of a period without pain was something they had not considered possible.

The concept of having to endure menstrual symptoms as an integral part of female life is common amongst women with dysmenorrhea (Brantelid, Nilvér & Alehagen 2014; Cronjé & Kritzinger 1991; Scambler & Scambler 1985; Wong 2011). Participants in our post-trial interviews, almost without exception, expressed that, prior to enrolling in the trial, they thought that period pain was, to at least a large extent, a normal part of being a woman, with one participant echoing the historic idea “because you are a woman, this is what you get”. Despite an understanding of the physiological basis of primary dysmenorrhea, over the last 20 years attitudes by women in the community seem not to have changed.

Interview participants cited information from family, friends and also traditional media, such as magazines like Cleo, which is aimed at teenage girls, as reinforcing the concept of normality of pain. Knowledge of dysmenorrhea from non-medical sources, such as family and friends, is common (Brantelid,
Nilvér & Alehagen 2014; Kissling 1996) with many women receiving information from their mother (Brantelid, Nilvér & Alehagen 2014; do Amaral, Hardy & Hebling 2011), who often has also had dysmenorrhea (Chang & Chuang 2012). Zhu and colleagues (2010) found that in Australian women with primary dysmenorrhea, two-thirds had a family history of period pain (Zhu et al. 2010). This observation is supported by evidence of a genetic contribution towards dysmenorrhea (Treloar, Martin & Heath 1998). Awareness of a genetic contribution to period pain was demonstrated by participants who mentioned that if their mother or close family had dysmenorrhea this meant that they, too, would inevitably suffer from it. This is consistent with the concept that women “assemble” an idea of a normal period from their own experiences (Wood, Barthalow Koch & Mansfield 2007). Wood and colleagues (2007) found that women with consistent menstrual pain, even if they knew from other sources that pain was “abnormal”, incorporated it into their idea of a normal cycle, because that is what they had always known. Therefore the presence of pain or other bothersome symptoms every cycle became normalised over time. The exception to this was if the pain was very severe, to the extent that it affected women’s daily activities. This is similar to comments from some practitioners in our interviews who felt that women did know that if they were bedridden from pain that this was not a normal experience. However, for most of our participants their pain was moderate, and often reduced to a tolerable level by analgesic medication and therefore appeared to be re-narrated as a normal experience.

This normality is often reinforced by the fact that most women in our interviews commented that they have friends who also have dysmenorrhea, which is not surprising given the high prevalence of dysmenorrhea, especially amongst adolescents, with most teenage girls knowing someone who suffers from period pain (Chang & Chuang 2012).

Almost half our interview participants had at least some training in biological or biomedical sciences; two were psychologists, one a neuroscientist, one was a physiotherapist and one a physiotherapy student. Despite this background, which may expose women to the biological theory behind primary
dysmenorrhea, these women also commented that until discussing their symptoms with their study practitioner, they understood that period pain was, if not normal, then at least medically untreatable and therefore immutable. This perception amongst women with medical knowledge of the inability to alter period pain is not unusual, with medical students engaging in less self-care practice than non-medical students (Chia et al. 2013). All participants commented on how TCM explanations, given as part of their acupuncture consultations during the RCT, were an important turning point in how they viewed their period pain; it changed from an evitable “part of being a woman” to something that could be modified so they no longer had to “put up with it”.

7.4.2.2: Changing views on what’s normal

Explanations and education form the second component of Engel’s “double need”: the patients need to know and to understand their condition (Engel 1988). Patients often feel that in orthodox medical consultations they do not get sufficient explanations for what is causing their condition, something that they feel they do obtain from CAM therapies (Cartwright & Torr 2005). Doctors provide explanations without contributions from the patients themselves, and tend to focus on biomedical interventions and tests and/or assessments (Collins 2005). With general practitioners, women often found that they were just told that a particular issue was the problem, even if it did not make sense to them. One participant remembers being told that her weight was a problem, despite having had period pain long before her weight increased. Women felt they weren't able to ask questions or seek clarification on issues, leaving them to rely on other sources of information to understand what is “normal” menstruation.

Women expressed how the explanations were framed in terms that they could understand, using a mixture of lay concepts (such as “energy”), the use of specific TCM concepts and/or analogies depending on the individual circumstances. Women often did not remember all the TCM explanations, but rather how their practitioner distilled it into something that made sense to them.
One of the key ways in which practitioners in our interviews used the TCM explanatory model was by explaining patterns and connections between behaviours (such as eating an ice cream) and the subsequent increase in period pain or associated symptoms. The concept of linkages between the external (physical) world and internal (physiological) world is common amongst a variety of CAM modalities (Cartwright & Torr 2005). Linkages between internal and external are implicit in the TCM understanding of the body.

Qi is the origin of “heaven, earth and everything in-between” and all phenomena are made up of Qi (Lewith & Birch 2007, p. 19). This interconnection means the body is viewed as a microcosm of nature (Beinfield & Korngold 1991), therefore there is much less of a distinction between the external and internal world in TCM as all phenomenon are considered as various forms of Qi. Credible explanations for symptoms are an important part of how patients attribute expertise to practitioners outside the mainstream medical system (Pedersen & Baarts 2010). These explanations were an important part of the credibility of the intervention for women in our interviews; that their study practitioner could explain why they were experiencing their particular symptoms and why certain lifestyle choices improved or worsened those symptoms. Women also commented that they had never thought to look for these links before. For some participants these explanations were so important that it was one of the defining differences between their experience of acupuncture during the trial and their previous experiences of acupuncture. This explanation of linkages often ran parallel to the giving of self-care advice; while the advice was more prescriptive in nature (such as “do not drink cold water”), the explanation of linkages was an important component of why they should not drink cold water.

Women commented that the alternative health paradigm provided by TCM lead to a new, more “hopeful” idea about what constituted a normal period, with expectations of being in less pain over time as a result of being able to manage their symptoms via lifestyle choices. Hope and anticipation of improvement are an important aspect of treatment and can influence physiological processes, especially pain (Walach 2003). Women discussed how these new explanations given to them in the RCT helped them understand what was happening during
their menstrual cycle. Period pain was now often re-interpreted to be a “holistic” issue, with physical and emotional contributors, rather than a specific gynaecological disease that needed to be treated as they had previously thought. The trial-exit questionnaire filled in by all study participants showed that 84% valued an “alternate way of looking at their health and wellbeing”, coming second only to the relationship with the practitioner themselves.

7.4.3 Taking back control: TCM self-care for period pain

A major theme of taking back control of the menstrual cycle, specifically around reducing pain and other symptoms, first emerged in practitioner interviews and focus groups, where practitioners discussed empowering women to be able to treat themselves and bring themselves back to “balance” without needing to rely on the acupuncturist indefinitely. Self-care advice was seen as the modality that could enable women to self-treat effectively. Self-care advice based on TCM principles was delivered as part of the RCT with the trial-exit questionnaire showing that over two-thirds of participants found this helpful. Participants in the follow-up interviews discussed their experiences with TCM self-care advice, sharing how they felt it empowered them to have more control over their own health, rather than having to rely on external agents for help.

7.4.3.1 Self-care: a common way to manage period pain

Participants in our RCT used a variety of self-care methods at trial entry, including analgesics, rest, heat, exercise and other interventions, such as yoga, to help control their period pain. The idea that period pain should be treated via self-care and dealt with without consultation with a medical practitioner appears to be a behaviour that spans various cultural and ethnic backgrounds and across a broad range of time periods (Campbell & McGrath 1997; Chang & Chuang 2012; Chia et al. 2013; Johnson 1988; Klein & Litt 1981; Ortiz et al. 2007; Wong & Khoo 2010; Wong 2011), with even women with medical educations preferring to avoid discussion with their medical practitioners and preferring to self-treat (Singh et al. 2008).
Women in our study discussed how self-care was the most common way they dealt with their period pain, and each woman had tried a number of strategies to find the optimal combination. Most women in the study only got partial relief from analgesic usage, so increased rest and use of a wheat bag or hot water bottle were frequently observed, in addition to pharmaceutical interventions. The use of a variety of self-care devices outside of analgesic medication is common, with the use of rest and heat, via heat packs or baths, appearing to be prevalent across a wide range of ages and ethnicities (Banikarim, Chacko & Kelder 2000; Hillen et al. 1999; O’Connell, Davis & Westhoff 2006; Zhu et al. 2010). Chang and Chuang (2012) found that even when high school students perceived their dysmenorrhea as a serious problem, this did not correlate to an increase in medical consultations but did correlate to an increase in self-care activities (Chang & Chuang 2012).

7.4.3.2 Differences in self-care advice: empowerment versus intervention

TCM self-care advice tends to consist of both dietary advice and lifestyle suggestions. Chinese dietary advice is grounded in the framework of Chinese dietotherapeutics, or Shi Liao, which deals with the properties of foods and their effects on health. Foods (including spices) are classified primarily into Hot, Cold, Cool, Warm or Neutral. Heating foods, such as cinnamon, are used to dispel cold, while cooling foods, such as cucumber, are used to clear heat (Liu 1995). In primary dysmenorrhea foods that are warming are generally recommended, while emphasising an avoidance of raw and cold foods, however, this is tailored to specific patterns of disharmony (Lewis 2008; Liu 1995). Lifestyle advice is given based on the TCM understanding of organ systems, such as emotional stress causing liver Qi stagnation, exposure to environmental cold causing contraction and stasis of blood in the uterus, and overwork causing Qi and blood deficiency (Maciocia 1998).

In their interviews and focus groups, practitioners noted that the self-care advice they gave was, due to its grounding in the TCM framework, likely to be substantively different from that given by patients’ general practitioners,
similar to comments made by other acupuncture practitioners (MacPherson & Thomas 2008).

Despite evidence suggesting that self-care information is present in many general practitioner interactions (Hillen et al. 1999; Sorjonen et al. 2006), women in post-trial interviews confirmed that self-care advice given by their study acupuncturists was very different to that given by their general practitioner. There has been very little research into the provision of biomedical lifestyle modifications and their effect on primary dysmenorrhea (French 2008). In terms of self-care advice given by general practitioners, a recent 2006 review discussed that interventions such as heat and exercise may be effective and advised general practitioners to discuss this with patients (Proctor & Farquhar 2006), while two online patient information sheets from the UK (*Period Pain (Dysmenorrhea)* n.d.) and US (*Painful Menstrual Periods - American Family Physician* n.d.) mention the use of heat during menstrual cramping. Current consensus guidelines by the Society of Obstetricians and Gynaecologists in Canada also suggest that heat and additional vitamin intake may be beneficial (Lefebvre et al. 2005). In New Zealand, advice provided by the New Zealand Family Doctor website does not mention any non-pharmaceutical treatments for period pain (*Painful periods (Dysmenorrhoea) - a patient's guide* n.d.), while that provided by the Monthly Index of Medical Specialities (MIMS) as part of everybody.co.nz (*Period Pain and Endometriosis* n.d.) provides advice on using heat, exercise and diet. However, despite these recommendations women commented that they often had been given very little to no non-pharmaceutical advice on how to manage their period pain by their general practitioners. General practitioners provided almost solely interventional advice to women in our study; either taking analgesic medication or starting the oral contraceptive pill. The reasoning for this, when given, was that period pain was either normal or at least common and was something that couldn’t be fixed, but had to be endured with the help of medication. The emphasis on medical intervention and subsequent dissatisfaction has been seen in other populations with primary dysmenorrhea. Australian adolescents were advised to take simple analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs) or the oral contraceptive pill...
(OCP) after consulting a doctor or school nurse (Hillen et al. 1999). Banikarim and colleagues (2000) found that although almost 50% of adolescent girls had visited the school nurse, 77% did not find that this visit provided them with satisfactory relief (Banikarim, Chacko & Kelder 2000). Similarly, Hewison and van den Akker (1996) found that less than a third of women with dysmenorrhea visited their general practitioner for this condition, but of those that did two-thirds were not satisfied with the result (Hewison & van den Akker 1996). This dissatisfaction with the consultation and treatment outcome appears to be present across a range of locations and cultures. This is possibly due to the difficulty in “fixing” primary dysmenorrhea when there is no medical procedure to cure it, or specific medication available that would “fix” the condition. Therefore, the “doctor as mechanic” may discount, ignore or minimise the importance of symptoms that are troublesome to address.

7.4.3.3 TCM Self-care advice: uptake, effectiveness and influences on health locus of control

Despite the importance acupuncture practitioners place on self-care advice, there is very little research to examine its effect on the outcomes of primary dysmenorrhea. The uptake of TCM self-care advice by women is currently unknown and its perceived benefits are unclear.

The central importance of diet and lifestyle advice was reinforced in both the focus groups and interviews, with both western- and Chinese-trained acupuncture practitioners emphatic about the importance of diet and lifestyle advice being an integral part of their treatment process. In the interviews, practitioners felt that, without exception, if participants did not adhere to the diet and lifestyle advice the treatment would either not achieve its full potential, or that upon conclusion of the course of treatment the symptoms would soon reoccur. Prevention of disease recurrence is an important concept in TCM, due to the emphasis on treating the “root cause” of illness (Tang & Easthope 2000), with practitioners in our focus groups discussing how they felt that analgesic medication and the oral contraceptive pill masked symptoms rather than treated the cause of the period pain.
Interviewed practitioners described how they based their advice upon their patient’s pattern of disharmony, and thus the advice was grounded in the TCM framework and guided by the explanatory model of disease in TCM. It was also adapted to the specific needs of the participant and delivered over several treatments, with adaptations as necessary based on women’s personal circumstances. Practitioners explained how they often discussed and compromised with their patients, preferring to allow patients to make small, achievable changes over time.

Self-care advice was delivered in the RCT using this mechanism, with printed patient handouts being given to participants based on their individual TCM diagnosis, and with advice delivered over the three treatment cycles. Women confirmed that the information they were given was delivered in small, manageable pieces personalised to their circumstances and this meant it was easy to implement without feeling overwhelmed.

Uptake of the self-care advice during the trial was high. Interview participants discussed following the dietary and lifestyle advice in two time periods: one during the active phase of the trial and one during the time between trial exit and the follow-up interview, which was between 10–14 weeks from trial exit, therefore women interviewed had at least two menstrual periods after trial exit.

During the active phase of the trial all but one of the interview participants discussed following at least some of the diet and lifestyle advice given to them by practitioners. All the women who incorporated the diet and lifestyle advice emphasised that, whether they understood or agreed with the TCM rationale behind it or not, they made their best attempt to incorporate it into their daily routine during the trial. There was no difference amongst our interview participants on the uptake of lifestyle and diet advice between the responders and non-responders during the study period.

The second time period where interview participants discussed the diet and lifestyle advice was during the time from trial exit to the follow-up interviews. We found that most of the participants in the trial had continued with at least some of the diet and lifestyle advice given, selecting that which they felt was
most beneficial and modifying or discontinuing advice they felt was not contributing to positive outcomes or was inconvenient to continue with. This self-selection by participants of advice that they perceive as beneficial and congruent with their social and economic needs also occurs in medically prescribed diet and lifestyle advice (Barter-Godfrey, Taket & Rowlands 2007). In contrast to Hopton (2014), we did not find that lack of rapport was a factor in the uptake or implementation of advice (Hopton, Eldred & MacPherson 2014); participants in the interviews and in the trial-exit questionnaire were overwhelmingly positive with regards to the therapeutic relationship between themselves and their practitioners, therefore it is possible that the issue with rapport was due to Hopton’s population being treated for depression. Those who did not find the TCM rationale for advice convincing, regardless of the symptomatic improvements during the trial, did not continue after trial exit, but did not report that there had been any negative consequences to their dysmenorrhea symptoms upon discontinuation. The plausibility of the advice was lower for those women with a biomedical background than for those without. Some of the study participants who were initially sceptical may have changed their beliefs as a result of treatment (Rugg et al. 2011). However, in our participant interviews it appears that those who held on to strong biomedical views did not appear to change their views on the validity of the TCM framework, regardless of changes in symptomology, often compartmentalising TCM beliefs as a separate but ultimately implausible health framework. Paterson and Britten (2004) found similar comments, with those with a biomedical background sometimes being unsatisfied with the answers from TCM not being “cut and dried” (Paterson & Britten 2004). Therefore it appears the determinant to continuing the diet and lifestyle advice after trial exit is primarily the participants’ belief in the plausibility of the underlying TCM framework, rather than the treatment outcome itself. Patients pre-existing belief systems are most likely responsible for this plausibility, with participants who had biomedical backgrounds being the most sceptical about the rationale given.
From our post-trial interviews we have confirmation that practitioners dispensing self-care advice does increase women’s ability to “self-treat.” Interview participants felt the advice they received empowered them to be able to take more control over their menstrual cycle. A plausible explanation for the empowering nature of the self-care advice is that it increases women’s health locus of control (HloC). Health locus of control is a measure of how much control individuals feel that they can exert over their own health, as opposed to their health being strongly influenced by either luck and/or chance, or powerful external entities, such as God or a doctor (Wallston, Wallston & DeVellis 1978). Previous research has found that CAM users, or those that rate CAM use highly, have a higher HloC than those who use predominantly biomedicine (Sasagawa et al. 2008; Schützler & Witt 2014). What is not clear from this research is if CAM use increases HloC, or if people with high HloC are attracted to CAM due to its emphasis on empowering patients to manage their own health (Coulter & Willis 2004; Ernst & Hung 2011; Thorne et al. 2002). While we did not measure HloC before and after our acupuncture intervention, it appears that the self-care advice given during the trial could be a key contributing factor to increasing participants’ HloC.

Women discussed how the self-care advice gave them tools to be able to modulate their symptoms without having to rely on outside help or take analgesic medication, which many of the women felt was a convenient but ultimately unhealthy choice. Women responded to this increased feeling of personal responsibility over their own health in various ways: most enjoyed their newfound ability to have more control over their own health, however, some commented that it was too difficult. These women explained that because they felt like they had already tried so many different things in the past and that they already felt like period pain constrained their lives, taking on additional advice felt like they were capitulating to the demands of their period pain. The empowering nature of the advice was not constrained to those who rated significant improvements in the trial. Women whose symptoms did not improve during the trial appreciated that they had something else “natural” to try and felt confident that it would help them improve their general health and
eventually their period pain. This concept of acupuncture increasing general resilience, even in the face of negative or neutral treatment outcomes, has also been seen previously in women undergoing IVF (de Lacey, Smith & Paterson 2009). Patients see an increase in coping ability via increased self-efficacy as an important part of CAM treatments (Cartwright & Torr 2005).

Despite the importance placed by practitioners on self-care advice for positive treatment outcomes, we did not find any evidence from our participant interviews that non-responders were less likely to incorporate the diet and lifestyle advice during the treatment period or during follow-up, however, caution must be taken in extrapolating this to all women who participated in the trial. At trial exit, the helpfulness of diet and lifestyle advice was indicated by 66% of women. It is likely, based on the comments made by interview participants, that if study participants found the advice helpful they were likely to implement some or all of the advice. The percentages of women in each group who found diet and lifestyle advice helpful was not significantly different, however, it is interesting to note that the two manual acupuncture groups, HF-MA and LF-MA, had higher percentages of women who found the advice helpful, 80% and 75% respectively, than the electro-acupuncture groups, HF-EA and LF-EA, at 52% and 57% respectively. These two manual acupuncture groups had the highest proportion of responders with clinical reductions in worst and average pain from baseline, and the greatest reduction in analgesic usage and secondary symptoms. The study was not powered to detect differences between groups for this outcome therefore it is possible that there is a significant difference between groups in the uptake of diet and lifestyle advice. The differential uptake of self-care advice may be a contributing factor to the observed differences in pain, symptoms and analgesic reduction between groups.

**7.4.4 Summary of “more than needles”**

The common thread of acupuncture treatments for primary dysmenorrhea consisting of acupuncture, moxibustion, TCM explanations and self-care advice, ran through all phases of our study. Patients with primary dysmenorrhea
commonly use self-care advice, derived from friends and family, however, the uptake of TCM-based self-care was high amongst our participants. The continuation of self-care post-trial was more likely to be based on the plausibility of the explanatory TCM model, than the immediate symptomatic changes, with women who did not respond still showing high levels of engagement with the self-care advice and exhibiting optimism for future results.

The explanatory models of primary dysmenorrhea provided by TCM were acceptable to the majority of participants interviewed, however, those with a biomedical background were more sceptical of their validity, irrespective of symptom changes.

The partnership that occurs between practitioners and patients is an important component of the treatment model, providing a supportive, open environment, encouraging discussion and enhancing trust.

Self-care advice grounded in the TCM diagnostic pattern increases patients’ expectations for improvement, agency, and ultimately improves their health locus of control.

These factors, in addition to the application of acupuncture needling, are causally responsible for at least some of the improvements in pain and secondary symptoms seen in the RCT.

Chapter Eight discusses the importance of the thesis findings, how these findings compare to current research and the impact of these findings on clinical practice and future research.
Chapter Eight: Discussion and conclusion

8.1 Introduction

The overall aim of this thesis is to examine the practice and therapeutic effects of acupuncture treatment to reduce primary dysmenorrhea. This thesis provides evidence of how acupuncture was delivered in contemporary clinical practice to treat primary dysmenorrhea, and how a clinical trial protocol was developed, informed by clinical practice and research evidence, and subsequently used to examine the effects of timing and mode of stimulation on primary dysmenorrhea. The trial delivered a semi-standardised TCM acupuncture treatment, which allowed subsequent investigation of the impact of TCM self-care advice and any changes in participants’ understanding of, or views on, their menstrual cycle that occurred during the trial. To achieve these objectives, four separate research phases were undertaken using a pragmatic approach to mixed methods research. These studies examined:

1) how menstrual and gynaecological treatment was delivered by acupuncturists in New Zealand and Australia, via a survey of practitioners,
2) the different components used in the treatment of primary dysmenorrhea, via practitioner interviews and focus groups,
3) the effect of timing and mode of stimulation on primary dysmenorrhea via a clinical trial, and
4) the experiences of women with primary dysmenorrhea who participated in the clinical trial, via post-trial interviews.

Chapter Seven integrated the datasets across three or more of the study phases and discussed the effectiveness of the acupuncture intervention with the improvements seen in the clinical trial: this was reinforced and enriched by women in the post-trial interviews. Chapter Seven also discussed the importance of acupuncture treatment being “more than needles,” where acupuncture treatment was seen as a complex intervention, with a number of important aspects for women, including the partnership with their practitioners and the importance of self-care advice.
In this chapter the following will be discussed: the importance of the thesis findings, the findings from the RCT compared with those of other clinical trials, possible reasons for the lack of difference in modes of stimulation, possible mechanisms by which the self-care advice could alter menstrual pain, and how the study findings impact future research, as well as clinical practice.

8.1.1 Key findings from this thesis

This thesis makes a significant contribution to the body of knowledge concerning the usage and effectiveness of TCM acupuncture to treat primary dysmenorrhea and the experiences of women undergoing this treatment. Acupuncture is an effective treatment for primary dysmenorrhea and consists of “more than needles”, with the partnership between patient and practitioner being crucial in delivering an intervention consisting of needling, moxibustion and self-care advice. Study findings show that acupuncture is widely used to treat primary dysmenorrhoea, and in addition to acupuncture, New Zealand and Australian practitioners use a diverse range of modalities related to TCM to treat primary dysmenorrhea in clinical practice. Practitioners base their clinical decision making on their own individual hierarchies of evidence, where textbook knowledge tended to be viewed as the basis on which experiential clinical knowledge, either their own or others, was layered. Self-care advice, based around TCM diagnostic considerations and personalised for individual circumstances, was considered by practitioners to be a vital part of treatment and the adherence to this advice directly influenced long-term prognosis and rates of remission. Therefore acupuncture trials that rely solely on textbooks for treatment protocols, and do not include self-care advice or limit co-interventions, such as moxibustion, may not be representative of the style of acupuncture that is delivered in a community setting when treating women with primary dysmenorrhea. This in turn may underestimate the magnitude of benefit that the entire package of acupuncture care may provide.

Practitioners expressed concern that women often had issues finding time for treatment, due to busy social, family and work schedules. Women who participated in the study found that scheduling was a minor issue, especially in
the groups that had treatment once a week. Some women commented on how important it was to be able to have the treatments in relatively quick succession as it suited their lifestyle. These findings show that practitioners can implement a flexible treatment schedule, either weekly, or more frequently just prior to menses, to allow women to incorporate effective treatment based on their availability without affecting treatment outcomes.

This is the first study to examine the effect of changing acupuncture dosage, via treatment timing/frequency and mode of stimulation, on the symptoms of primary dysmenorrhea. Previous research has been conflicting about the importance of these two dosage factors, and it was unclear whether this represented clinical practice or was an artefact generated by research conditions and choice of methodology. These findings indicate that acupuncture, irrespective of treatment timing and frequency, was an acceptable, safe and effective treatment for women producing positive results for all primary and secondary outcome measures examined in the clinical trial, except for absenteeism.

Women found TCM acupuncture to be an effective treatment for both their pain and secondary symptoms of primary dysmenorrhea, enabling them to reduce their need for analgesic medication and improve their health-related quality of life. These improvements were consistent across all measures of pain intensity and duration, and their magnitude and importance was confirmed by the post-trial interviews.

Electro-acupuncture was well tolerated but did not always provide the same magnitude of improvements as manual acupuncture, especially with relation to secondary symptoms and analgesic medication intake. Manual acupuncture provided the same or greater pain relief as electro-acupuncture, but with less analgesic medication required to achieve this pain reduction.

Timing of treatment was associated with non-significant differences in clinical outcomes. Most of the women in the trial, regardless of the degree of improvement, voiced concerns about ongoing cost of treatment, which appeared to be a significant barrier for many. These findings provide new
knowledge to develop clinical guidelines for optimising acupuncture treatment for primary dysmenorrhea and the importance of delivering treatment that is cost effective for women.

Women who participated in the RCT valued multiple aspects of their acupuncture treatment. They found the non-judgemental support and communication style of their practitioners engendered a sense of trust and honesty, in contrast to their previous medical interactions with health professionals. This partnership provided the foundation that enabled women to feel supported in implementing the self-care advice; women felt “heard” and understood, and they trusted the explanations their practitioners had given them as accurate.

Participants had previously constructed the concept of a normal period from their own experience, and the experiences of family or close friends. The TCM explanatory model gave them a new understanding of what constituted a normal period and provided expectation for positive changes to their menstrual cycle in the future.

The TCM self-care program contained unique components of advice and gave them tools to improve their sense of self-efficacy when faced with ongoing pain, whereas previously they felt that they just had to accept the inevitability of pain during menses. The uptake of self-care was related to the plausibility of the TCM framework, rather than the symptomatic improvements seen by women in the trial. Women continued using the self-care advice that they felt was beneficial after the trial concluded. There were differences between the electro-acupuncture and manual acupuncture groups, in terms of self-care advice uptake, however these were not statistically significant. This finding on the effectiveness of TCM self-care advice provides new knowledge on the acceptability and perceived effectiveness of this style of advice in women with primary dysmenorrhea.
8.2 Discussion of findings from the randomised controlled trial

The women who participated in the trial suffered from moderate to severe dysmenorrhea, with a mean worst pain score of 7.1/10 on the 0–10 Numeric rating scale (NRS). They also suffered from a variety of secondary symptoms, including back pain, fatigue, breast tenderness, nausea, headaches and bowel changes, consistent with many other populations with primary dysmenorrhea (Banikarim, Chacko & Kelder 2000; Hillen et al. 1999; O’Connell, Davis & Westhoff 2006).

Analgesic usage amongst the study participants was very prevalent (81%), almost identical to the prevalence of analgesic usage in Australian women with dysmenorrhea (80%) (Zhu et al. 2010). The RCT participants were primarily taking paracetamol (43%) and ibuprofen (51%) as their analgesic. The high usage of paracetamol is concerning, as there is no evidence paracetamol is better than placebo for treating primary dysmenorrhea, and it is less effective than ibuprofen (Marjoribanks et al. 2010). The choice of over-the-counter (OTC) analgesic medication is similar to other studies examining medication usage in primary dysmenorrhea in the US (O’Connell, Davis & Westhoff 2006) and Canada (Campbell & McGrath 1997), but different to Mexico, due to differences in pharmaceutical branding and differences in OTC versus prescription medication (Ortiz et al. 2007). They also, like many other women with primary dysmenorrhea, did not always get complete or reliable relief from their period pain when using nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesic medications (Chia et al. 2013; Hillen et al. 1999). Interestingly, very few participants in this study were currently taking the oral contraceptive pill (COC); only five of the 74 (6.7%) participants were currently on the oral contraceptive pill. Zhu and colleagues found a similar rate of COC usage in Australian women with primary dysmenorrhea (Zhu et al. 2010). This may be due in part to women’s concerns around long-term health consequences of the COC, which may or may not be justified (Wong et al. 2009). Misunderstandings around the positive and negative aspects of oral contraceptive use is common
(Picardo et al. 2003; Tessler & Peipert 1997). A possible reason for the low number of women in the trial on the COC, was that COC usage reduced their dysmenorrhea to an extent it was no longer bothersome enough to seek additional treatment for. However, many women in this study noted in their history taking that they had, at least at some stage, tried the COC and had gone off it due to side effects (weight gain and headaches were commonly cited) or due to lack of perceived efficacy.

Despite the moderate severity of pain noted by participants, absenteeism rates were low throughout the study, compared with previous community surveys which showed that 17% (Burnett et al. 2005), 19% (Chia et al. 2013), 38% (Banikarim, Chacko & Kelder 2000) and 40% (O'Connell, Davis & Westhoff 2006) of women missed at least one day of work or school per month. Surveys of adolescents show higher rates of absenteeism than those of older women. The mean age of participants in this study was 30 years old, which may explain the lower rates than those observed in some surveys. Overall the participants in this study appeared to be similar to those from other populations suffering from the symptoms of primary dysmenorrhea, suggesting the inclusion criteria was effective in including a broad range of women with primary dysmenorrhea, similar to those in the community that may present at private acupuncture clinics.

**8.2.1 Changes in pain intensity and duration**

In terms of pain intensity, the trial findings sit within the mid-range of the continuum of results provided by previous studies. Direct comparison to studies performed in China (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Ma et al. 2013; Shi et al. 2011) with very short timescales of measurement post-treatment are problematic. The timescale used in the RCT did not attempt to measure pain immediately following needle insertion and soon after. Measurement at 30–120 minutes post-needle removal may not necessarily reflect meaningful changes in pain over the menstrual period itself. Reductions in pain in other trials undertaken in China (Bu, Du & Chen 2011; Huang et al. 2013; Xiong et al. 2012) were significantly larger than those observed in this
study, either in magnitude or duration. This was further complicated by the lack of clear reporting on how pain scores were calculated. Differences between this trial and those undertaken in China may also be due to differences in the sample demographics, with younger participants in those studies in China, cultural expectations of acupuncture’s effectiveness influencing the outcome (Tang & Easthope 2000; Xu et al. 2006), different concepts of menstrual pain severity between cultures and ethnicities (Wong & Khoo 2010; Zhu et al. 2010), or a publication bias (Vickers et al. 1998). Comparisons with other trials outside of China tend to show similar results to this study. Absolute pain reductions were less than Witt (Germany)(2008) and Helms (US)(1987) but similar to that found by Smith (Australia)(2011). Comparison with Helms (1987) is complicated by the fact that the sample size was very small, showing no between group differences and the use of a custom pain scale that was not validated. The greater absolute pain reduction found by Witt (2008) may be due to the nature of the intervention, where physicians were allowed to choose treatment without restriction, or due to the greater sample size, almost ten times the size of this study. However, the responder rates (>30% reduction in average pain from baseline) were similar to Witt’s, showing that the percentage pain reduction from baseline was relatively equal between the two studies. Similarly to Smith (2011) and Witt (2008), reductions in pain in this study appeared to be sustained or increased after the trial period ended, with the average pain, worst pain scores and analgesic usage in the manual acupuncture groups remaining stable or continuing to decrease after the conclusion of the treatment phase of the trial. In contrast, the electro-acupuncture groups began to show a return towards baseline during the one-month follow-up.

8.2.2 Health-related quality of life

Witt (2008) and Smith (2011) both used SF-36 to record health-related quality of life data. This study used norm-based scoring (NBS), the current recommended method for scoring the SF-36 (Ware et al. 2008). This differs to the slightly older 0–100 method used in Witt’s (2008) and Smith’s (2011) studies. However, both the overall mental component and overall physical component scores are norm-based scores even when using the older scoring
method. This allows comparison between these two scores across studies. Participants baseline SF-36 scores for both physical component (51) and mental component (46.7) were similar to Smith’s (49/43.9) and Witt’s (48.3/40.8) scores, with participants in this trial having slightly better mental health scores than both. After the trial, participants’ physical component score had a statistically significant improvement overall (53.3), while the mental health component did not show a statistically significant change overall (47.8). Witt showed a similar improvement in physical component scores post-trial (53.1), and also showed a significant increase in the mental health component score (47.6), which was only observed in the HF–MA group (50.6) in this study. Smith did not show a significant change in physical component scores in the acupuncture group (49.6), but did show an increase in mental component scores (46.1). Therefore this trial shows similar results to Witt (2008), where overall health-related quality of life, especially physical functioning, is improved after acupuncture treatment.

8.2.3 Secondary symptoms

Liu (2011) used the Cox Menstrual Symptom Scale (CMSS) to examine the effect of single point acupuncture on menstrual symptom scores. There was a small (~20%) reduction in CMSS as measured by RSS-COX1 after two menstrual cycles. The reduction in menstrual symptoms appears to be smaller than that provided by the HF–MA and LF–MA groups in this study, which showed a 35% and 41% reduction in menstrual symptoms after two months of treatment. This may be related to the use of a single point, which provides less effective treatment than the multiple points this study used, however the CMSS also includes components related to pain that confounds the ability to make a direct comparison.

8.2.4 Medication intake

Several trials recorded analgesic medication intake during menses. Helms (1987) recorded medication intake and found there was a drop of 54% in their mean daily strength of analgesic usage. This trial showed similar results, with a
reduction of 51% and 49% in the HF–MA and LF–MA groups respectively. Liu (2011) recorded medication intake but did not report the data. Liu (2014) and Smith (2011) both recorded percentage of participants using medication, which did not allow comparison with this dataset. Comparisons between Chinese and western patients is also difficult given the differing cultural usage of analgesics during menstruation (Zhu et al. 2010).

8.2.5 Influence of possible co-factors

This study did not find that the pattern of disharmony was a factor influencing treatment outcomes. However, due to the small number of women having patterns such as Damp-heat or Liver-fire, which may be more difficult to treat or require a longer treatment course (Maciocia 1998), caution is advised in extrapolating these findings to women presenting with these patterns in clinical practice.

Expectation of improvement can modulate pain perception and can be an important factor in pain changes observed with acupuncture treatment (Kong et al. 2009). Expectation of acupuncture’s therapeutic effect was not a factor in this study. This study did not find that belief in acupuncture prior to treatment was related to any of the outcomes measured; this observation is similar to the findings of Xiong and colleagues (Xiong et al. 2012). A recent review showed mixed effects for expectancy on pain (Prady et al. 2015), with some studies showing expectation as a significant predictor of improvement (Vase et al. 2013; Wasan et al. 2010), while other studies have also shown that pretreatment expectation levels do not necessarily relate to greater improvements in pain (Cherkin et al. 2009; Sherman et al. 2010; Zheng et al. 2014).

8.2.6 Electro-acupuncture versus manual acupuncture

Electro-acupuncture did not deliver greater pain reduction than manual acupuncture. Manual acupuncture groups tended to have a higher responder rate, significantly greater reduction in secondary symptoms, and lower analgesic usage. Electro-acupuncture in the trial was delivered at a 2/100Hz frequency, which has been shown to provide maximal opioid gene expression
by combining both high and low frequencies to provide maximal pain relief (Guo et al. 1996). This high frequency–low frequency stimulation pattern is very common in gynaecological disorders (Mayor 2013), and is identical to the frequency used in many other trials of electro-acupuncture for primary dysmenorrhea (Liu et al. 2011; Liu et al. 2014; Ma et al. 2010; Shi et al. 2011).

A non-randomised controlled trial, which was not eligible for inclusion in Chapter Two, by Thomas and colleagues (Thomas et al. 1995) compared pre-emptive acupuncture using manual or electro-acupuncture as part of four groups used in a cross-over style treatment. They found that manual acupuncture, when used prior to menses, provided greater pain relief than electro-acupuncture, using either a high (100Hz) or low (2Hz) frequency. These were similar results to this study, where manual acupuncture showed a similar, or greater, pain reduction than electro-acupuncture. This study did not find, similar to Zhi and colleagues (Zhi 2007), that electro-acupuncture was superior to manual acupuncture. However, Zhi and colleagues used an undocumented style of superficial acupuncture, compared with the more traditional penetrating acupuncture used in this study. They also delivered the intervention on the first day of menses only, where the possibility of greater opioid release via electro-acupuncture may have had more of an impact.

A recent review on manual versus electro-acupuncture by Langevin and colleagues (Langevin et al. 2015) found that, in pain conditions, 70% of individual trials found in favour of electro-acupuncture having a superior “clinical effect” while systematic reviews showed superiority of electro-acupuncture in treating osteoarthritis, but not for other, non-pain-related conditions, such as depression and obesity. There are several plausible reasons for the lack of additional efficacy of electro-acupuncture when treating primary dysmenorrhea compared with manual acupuncture:

- Electro-acupuncture and manual acupuncture may work via differing central mechanisms (Kong et al. 2002) and there appear to be responders and non-responders to both manual and electro-acupuncture when using acupuncture points such as SP6 (Kong et al. 2005). It is
possible that the small group sizes over-represented non-responders to electro-acupuncture, however, this seems unlikely as there should have also been a similar representation of non-responders to manual acupuncture.

- Vixner and colleagues (2014) found that electro-acupuncture did not reduce the experience of pain, but reduced the need for epidural analgesia during labour compared with manual acupuncture (Vixner et al. 2014). However, this study did not find that electro-acupuncture reduced the need for analgesic medication in women with primary dysmenorrhea; in contrast, manual acupuncture reduced the need for additional analgesia to a greater extent than electro-acupuncture. The reasons for this are unclear, as electro-acupuncture should provide at least the same amount of relief as manual acupuncture, as the needles were stimulated to obtain DeQi prior to electro-stimulation, thereby delivering a manual acupuncture-like stimulus prior to the addition of the electro-acupuncture pulse (Langevin et al. 2015).

- Animal models suggest that needling at REN4, SP8 and SP6, used in 80%, 55% and 98% of all study treatments respectively, regulates neuroendocrine activities, including levels of progesterone (Liu et al. 2009); and needling SP6 has been shown to increase ovarian blood flow via a reflex response in rats (Stener-Victorin, Fujisawa & Kurosawa 2006). A similar reflex response exists in humans, increasing uterine blood flow by reducing sympathetic activity on vasoconstrictor fibres that innervate the uterus (Meiqing, Jiang & Lufen 2003; Stener-Victorin et al. 1996). Uterine blood flow is often reduced in women with primary dysmenorrhea (Celik et al. 2009; Dmitrović 2000) and increasing uterine blood flow appears to be related to some of the analgesic benefits of acupuncture in primary dysmenorrhea (Ma et al. 2010; Yu et al. 2010). The magnitude of the impact of needling SP6 and, to a lesser extent, REN4 and SP8, may be larger than stimulation-specific differences.

- Practitioner intention or “Yi” is the concept that the practitioner generates an intent to heal (Smith et al. 2012), which is transmitted via the acupuncture needles. Intention may have an effect on clinical
outcomes, however, this contribution is more important to quantify when there are sham acupuncture groups (Hammerschlag et al. 2007), which was not the case for this trial. A possible reason for the difference in groups could be due to the fact that the manual acupuncture group received one extra application of DeQi than the electro-acupuncture group, and that this manipulation of the needles transmitted this additional Yi. Current evidence suggests that the role of DeQi in treating primary dysmenorrhea, especially when using electro-acupuncture after the initial DeQi sensation, is likely to be small (Shi et al. 2014). Therefore it is questionable if this would be a significant contribution to the difference between groups.

- It is plausible that the endogenous opioids released by electro-acupuncture may work on a shorter time course, causing reductions in pain for short durations that are not captured on the menstrual pain diary. Electro-acupuncture is more likely than manual acupuncture to elicit endogenous opioid release, the most likely explanation being that electro-acupuncture provides more prolonged and intense stimulation (Mayor 2013). The quick-acting effect of acupuncture analgesia is modulated by these endogenous opioids and tends to peak within 60 minutes, then return towards baseline (Wang, Kain & White 2008). However, as Thomas and colleagues (1995) note, it is unclear how a stimulus that increases endogenous opioid release prior to the onset of pain could have a clinical effect several days later (Thomas et al. 1995). Liu (2011) showed that pain relief in primary dysmenorrhea from electro-acupuncture peaked after 30 minutes and began to return towards baseline at 60 minutes (Liu et al. 2011), suggesting a significant role for endogenous opioid release causing short-term pain relief in primary dysmenorrhea, however, it is unclear by what mechanism electro-acupuncture would cause greater pain relief when not delivered during a time when pain was present.

- It is likely that while endogenous opioid release can explain some of the pain-relieving effects of acupuncture seen in studies when electro-acupuncture was delivered while subjects were suffering from menstrual
pain, it cannot explain the increasing pain reduction that occurred progressively over the three months of treatment, nor the improvements sustained at one-month follow-up when no treatment was given. Prostaglandins, especially PGF$_{2a}$ have been implicated as the primary cause of symptoms in primary dysmenorrhea (Coco 1999; Dawood 1981). Shi and colleagues (2011) found that there was no reduction in prostaglandin levels after one session of electro-acupuncture, however, this was limited by a small sample size and the fact that only one treatment session was given. Lin and colleagues (2008) found that after three months of acupuncture treatment there was a reduction in PGF$_{2a}$ levels (Lin, Liu & Huang 2008). A recent meta-analysis including Chinese language research has shown that the effect of acupuncture on prostaglandins is still unclear due to poor trial methodology and small sample sizes (Xu et al. 2014b). However, given the reduction in secondary symptoms found in this trial, it is likely that there is a reduction in prostaglandins entering the circulatory system and this occurs independent of the mode of stimulation.

Therefore, these findings support those of the descending pain modulation hypothesis for primary dysmenorrhea proposed by Smith and colleagues (Smith et al. 2011), where multiple mechanisms contribute to the reduction of pain and secondary symptoms observed. These mechanisms, including possible increases in uterine blood flow and reduction in prostaglandins, appear to be greater than the magnitude of difference seen between manual and electro-acupuncture when acupuncture is delivered primarily outside the menstrual period.

### 8.3 Implications for research

#### 8.3.1 Recruitment and retention strategies

Despite the high prevalence of primary dysmenorrhea amongst women, it was found that due to the perceived “normality” of period pain, as discussed in Chapter Seven, targeting women with this condition was not straightforward.
Unlike other more defined conditions, such as polycystic ovary syndrome (PCOS) or endometriosis, there were very few “meeting places” where women with primary dysmenorrhea gathered for support, either online or physically. Previous studies have shown that recruitment amongst younger women requires researchers to use a variety of means to both recruit and retain participants (Fenner et al. 2012; Griffin et al. 2013; Leonard et al. 2014).

This study decided to target women via social media, in particular Facebook advertising, and also using a University of Auckland email list. These were the most successful in aiding recruitment, with women either responding to these recruitment opportunities directly, or sharing them with their friends and family who might be interested. The ability to “share” posts or forward emails created an unexpected snowball sampling effect, which allowed recruitment to proceed in a timely manner, with an average of seven women being recruited per month. In contrast to Griffin (2013), this study did not find that flyers placed at local family planning clinics and distributed to local businesses, were an effective recruitment tool (Griffin et al. 2013). Initially, consent forms and baseline forms were required to be emailed back to the primary investigator (MA), however, this often caused significant delays. Women were not used to having to post paper copies of documentation, and therefore did not visit their local post office or post box regularly, commenting they did managed most bill payments and correspondence by digital means. The recruitment process was updated to allow women to scan and email these consent forms and enabled the completion of the baseline forms online; this greatly increased the speed of completion and reduced the risk of losing forms in the post.

Women also commented on the convenience of being able to fill in the menstrual diary online; and from the researcher’s point of view this also reduced the risk of loss of the menstrual diary, as well as being able to send out email reminders if the diary entry was not completed. Retention rate in this trial was relatively high, with the most common reasons for dropout being a change in working hours or geographic location, or becoming pregnant. The use of text message reminders, as well as an online booking system (ezybook.co.nz), enabled women to manage their own appointments; these were all considered
important factors in this low-attrition rate (Leonard et al. 2014). Another possible contributing factor was that due to acupuncture being a complex intervention, the trial involved a high level of patient participation (Paterson et al. 2009), especially through the implementation of the self-care advice. Increasing active participation in this manner has been shown to help retention (Scott et al. 2011).

Email and text appointment reminders, a convenient and flexible booking system and the ability to fill out most of the trial paperwork online or by hand, but submit it via digital means, are all important factors to consider for future clinical trials involving women with primary dysmenorrhea.

8.3.2 The importance of co-interventions in acupuncture trials

Practitioners used a variety of modalities when treating primary dysmenorrhea; the most common modalities after acupuncture itself were diet and lifestyle advice (69.7%) and moxibustion (61.2%). While direct comparison to three other recent practitioner surveys, one from Australia (Moore 2014), one from the UK (Hopton et al. 2012) and one from the EU and China (Robinson et al. 2012) is not possible due to the different questions asked, there are some similarities. Robinson and colleagues (2012) found that 72% of European-based practitioners and 67.2% of Chinese-based practitioners gave diet advice as part of their treatments, while Moore (2014) found that TCM diet advice, lifestyle advice and moxibustion was used “Frequently / Almost always / Always” by 54%, 66% and 35% of practitioners respectively. While this was not condition-specific, this is a similar rate to that found in this survey for diet and lifestyle advice. The moxibustion usage is lower, but this may reflect that the questions in this survey were specific to gynaecological disorders, which commonly include conditions that TCM designates as related to either qi stagnation or cold. Hopton and colleagues (2012) found that 76% of acupuncture practitioners from the UK gave diet and lifestyle advice based on TCM considerations to women presenting with gynaecological conditions (Hopton et al. 2012). Unfortunately, no sub-categories of specific gynaecological disorders were given for this data, however, it is similar to, though slightly higher than the 69.7% of
surveyed practitioners who use diet and lifestyle advice for primary dysmenorrhea in this survey. This may reflect the lack of differentiation amongst differing gynaecological conditions in Hopton’s survey. In this survey other conditions lifestyle and diet advice was given by over 80% of practitioners when treating conditions such as menopause, therefore it is likely the overall proportion of practitioners giving diet and lifestyle advice is similar. The population of practitioners in Hopton’s survey was also different to this population, with only 41% of practitioners using TCM-style acupuncture compared with 90.6% in this sample. This is most likely due to the fact that the majority of acupuncturists in Hopton’s survey were working within the NHS in the UK and were doctors or physiotherapists. However, despite these differences in practice characteristics, the prevalence of usage of self-care advice in both general practice and in gynaecological conditions is clear from the survey data. This suggests that the lack of incorporation of these co-interventions in clinical trials may be a significant departure from the package of care that acupuncture delivers in the community.

Given the common presence of moxibustion and self-care advice in clinical practice, their characteristic nature (Langevin et al. 2011; Paterson & Britten 2004; Paterson & Dieppe 2005) and the importance that practitioners place on them (MacPherson & Schroer 2007; MacPherson, Thorpe & Thomas 2006; Smith et al. 2012), along with their potential to alter therapeutic outcomes, as discussed later in this chapter and in Chapter Seven, it would be imprudent to disregard these co-interventions in future research designs when examining primary dysmenorrhea.

8.3.3 The use of a manualised trial protocol

A manualised trial protocol informed by practitioner data was chosen to allow comparison between the differing dosages of acupuncture given, while still maintaining the integrity of the TCM framework. This allowed the delivery of a treatment that is representative of acupuncture as delivered in clinical practice (Schneyer, Birch & MacPherson 2007), as it incorporates differential diagnosis,
point selection based on TCM considerations and common co-interventions. The resulting protocol manual is included in Appendix A18.

Textbooks or expert opinion was a common source for point selection in studies examining primary dysmenorrhea, as discussed in Chapter Two. The focus groups and interviews found that practitioners did use textbooks as part of their practice, but they were placed at the bottom of their evidence hierarchy, below personal experience and the opinions of other expert practitioners. Jackson and Scambler (2007) and Hansen (2012) both found that for acupuncturists practising outside the biomedical model, their own personal experience was a key factor in whether a treatment worked or not, superseding all other forms of evidence (Hansen 2012; Jackson & Scambler 2007). Practitioners in the focus groups also ranked their own personal experience as the strongest evidence, with none of the practitioners participating discussing results from RCTs or systematic reviews influencing their practice. Most practitioners commented that they felt textbooks were a base to grow from, but didn’t realistically represent “real world” practice, which was far more complex than textbooks captured. Whether textbooks represent the clinical experience appears to depend on the condition treated. There is some evidence that textbooks do not match the experience of women with menopause (Scheid, Ward & Tuffrey 2010), but presentations for infantile colic were very close to the textbook description (Landgren 2013). Practitioners based their clinical decision making on an amalgamation of textbooks, prior clinical experience, expert opinion, postgraduate training, and sometimes their own intuition. This was similar to the findings by Moore (2014), where Australian acupuncturists rated their own experience and explanations by experienced practitioners as more important than either classic textbooks, such as the Huang Di Nei Jing, or modern textbooks (Moore 2014). Therefore it is important to incorporate practitioners’ input in designing treatment protocols, as recommended by Schnyer (2012), as this augments the information provided by textbooks and reviews of the literature (Schnyer & Allen 2002). In addition, because practitioners do not rely heavily on textbooks in clinical practice, using this as the sole source of
information for pattern differentiation and point selection in a clinical trial may underestimate the diversity of practice in the community.

Manualisation was successful in being able to deliver a flexible intervention, with the diagnostic categories covering the presenting patterns of disharmony. All the diagnostic categories provided by practitioner input were used in the trial, with the prevalence of each pattern in trial participants similar to that discussed by focus group practitioners. None of the practitioners involved in the study had any issues with being able to adequately diagnose patients within the framework provided by the protocol. Allowing two patterns to be used was also important, as 80% of women in the trial had two patterns of disharmony diagnosed. Multiple patterns of disharmony are common in TCM (Liu et al. 2012; MacPherson et al. 2004). Direct comparison between underlying patterns between trials was difficult due to either a lack of reporting of patterns (Smith et al. 2011), or different textbook sources being used for pattern definitions (Liu et al. 2012; Zhu et al. 2009). However, when categories were collapsed to allow more general comparison the results were similar, with 72% of participants having Qi or cold stagnation, compared to 65% of Australian women (Zhu et al. 2009). Liu (2012) found that Chinese women had a higher proportion of cold and dampness, and a lower proportion of Qi stagnation than this study, however, this may reflect cultural differences present in menstrual cycles (Zhu et al. 2010), which would in turn be reflected in different diagnostic patterns. Reinforcing the accuracy of diagnosis were those patterns that were rare in this study, such as Liver-fire or Liver and kidney Yin deficiency; these were also similarly rare in both Zhu (2009) and Liu (2012). Therefore it appears that using textbooks as a foundation, with further refining by experienced clinical practitioners, appears to elicit sensible and accurate diagnostic categories.

Point selection was linked to these diagnostic categories, and was also guided by practitioner feedback. Appendix A20 provides the points selected by practitioners for each pattern and Chapter Five contains a list of the frequency of usage in the clinical trial. Point selection was quite varied amongst practitioners in the focus groups and interviews, which is common amongst TCM acupuncturists (Birkeflet, Laake & Vøllestad 2011; Coeytaux et al. 2006;
Kalauokalani, Sherman & Cherkin 2001). Despite this, good consensus was to be found by using textbook patterns as a base. The point selection provided by practitioners appears to accurately reflect the usage of points in other TCM trials. Yu and colleagues (2015) used data mining of both English and Chinese language literature to examine which points were commonly used in the treatment of primary dysmenorrhea (Yu et al. 2015). Eighteen of the 20 points most commonly used in the literature were used in this study, with only Zi Gong (EX-CA1) and Shiqizhui (EX-B7) not being represented by practitioners. It should be noted that these points were less frequently found in the literature, and more commonly used in studies originating from China. Zi Gong was mentioned by several practitioners in the focus groups, but did not reach the 25% support needed to be included in the trial protocol. It’s possible that this difference is due to the relative popularity of points in different countries, or the different clinical experience of practitioners, which is known to influence their point selection (Alraek, Borud & White 2011; Stuardi & MacPherson 2012). The median number of points used per session was six, reflecting the fact that single point usage, as seen in some primary dysmenorrhea studies, is not common in clinical practice, as practitioners base their point selection on a diverse range of criteria (Alraek, Borud & White 2011; Kalauokalani, Sherman & Cherkin 2001; Sherman, Hogeboom & Cherkin 2001).

Despite the diversity in clinical practice seen, certain components of the treatment were common across most, if not all, practitioners. This included needle retention time, the importance of obtaining the DeQi sensation, and the importance of self-care advice and moxibustion in primary dysmenorrhea. These components can be safely standardised without fear of losing the diversity present in clinical practice, especially if a range of retention times based on pattern differentiation is stated.

Manualisation provided flexible treatment, based on the TCM theoretical framework, while still allowing a degree of standardisation and encouraged compliance amongst trial acupuncturists. The use of a manualised protocol allowed incorporation of additional, important modalities into treatment sessions based on practitioners’ clinical judgement. This confirms the findings
of Wayne (2008), who found that a similar protocol could be used for Japanese acupuncture treating endometriosis-related pain (Wayne et al. 2008). Manualisation warrants incorporation in future clinical trials of primary dysmenorrhea or other gynaecological conditions.

8.4 Implications for practice

8.4.1 Acupuncture provides significant reduction in pain severity, duration and secondary menstrual symptoms

Interview data from acupuncturists described their confidence in treating primary dysmenorrhea and of achieving positive results; however, there appeared to be a wide range of treatment frequencies and types of stimulation, especially related to differences between those practitioners trained in China and those in New Zealand. This is also reflected in the range of timings and dosages found in the literature, as discussed in Chapter Two, examining the effectiveness of acupuncture to treat period pain. Women allocated to all four acupuncture groups rated the intervention as acceptable and successful. There were no differences in self-rated improvement scores, despite differences in pain scores at trial exit. In chronic pain patients it is generally accepted that a two-point reduction on the NRS or a >30% reduction in pain scores are clinically important differences (Dworkin et al. 2009). Often the electro-acupuncture groups demonstrated clinically significant reductions during the trial, however, by the one-month follow-up those reductions had regressed. The HF–MA group showed less reduction in most pain scores at three months but appeared to continue to improve after trial exit, and at one-month follow-up demonstrated greater reductions than at the end of the intervention. The reason for this delayed improvement is unclear, however, it has been observed in other acupuncture studies on primary dysmenorrhea, where pain scores continue to decrease for several menstrual cycles after conclusion of treatment (Liu et al. 2014; Ma et al. 2013; Smith et al. 2011).
Interviews with practitioners described their concerns over using electro-acupuncture for period pain, especially amongst western-trained practitioners who felt it may be uncomfortable or overstimulating. This study supports the use of manual acupuncture as an effective treatment for primary dysmenorrhea. Electro-acupuncture did not provide any additional benefits and was less effective than manual acupuncture in reduction of analgesic medication and secondary symptoms. These findings suggest that practitioners can use manual acupuncture without concern that they are delivering a less effective treatment than electro-acupuncture.

The survey data showed that there was very little referral from biomedical practitioners to acupuncturists for gynaecological issues, significantly less than for pregnancy and fertility. This may be due to the popularity of CAM referral by midwives and obstetricians (Gaffney & Smith 2004; Münstedt, Brenken & Kalder 2009), despite a low evidence base for many of the therapies being a concern for some obstetricians (Rayner et al. 2010). The lack of referrals by general practitioners for gynaecological issues is somewhat surprising as many general practitioners in New Zealand refer patients to acupuncturists and view acupuncture as beneficial (Poynton et al. 2006). It is possible that the lack of evidence base for using acupuncture in many gynaecological conditions prevents referral (Smith & Carmady 2010). Treatment options chosen by general practitioners tend to be limited to NSAIDs and COC usage.

As discussed in Chapter Seven, women in this study indicated pharmacological management often provided partial, but usually inadequate relief. This study shows that in a community setting a short course of acupuncture can reduce severity and duration of pain, and reduce the need for analgesic medication. Therefore this study should add to the evidence base on the effectiveness of acupuncture for obstetric and gynaecological complaints that practitioners have requested (Robinson et al. 2012), and allow general practitioners to feel confident in referring patients for acupuncture if standard NSAIDs and COC usage do not provide adequate relief of pain and secondary symptoms.
8.4.2 Treatment frequency and duration

In focus groups and interviews practitioners and participants alike expressed concerns around the ability to schedule treatments; for practitioners, their concern was around finding space in their often single-bed clinics, while for participants it was fitting treatments in around child care, work and social commitments. These findings suggest that while the number of treatments remains similar, there is very little clinical difference between delivering treatments weekly or clustering the treatments in the week prior to menses. The importance of the total number of treatments, rather than treatment timing, is similar to findings by Yuan and colleagues (Yuan et al. 2009). This is in contrast to the findings of Harris (2005) for treating fibromyalgia, who found that three sessions weekly provided greater pain reduction than once weekly (Harris et al. 2005). This difference may be explained by the fact that pain in fibromyalgia, a rheumatic disorder (Yang et al. 2014), is generated by a different physiological mechanism than pain in primary dysmenorrhea (Rahman, Underwood & Carnes 2014); therefore, pain reduction in fibromyalgia occurs via a different mechanism of action than pain reduction in primary dysmenorrhea. This difference in the underlying mechanism of pain is supported by the fact that, upon cessation of treatment, pain increased, while in this study pain results stayed similar or reduced further during the one-month follow-up. Therefore practitioners should feel confident offering a treatment schedule that suits their patients, as there does not appear to be any significant advantage to one treatment frequency over the other.

Interestingly, just over one third of participants had the full 12 treatments. This was mostly due to scheduling issues around the menstrual period itself, with some women having changes in cycle length upon starting the acupuncture, especially in the first month of treatment, which meant they did not get the full number of treatments in before menses. There was no difference in treatment outcomes based on the number of treatments received. It appears that the regularity of treatment over time, rather than the total number of treatments, proved to be the important factor. Therefore continuation of treatment, even
when treatments have been missed during the cycle, should still provide satisfactory results.

An important factor to account for is that most acupuncture appointments given by the focus group practitioners tended to be 45–60 minutes (a length that was replicated in the RCT), which is very similar to that of other acupuncture practitioners in Australia (Moore 2014). While part of the treatment session is taken up by needle insertion, which can cause a break in the conversation, acupuncturists continue discussion with their patients throughout the treatment session; this can contain one or more components of self-care advice, social talk, discussions relating to acupuncture and TCM, and biomedical talk amongst others (Evans et al. 2011; Paterson et al. 2012). This allows acupuncture practitioners more time to discuss issues with patients and develop rapport. This was also discussed briefly in Paterson and Britten (2004), where they noted “the length of the treatment was experienced both as a luxury and as a critical factor in building the relationship and enabling talk and reflection” (Paterson & Britten 2004). Interview participants did appreciate the rapport that they developed with their study practitioners; they felt that their practitioners were approachable and often light-hearted. Therefore it is important that practitioners do not shorten treatment sessions excessively, as this may reduce the therapeutic outcome, as less rapport is generated and less support may be provided to patients.

However, session length must be balanced with the financial impact on patients. An important concern for many of the women in the study was the affordability of ongoing treatments, with most of the women interviewed expressing concern over financial strain from having to afford four treatments per month for a three-month (or longer) period of time. This was a concern for women irrespective of the magnitude of relief they obtained from the treatment sessions. This was sometimes framed as a contrast to the inexpensive cost of analgesic medications, despite many women not wanting to take analgesics on a regular basis; the cost–benefit ratio was felt to be high. Therefore, practitioners need to be mindful that while achieving significant reductions in pain and secondary symptoms, these may not be enough to offset the issue of financial
constraint. A possible solution to this would be delivery of treatment in a community style clinic, which lowers cost barriers, enables more frequent treatment (Chao, Tippens & Connelly 2012) and still provides high-quality acupuncture care (Tippens et al. 2013).

8.4.3 Incorporation of self-care advice provides positive treatment outcomes

As discussed in depth in Chapter Seven, self-care advice was an important component of acupuncture treatment for both participants and practitioners. These results support previous findings on the importance of self-care advice from a practitioner perspective (Hughes et al. 2007; MacPherson & Thomas 2008; MacPherson, Thorpe & Thomas 2006; Smith et al. 2012), and confirmed that most participants also considered it a vital part of their treatment, linking it to positive outcomes in relation to mental and physical health, and an increase in enablement and self-efficacy. These changes across a broad range of domains are commonly observed in acupuncture treatment (Hopton, Eldred & MacPherson 2014; Hughes 2009; Paterson & Britten 2004; Tang & Easthope 2000). The self-care advice played a key role in patients becoming their own “disease manager” (Paterson et al. 2009).

Given the nature of the advice was different to that given by other non-TCM sources, the content was linked to the TCM diagnosis and delivered as an integral part of the treatment and individualised to women’s own circumstances, as seen in previous studies (Evans et al. 2011; Paterson et al. 2012), it is without a doubt a characteristic component of acupuncture (Paterson & Dieppe 2005). Self-care advice fits the holistic model of acupuncture by providing new holistic understandings. As well as affecting changes in symptoms, changes in energy, strength and relaxation are also noted, as well as some effects on women’s social and personal identity (Paterson & Britten 2004). Therefore, in both clinical practice and clinical trials, the delivery of this advice should be considered as having a strong link with therapeutic outcomes, and contributing towards the development of the partnership between the practitioner and patient.
8.4.4 Contributions of self-care advice to therapeutic outcomes

As discussed in Chapter Seven both the electro-acupuncture groups had lower numbers of women who rated the self-care advice as useful. Both these electro-acupuncture groups showed a trend towards lower responder rates and had higher analgesic usage than the two manual acupuncture groups, both of which had higher proportions of women who rated the advice as useful. In addition to the self-care advice providing increased enablement and increasing health locus of control (HloC), there are possible physiological pathways through which the self-care advice could decrease pain and secondary symptoms of primary dysmenorrhea that may account for some of the observed differences in pain scores and analgesic usage between groups.

Three major categories of advice were given, all dependent on the underlying differential diagnosis: stress reduction, dietary changes and modification of exercise.

Many of the women mentioned stress as a trigger that they felt made their period pain worse. High levels of stress have been shown to increase dysmenorrhea (Christiani, Niu & Xu 1995; Gordley et al. 2000; László et al. 2008; Wang et al. 2004). Women, especially those diagnosed with Qi stagnation, were encouraged to take up meditation, yoga or tai chi practice. There is evidence mindfulness meditation reduces the stress response (Marchand 2012), pain intensity (Omidi & Zargar 2014) and increases pain acceptance (Cramer et al. 2012) in other chronic pain conditions. Yoga Nidra, a type of meditation, has been shown to reduce menstrual irregularities, including menstrual pain (Rani et al. 2013). Yoga postures (asanas) have also been shown to reduce menstrual pain in both intensity and duration (Chien, Chang & Liu 2012; Rakhshae 2011). There is also some evidence that tai chi is helpful in treating chronic pain conditions (Peng 2012). These modalities may have contributed to the reduction in pain intensity and duration seen in the trial.

Exercise is often recommended as a treatment for primary dysmenorrhea due to the effect of exercise on increasing pelvic blood flow and stimulating
endorphin release (Golub, Menduke & Lang 1968), however, evidence is conflicting on its effectiveness (Blakey et al. 2010; Daley 2008). Many women’s natural inclination is to reduce exercise during menses (Banikarim, Chacko & Kelder 2000; Chang & Chuang 2012; Chen et al. 2006). This individual response to exercise, with some women preferring to increase while others reduce exercise (Banikarim, Chacko & Kelder 2000), may be explained by the difference in the underlying pattern causing that pain. Women with Qi stagnation were encouraged to exercise more, although not necessarily during menses itself, while women with mixed or deficiency conditions were advised to reduce their exercise during and outside of menses, and to rest more during menses. Therefore this exercise-related advice, specific to the underlying pattern, may have contributed towards the positive outcomes seen.

Dietary changes included recommendations to reduce alcohol and caffeine intake, increase oily fish and dark green leafy vegetable intake, to include walnuts in the diet and increase consumption of warming spices, such as ginger and cinnamon. Low fish consumption has been correlated with increased menstrual pain (Balbi et al. 2000) and almost half of New Zealand women only eat fish once or twice per month (Seafood council. Omnibus recreational fishing survey 2007 n.d.). Walnuts, oily fish and dark green leafy vegetables (such as kale) are all good sources of omega-3 fatty acids (Ask the Expert: Omega-3 Fatty Acids n.d.), with supplementation of omega-3 (Fjerbæk & Knudsen 2007) and increased fish intake (Latthe et al. 2006b) both reducing primary dysmenorrhea symptoms. Effectiveness of these foods in reducing period pain is most likely due to competition by omega-3 for the enzyme prostaglandin synthetase, with omega-3 fatty acids producing less potent versions of leukotrienes and prostaglandins than those of omega-6 (Hansen 1983). Ginger intake has also been shown to reduce pain scores in primary dysmenorrhea, although this was from encapsulated ginger extract, rather than dietary ginger (Rahnama et al. 2012; Shirvani, Motahari-Tabari & Alipour 2014). Other aromatic spices, such as cloves and cinnamon, may also have an effect in reducing menstrual pain (Marzouk, El-Nemer & Baraka 2013). Reduction in alcohol and caffeine intake was also advised, however, there is no evidence that lowering caffeine intake
reduces the symptoms of primary dysmenorrhea. Alcohol intake is slightly more complex; when consumed regularly it reduced the risk of menstrual cramps, however, when cramping was present it increased the severity and duration of pain (Harlow & Park 1996). Therefore, for the women in this study who already suffer from menstrual pain, reduction in alcohol consumption may have been beneficial in terms of reducing their pain.

The advice given as part of TCM acupuncture consultations has possible therapeutic value over and above increasing psychological factors, such as hope and enablement, and likely contributes at least partially to the clinical outcomes seen in clinical practice and in this trial.

**8.5 Strengths of this study**

Using mixed methods allowed the weakness of each individual method to be offset by the strengths of other methods, providing an overall strength greater than the sum of the individual parts.

This clinical trial has several strengths. The use of a randomised controlled trial is the gold standard for comparing interventions, by removing the potential effect of confounders and minimising systematic bias (Britton et al. 1998). The central randomisation and allocation concealment used meant that the risk of bias was low. Randomisation was successful: similar to Smith (2011) and Witt (2008) there were some potential confounding factors that were not evenly distributed amongst groups, however, these were included as co-factors in the analysis and shown not to influence clinical outcomes. This study had a low attrition rate, similar to Smith (2011), with none of the participants withdrawing for treatment-related reasons.

The biggest strength of this trial was that the acupuncture intervention was delivered in a manner reflecting clinical practice in New Zealand and Australia, with flexible diagnosis and point selection, as well as the use of co-interventions. This allowed a comparison of the magnitude of changing dosage components within the acupuncture package of care on therapeutic outcomes.
The lack of a sham needling group was also a strength for this trial. While this may appear paradoxical, this not only avoided the issue of the inertness of sham acupuncture (Lundeberg et al. 2008), but also allowed better exploration of the importance and impact of self-care advice. Participants in trials that have sham acupuncture act differently to “real life” patients, with patients in sham controlled trials feeling like research subjects rather than patients, which affects their expectations and behaviour (Paterson et al. 2008). This altered behaviour results in less talk, information seeking and participation (Paterson et al. 2008), and participants in sham controlled trial often feel as though their choice of treatment is often removed (Kaptchuk 2001). Therefore, the use of sham in this trial could have reduced some of the effects of self-care advice and consequently underestimated its importance.

The inclusion criteria used in this trial were broad and designed to reflect the presentation of women in clinical practice with primary dysmenorrhea. The broad range of secondary symptoms, the use of analgesic medication and prevalence of self-care is similar to that of community surveys of women with primary dysmenorrhea, suggesting that trial participants were an accurate representation of the presentations that would occur in clinical practice.

This study used a variety of sources to develop the clinical trial protocol, with several checks and balances to ensure it was representative of clinical practice in New Zealand and Australia. Survey data was used to gain an understanding of the different modalities used as part of an acupuncture treatment when treating primary dysmenorrhea, and focus groups were used to gain more understanding in the choice of modalities used and what guided practitioners’ clinical decision making. The use of an online survey and Skype meant that practitioners, who would otherwise be unable to participate due to geographical or logistical issues, were able to be included, while digital delivery meant no significant costs were incurred that are usually associated with traditional, paper surveys. The use of mixed methods meant that data around modality choices from the focus groups and interviews was checked against the survey data to ensure that it still reflected wider clinical practice. This integration of
data from multiple sources ensured a greater understanding of contemporary clinical practice.

The incorporation of a significant number of practitioners who were experienced in the treatment of women’s health conditions means that individual differences in practice have less impact on the final treatment protocol, unlike where expert opinion or a single textbook is used. By involving practitioners who are in clinical practice, rather than solely in academia, the issue of a “disconnect” between theoretical and practical knowledge, as occurred in the ACUFLASH study (Alraek, Borud & White 2011; Borud et al. 2009) was avoided. This was reinforced by the usage of all the points outlined in the protocol by the study acupuncturists, suggesting that they were comfortable and experienced in using these points, meaning it is likely that practitioners in the community would have a similar experience, therefore the protocol used in the trial could easily be adapted for use in clinical practice.

The incorporation of both responders and non-responders in the post-trial interviews allowed for a balanced perspective of trial experiences, independent of the success of each individual participant. Additionally, women were selected from both sites, to ensure that all study practitioners were represented and any individual differences between practitioners could be explored. Interview data showed that treatment did not appear to be delivered differently between the study practitioners, and that women had been treated according to the study protocol.

Study practitioners confirmed that they found compliance to the protocol to be straightforward. Women discussed their pain and symptom changes, which both confirmed the results found in the menstrual pain diary, but also allowed for a deeper understanding of what these changes meant to women’s quality of life. Some of the changes, which were unrelated to pain, were very significant to women and affected their daily lives more than the pain itself. The magnitude and range of changes that women experienced may not have been evident from the menstrual pain diary alone.
8.6 Study limitations

Each of the studies has one, or more, small methodological limitation. The low response rate of the survey limits the validity of the data obtained. Low response rates have been seen previously in surveys of health care professions (Cook, Dickinson & Eccles 2009), including Australian acupuncture practitioners (Choy, Walsh & Smith 2010). This low response rate may reflect that the survey was unable to specifically target those practitioners working in the area of women’s health. It is also possible that only those working specifically in this area may have chosen to respond to the survey, while those working as generalists did not respond. This has been seen previously when trying to survey specialist sub-populations (Betts, Smith & Dahlen 2014). Robinson (Robinson et al. 2012) found that in the EU 44.4% of practitioners were specialists, and of those 44% of the specialities were related to obstetrics and gynaecology. This suggests that approximately 20% of practitioners in the EU specialised in obstetrics and gynaecology. This is very similar to the response rate of the New Zealand practitioners. Calculating an accurate response rate is further confounded by the fact that some New Zealand and Australian practitioners may have belonged to more than one professional association, however, data on dual membership was not available from the professional bodies in New Zealand. Choy (2010) found that multiple membership associations amongst Australian acupuncturists was common, and adjusting for this increased their response rate from 15.7% to 25% (Choy, Walsh & Smith 2010). Therefore, it is likely that the response rate would be higher if it were possible to remove dual membership accurately.

The survey data suggests there may have been responder bias. Due to privacy laws, all contact with members of these professional bodies was undertaken anonymously via the professional bodies, with no direct contact from the primary investigator (MA), therefore there was no available data on duplications, un-contactable members or the demographics of those responders versus non-responders.
The predominate use of an online survey may have introduced some responder bias, favouring those who are greater users of the internet. The addition of a paper survey was undertaken amongst New Zealand practitioners to reduce this bias, however, this may have inadvertently increased the responder bias, as there were not enough funds to send a paper survey to Australian acupuncturists. Finally, as the data was self-reported there was no way to validate that it accurately represents acupuncturists’ practice, however, the similarity to other published surveys suggests that this is unlikely. Because the data from the survey and practitioner focus groups and interviews was all sourced from practitioners in Australia and New Zealand, generalisation to representing clinical practice other geographical areas is not possible.

As this was an exploratory study it was not powered to detect small differences between groups. A post-hoc power analysis shows that a sample size of 192 would be required to determine the difference between groups for secondary symptoms of primary dysmenorrhea. While a difference of >30% from baseline is considered clinically important, the size of differences between groups that are important to participants appears to be dependent on the condition treated (Dworkin et al. 2009). In this case, these between group differences do not appear to significantly alter how successful women felt their treatment was. This is supported by the fact there was no difference in self-reported improvement score between groups, however, future studies with significantly more participants would be required to answer this question.

No physical screening (ultrasound scan or laparoscopy) for primary dysmenorrhea was undertaken before entry into the study; therefore it is possible that some of the women in the study had secondary dysmenorrhea. Primary dysmenorrhea is a diagnosis of exclusion, with most of the women presenting in the study having had no investigations undertaken or referrals given by their general practitioner. This is likely to be very similar to the presentation of women in community clinical practice, where women were given a diagnosis of primary dysmenorrhea by their general practitioner without further investigations into their menstrual history to support the
diagnosis (Coco 1999; French 2008), therefore, due to the emphasis on clinical applicability of this study, it has minimal impact on its generalisability.

The RCT, due to its design in comparing effectiveness of differing doses of acupuncture, did not have a usual care group. This limits the ability to determine if acupuncture treatment is responsible for the changes in pain, menstrual symptoms and health-related quality of life. Pain can be modulated by expectations (Walach 2003), however, in this trial expectancy was not a factor in any of the primary or secondary outcomes, despite differing levels of expectancies between groups. Additionally, the differences between baseline and the one-month follow-up are significant and are unlikely to be due to natural reductions in the pain from primary dysmenorrhea (Weissman et al. 2004).

The RCT had a short follow-up time of one-month, this was due to the time constraints of PhD submission, however, an ethics amendment has been lodged, which allows collection of data at six and 12 months. This data will be analysed once collection is complete and will provide further information on the duration of the improvements seen in the trial.

With respect to self-care advice, there was no measurement of HloC prior to trial entry, therefore while it appears from post-trial interviews that the self-care advice did increase participants HloC, no quantitative measurements were taken to show HloC changed during the trial. Additionally, while the self-care advice was highly regarded by women, this study did not investigate the effect of each component to their changes in wellbeing, therefore the contributions of individual components cannot be ascertained from this study.

8.7 Future research directions

1. A larger study, powered to detect differences between TCM patterns, may provide more useful clinical information. TCM theory supports differing improvement rates for these categories, however, due to the uncommon nature of some of these patterns there were not enough
participants in each of these categories to do an appropriate sub-analysis. This would provide practitioners with clinically useful information on expected magnitudes and rates of improvement based on the presenting clinical pattern.

2. The number of treatments is directly related to the financial cost for patients. Future research could examine how many treatments are required to elicit the clinically significant improvement of 30% or greater. This would provide useful clinical information to practitioners around pricing treatment courses and the results that could be expected from shorter courses of acupuncture.

3. The mechanism(s) by which acupuncture exerts its effects on reducing pain and secondary symptoms of primary dysmenorrhea could be examined by repeated doppler scanning of uterine arteries and measurement of prostaglandin levels to determine the contribution of each of these possible pathways.

4. The contribution and uptake of individual self-care components could be investigated using a design suggested by MacPherson and Thomas (MacPherson & Thomas 2008). Future acupuncture trials could include a group that receives TCM self-care advice, another group that receives biomedical self-care advice, and a third group that receives no self-care advice. This would further the understanding of the magnitude of the contribution of the contents of the advice itself, rather than just the giving of advice.

8.8 Conclusion

Primary dysmenorrhea is a common gynaecological condition in women of reproductive age and results in reduced quality of life and absenteeism from work or school, often on a monthly basis. Current biomedical treatments of NSAIDs and the COC are effective for some, but not all women, with many women experiencing only partial relief.
Acupuncture practitioners commonly treat primary dysmenorrhea successfully within their practice, using a variety of modalities, most commonly moxibustion and lifestyle and diet (self-care) advice, in addition to acupuncture needles themselves.

The partnership between patients and practitioners, and the TCM self-care advice given during treatment, were key factors in successful treatment.

Acupuncture, when delivered via a manualised trial protocol, was safe, acceptable to women and successful in reducing pain severity, duration, secondary symptoms of primary dysmenorrhea, need for analgesic medication and improving HRQoL.

Participants, almost without exception, thought that period pain was a normal part of life. After acupuncture treatment, menstrual pain was now conceptualised as an issue of imbalance, which could be rectified by changing diet and lifestyle components, as well as by acupuncture treatment.

Prior to trial entry, women used a variety of self-care strategies, most commonly rest and the usage of heat. The TCM self-care advice given by their study practitioners was implemented by most women who linked the advice to improvements in their menstrual pain and other symptoms of primary dysmenorrhea.

TCM acupuncture is a safe and effective intervention for women who suffer from primary dysmenorrhea, reducing pain and secondary symptoms.

Manual acupuncture appears to be superior to electro-acupuncture in the reduction of analgesic usage.

Self-care advice is a key component of the acupuncture intervention and has significant psychological and physiological effects.
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Appendices

A1 Patterns underlying primary dysmenorrhea
A2 New Zealand and Australian Practitioner survey
A3 Survey announcement email sample
A4 Covering letter and information sheet for practitioner survey
A5 UWS Ethics approval (H9866) for practitioner survey/focus groups and interviews.
A6 Consent form and information sheet for practitioner focus groups and semi-structured interviews.
A7 Practitioner data sheet for primary dysmenorrhea.
A8 Question schedule for focus groups and practitioner interviews.
A9 Google keywords used in advertising the RCT
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A12 RCT/post trial interview consent form and information sheet
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A16 Ethical approval for RCT and post-trial interviews (H10082) and (13CEN/60)
A17 Interview schedule for post trial interviews
A18 Protocol manual for the RCT.
A19 Adverse events sheet
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A21 Smith, Armour and Betts (2014) - Treatment of women's reproductive health conditions by Australian and New Zealand acupuncturists.
A22 Search strategies for literature review.
A23 Table of primary outcomes for included RCTs.