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A Mixed Methods Study of Acupuncture Treatment for Chronic Pelvic Pain in Women

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Declaration

This is to certify that I have composed the work contained within. Where others have been involved, this has been acknowledged. No part of this thesis has been submitted for any other degree or professional qualification.

Signed:

Date:
Abstract

Chronic pelvic pain (CPP) is defined as constant or intermittent lower, cyclical or non-cyclical abdominal pain of at least six months’ duration. In the United Kingdom, over 1 million women suffer from CPP, with an estimated annual healthcare cost above £150 million. The aetiology of CPP is unknown in up to 50% of women, and in the remainder, the symptoms of CPP is associated with endometriosis, pelvic adhesions, irritable bowel syndrome or painful bladder syndrome. CPP is often accompanied by painful periods, pain during sexual intercourse and defaecation. Fatigue, sleep disturbances and depression are also common among this group of women. CPP asserts a heavy emotional, social and economic burden. Standard treatments such as hormonal and analgesic regimens are often associated with unacceptable side effects, even if helpful for the pain, underlining an urgent need for a satisfactory treatment. The meridian balanced method (BM) electro-acupuncture (EA) treatment (acupuncture needling + traditional Chinese medicine health consultation [TCM HC]) may be effective in managing CPP symptoms. Thus, I have completed a pilot study comprising of a three-armed randomised controlled trial (RCT), using a mixed methods research (MMR) approach, to assess the feasibility of a future large-scale RCT to determine the effectiveness of the meridian BMEA treatment on CPP in women. My hypothesis is that it is feasible to conduct such a large-scale RCT for CPP in women. The primary objectives were to determine recruitment and retention rates. The secondary objectives were to evaluate the, acceptability of the methods of recruitment, randomisation, interventions and assessment tools and any signals of effectiveness of the interventions.

Thirty (30) women with CPP were randomised into three groups: BMEA treatment, TCM HC, or National Health Service standard care (NHS SC) group. The effects of my interventions were assessed by validated pain, physical and emotional functioning questionnaires, completed at weeks 0, 4, 8 and 12 of the study. Semi-structured telephone interviews and focus group discussions to explore participants’ experience of the study were conducted.

Of the 59 women who were referred to the study, 30 women (51%) were randomised. There was a statistically significant difference in retention rates between the three groups. The retention rates were 80% (95% CI 74-96), in the BMEA treatment group, 53 % (95% CI 36-70) in the TCM HC group and 87% (95% CI 63-90) in the NHS SC group. (Chi-square test, p=0.08) The attendance rates of the BMEA treatment group were 90% compared to 56% in the TCM HC group. There was a statistically significant difference (Mann-Whitney test,
Telephone interviews regarding the acceptability of the methods of recruitment, randomisation, assessment tools and interventions were positive. No adverse effects that were directly related to BMEA treatments were reported or observed.

A higher proportion of the BMEA treatment group achieved clinical significance in the VAS-pain, BPI-pain severity, interference, and sleep scores, when compared to the other two groups. Due to small sample sizes, there was insufficient power to show statistically significant difference. (Fishers Exact Test, p=1.0)

Analyses of the questionnaire data per group showed statistically significant differences in the following: the BMEA treatment group experienced less in pain at weeks 4 (p=0.01) and 8 (p=0.005); less helplessness (p=0.03) and their anxiety and depression scores declined at week 4 (p=0.04). The NHS SC group also reported less pain at week 4 (p=0.04). However, this group scored higher in anxiety and depression at weeks 8 and 12 (p=0.04).

No statistically significant differences were achieved between the three groups at baseline, weeks 4, 8 and 12 in all scores. The therapeutic benefits gained by the TCM HC group were less compared to those of the BMEA treatment group, but better when compared to the NHS SC group. The BMEA treatment and TCM HC groups showed lower scores in anxiety and depression while the NHS SC group showed higher scores in anxiety and depression. The NHS SC group also tended to ruminate and magnify their problems as well as feeling more helpless than the other two groups.

The three key themes that emerged from thematic analysis of focus group discussions were the “whole person effects” where participants reported an improvement in pain, sleep and a general sense of wellbeing in the two intervention groups; the “experience of standard care” and “impact of living with CPP”.

In conclusion, the results of my pilot study are supportive of the feasibility of a future large-scale study. There were signals of effectiveness of interventions but the sample size was too small to make a definitive conclusion.
Lay Abstract

Chronic pelvic pain (CPP) is common among women in the United Kingdom. We do not know the exact cause(s). Women who suffer from CPP may have painful periods, pain during sex or on going to the toilet. This group of women often feels anxious and down. There is no one cure for CPP but it can be managed by medications or surgery. However, there can be side effects with these treatments.

I proposed that acupuncture treatment might be helpful for women with CPP. Some acupuncture studies on other chronic painful conditions seemed to indicate a reduction in pain. To find out if acupuncture treatment is helpful, I need to do a big study. Before doing so, first I needed to do a small study, called a pilot study, to find out if the large study is doable. I completed a pilot study on women with CPP who volunteered to be in the study. Volunteers with CPP who helped in the study, randomly (toss of a coin) received 1 of 3 treatments: acupuncture treatment, Chinese medicine health consultation, or standard treatment provided by the National Health Service (NHS). The objectives of my study were to find out if I had enough volunteers to take part, how many would stay till the end of the study and if the way my study was conducted was acceptable to the volunteers. Also my study wanted to see if there were any signs that the acupuncture treatment and the Chinese medicine health consultation had helped the volunteers. To do this I asked the volunteers to complete some paper questionnaires. The volunteers attended group discussions to talk about their experience of the study. I also asked each volunteer via telephone her opinion of the way my study was conducted.

Thirty (30) women with CPP volunteered for my study. Almost three quarters of the volunteers completed my study. Individual telephone conversations regarding the way my study was conducted, were positive. There were some signs that the acupuncture treatment was more helpful than the Chinese medicine health consultation and NHS standard treatment. In the group discussions, some volunteers in the acupuncture treatment group and the Chinese medicine health consultation group reported that they had less pain, slept better and generally felt better when compared to the group that received NHS standard treatment.

In conclusion, the results of my pilot study showed that a future large-scale study of acupuncture treatment for CPP in women is doable. Unlike a pilot study, a future large-scale study will be able to show if acupuncture treatment is helpful for women with CPP.
Preface

My thesis is composed of six chapters.

Chapter One outlines the theme of my thesis, which is the potential for acupuncture treatment as a management strategy for chronic pelvic pain (CPP) in women. It describes the key clinical background and the challenges of CPP in women, and in acupuncture research. I begin with an overview of CPP, its financial, social and emotional impact on the lives of women as well as its standard medical and surgical management. Chapter One also draws attention to the lack of satisfactory standard management of CPP. Large-scale studies using acupuncture on other chronic pain conditions such as headache and osteoarthritis of the knee showed some efficacy. Thus, I proposed that acupuncture treatment might be helpful in managing the symptoms of CPP. My thesis goes on to explore the feasibility of a future multi-centre RCT to evaluate the role of acupuncture treatment in the management of CPP.

Chapter Two focuses on the methodology of my pilot study of acupuncture treatment in CPP, which utilised an embedded mixed methods research (MMR) design to capture the quantitative data and the subjective experience of the participants of the study, via focus group discussions and semi-structured telephone interviews. A reflective journal was kept throughout the study. Writing a reflective journal is an attempt to make my thoughts and feelings available to others and myself in order to call attention to any bias that I might have as a researcher and practitioner. Interventions were audio-recorded to ensure standardisation of procedures.

Chapter Three presents the methods and materials employed to meet the objectives of my study. It provides a full account of the protocol for choosing the therapeutic acupuncture points in the chosen acupuncture treatment for my study which is the meridian balance method (BM) electro-acupuncture (EA) treatment. Additionally, this chapter describes how the focus group discussions were conducted and how the data were thematically analysed. To ensure independence, the focus group discussions were led by Dr. G Highet, University of Edinburgh (UoE). The results of the quantitative data, focus group discussion findings and telephone interviews are presented in separate chapters.

Chapter Four presents the quantitative results from the analysis of the questionnaire data by clinical significance, per group and between groups. Analyses of the questionnaire data were
performed with the help of a statistician, Dr Linda J Williams, UoE. A full discussion of results is presented in Chapter Six.

*Chapter Five* describes the findings of the focus group discussions. I conducted the thematic analyses of the focus groups data and telephone interviews. A discussion of the findings is presented in this chapter.

*Chapter Six* discusses the outcome of my pilot study and critically evaluates their implications. The strengths and limitations are outlined and recommendations offered.
Acknowledgements

The journey of a thousand li, starts with the first step…
(From an old Chinese proverb)

To those who accompanied me in my thousand li journey, I would like to express my sincere and heartfelt gratitude and appreciation to:

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GLOSSARY of CHINESE MEDICINE TERMS

1. Ashii Points
These are tight and tender points in the muscles.

2. Acupuncture Treatment
There are three components to acupuncture treatment: traditional Chinese medicine health consultation (TCM HC), acupuncture needling component and the environment in which the treatment is given.

3. Chinese Medicine Diet
Food as medicine is a concept used often in Chinese medicine. Food is also understood in terms of yin/yang i.e. food is selected based on the patient’s presentations. For example, patients who are cold and dry need warm and rehydrating foods; patients who are hot and damp need drying food; patients who are depleted need replenishing food. Thus food that is good for one patient is not necessarily appropriate for another. Dietary recommendations that based on Chinese medicine is individualized to the patient’s condition, whether (s)he is hot or cold, damp or dry or recovering from an illness. (Benfield, 1991)

4. Eight Principles and Pattern Diagnosis
One of the several methods used for pattern diagnosis in Traditional Chinese medicine is the “eight principles”. The objective of pattern diagnosis is to formulate a pattern that best reflects the patient’s condition in order to guide treatment. Pattern diagnosis according to the eight principles is based on Interior/Exterior, Hot/Cold, Full/Empty and Yin/Yang. It sets out to organize these sets of parameters and interpret how they are related to each other. It takes into account the physical, emotions and lifestyle of the patient. The yin/yang theory is applied here for example, Interior is yin and Exterior is yang, Hot is yang and Cold is yin, Full is yang and Empty is yin. (Maciocia, 1989)

5. Three Jiaos/Heaters
In Chinese medicine the body is divided into three Jiaos or Heaters: the Upper Jiao, the Middle Jiao and the Lower Jiao. The function of the three Jiaos is primarily that of fluid metabolism. The Upper Jiao corresponds to the Lung and Heart organ system, the Middle Jiao to the Spleen and Stomach, Liver and Gallbladder organ
system and the Lower Jiao the Bladder, Kidneys and the Intestines system. (Maciocia, 1989)

The Tongue Correspondence to the Three Jiao (below)

6. Tongue Examination

Tongue examination is an important part of Chinese medicine. Examination of the tongue offers an immediate method of discerning a patient’s physical as well as emotional status. The upper section of the tongue corresponds to the Lungs and Heart organ system (upper Jiao). The middle section corresponds to the Liver, Gallbladder, Stomach and Spleen organ system. The lower section corresponds to the Kidney, Bladder and Intestines system. These mapping or correspondences are very useful in tongue examination.
7. **Yin Yang**

This is probably the most important Chinese medicine theory. Yin Yang theory is the comparison of two opposites and yet complementary qualities, for example hot (yang) / cold (yin), back (yang)/front (yin) of the body, white (yang)/black (yin), day (yang)/ night (yin) and man (yang)/woman (yin). The Yin- Yang theory has great applications in Chinese medicine. Yin Yang important qualities include, interdependence, mutual consumption, opposition, and ability to transform each other.

The Yin Yang Symbol  (http://www.balancedhorsevet.com/blog/2015/1/9/yin-yang on 21 November 2016)
List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ACCORD</td>
<td>Academic and Clinical Central Office for Research and Development</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
<tr>
<td>ART</td>
<td>Acupuncture Research Trials</td>
</tr>
<tr>
<td>BAcC</td>
<td>British Acupuncture Council</td>
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<tr>
<td>BM</td>
<td>Balance method</td>
</tr>
<tr>
<td>BDI</td>
<td>Beck Depression Inventory</td>
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<tr>
<td>BMAS</td>
<td>British Medical Acupuncture Society</td>
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<tr>
<td>BMEA</td>
<td>Balance method electro-acupuncture</td>
</tr>
<tr>
<td>BMEA treatment</td>
<td>Balanced method electro-acupuncture treatment and TCM HC</td>
</tr>
<tr>
<td>BOTOX</td>
<td>Botulinum toxin</td>
</tr>
<tr>
<td>BPI</td>
<td>Brief Pain Inventory</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>CCM</td>
<td>Classical Chinese medicine</td>
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<tr>
<td>CM</td>
<td>Chinese medicine</td>
</tr>
<tr>
<td>CPP</td>
<td>Chronic pelvic pain</td>
</tr>
<tr>
<td>CRF</td>
<td>Case record form</td>
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<tr>
<td>DIE</td>
<td>Deeply infiltrating endometriosis</td>
</tr>
<tr>
<td>EA</td>
<td>Electro-acupuncture (stimulation of needles with micro-current)</td>
</tr>
<tr>
<td>ESHRE</td>
<td>European Society of Human Reproduction and Embryology</td>
</tr>
<tr>
<td>EXPPECT</td>
<td>Edinburgh Centre for Pelvic Pain and Endometriosis Care and Treatment</td>
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<tr>
<td>GERAC</td>
<td>German Acupuncture Trials</td>
</tr>
<tr>
<td>GnRH</td>
<td>Gonadotropin Releasing Hormone</td>
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<tr>
<td>IBS</td>
<td>Irritable bowel syndrome</td>
</tr>
<tr>
<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
</tr>
<tr>
<td>HRT</td>
<td>Hormone replacement therapy</td>
</tr>
<tr>
<td>JA</td>
<td>Japanese acupuncture</td>
</tr>
<tr>
<td>LUNA</td>
<td>Laparoscopic utero-sacral nerve ablation</td>
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<tr>
<td>MA</td>
<td>Manual stimulation of acupuncture needles</td>
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<tr>
<td>MMR</td>
<td>Mixed methods research</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
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<tr>
<td>MPS</td>
<td>Myofascial pain syndrome</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Clinical Excellence</td>
</tr>
<tr>
<td>NCCAOM</td>
<td>National Certification Commission for Acupuncture and Oriental Medicine</td>
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<tr>
<td>NHS SC</td>
<td>National Health Service standard care</td>
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<tr>
<td>OCPs</td>
<td>Oral contraceptive pills</td>
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<tr>
<td>PBS</td>
<td>Painful bladder syndrome</td>
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<tr>
<td>PCQ</td>
<td>Pain Catastrophising Questionnaire</td>
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<tr>
<td>PID</td>
<td>Pelvic inflammatory disease</td>
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<tr>
<td>PIS</td>
<td>Patient information sheet</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>RIE</td>
<td>Royal Infirmary of Edinburgh</td>
</tr>
<tr>
<td>SAQ</td>
<td>Sexual Activity Questionnaire</td>
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<tr>
<td>SCRH</td>
<td>Simpson Centre for Reproductive Health</td>
</tr>
<tr>
<td>SF-12</td>
<td>Short Form 12</td>
</tr>
<tr>
<td>SF-16</td>
<td>Short Form 16</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for Social Sciences</td>
</tr>
<tr>
<td>STRICTA</td>
<td>Revised Standards for Reporting Interventions in Clinical Trial in Acupuncture</td>
</tr>
<tr>
<td>TA</td>
<td>Traditional acupuncture</td>
</tr>
<tr>
<td>TCM</td>
<td>Traditional Chinese medicine</td>
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<tr>
<td>TCM HC</td>
<td>Traditional Chinese medicine health consultation</td>
</tr>
<tr>
<td>TP</td>
<td>Trigger point</td>
</tr>
<tr>
<td>UoE</td>
<td>University of Edinburgh</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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<tr>
<td>WPAIQ</td>
<td>Work Productivity and Activity Impairment Questionnaire</td>
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Chapter One  Introduction

1  Background

The primary intent of my thesis is to determine the feasibility of a future multi-centre randomised controlled trial (RCT) to evaluate the effectiveness of the meridian balance method (BM) electro-acupuncture (EA) treatment in addressing the symptoms associated with chronic pelvic pain (CPP) in women. Thus I have undertaken a pilot study in a three-armed RCT using a mixed methods research (MMR) approach. To my knowledge, this is the first study that utilised the meridian BM acupuncture style for CPP in women.

CPP is often associated with gynaecological, urological gastrointestinal, and musculoskeletal conditions such as endometriosis, painful bladder syndrome (PBS), irritable bowel syndrome (IBS) and spasm of the pelvic floor respectively. However, about one third of the women referred for diagnostic laparoscopy, were found to have no underlying pathology. (Howard, 2000) Treatment for CPP is complex, challenging and is often presented in literature as unsatisfactory. A significant number of women with CPP develop chronic pain syndrome with anxiety, depression, fatigue, sleep disturbances that ultimately impact on their career, home and social life.

Very few studies have been undertaken to evaluate the effectiveness of acupuncture on CPP in women. Large-scale acupuncture studies on other chronic pain conditions such as backache and headache have demonstrated some effectiveness.

The purpose of the present chapter is to set the scene for my thesis by introducing the important clinical issues surrounding CPP and research in acupuncture.

1.1  Chronic Pelvic Pain in Women

CPP is a major women’s health issue. The management of CPP symptoms is complex and treatment is often unsatisfactory. (Cheong, 2006) The debilitating effects of CPP reverberate throughout the life-span of a significant number of women and impact negatively on almost all aspects of their lives such as their emotions, relationships and work. (Sundell et al., 1990)

Pain, whether chronic or acute, is a very distressing experience. The experience of pain is multi-dimensional, fiercely subjective and private and it is not easy to measure. (Melzack, 1984) CPP is a symptom and not a diagnosis. Its definitions are based broadly on its duration, anatomical location and psycho-emotional-behavioural aspect (Mathias et al.,
1996). The most commonly cited definition is “cyclical or non-cyclical pain in the lower abdomen or pelvis, of at least six months’ duration, occurring continuously or intermittently, that causes functional disability or limits activities of daily living”. (Daniels et al., 2010) The Royal College of Obstetricians and Gynaecologists (RCOG) defined CPP as “intermittent or constant pain in the lower abdomen or pelvis of at least 6 months duration, not occurring exclusively with menstruation or intercourse and not associated with pregnancy”. (Kennedy and Moore, 2005) CPP has also been defined as “non-cyclical pain of more than 6 months duration and is of sufficient severity to cause functional disability or medical care”. (Merskey, 1986) There is no one unified definition of CPP. This is problematic when it comes to estimating its real incidence or prevalence.

1.2 Epidemiology of CPP

Table 1.1 (page 3) presents the estimates of the prevalence of CPP in the United Kingdom (UK), United States of America (USA) and the world. The real prevalence is difficult to ascertain due to the lack of a unified definition of CPP and also not all women who suffer from CPP seek medical treatment. (Zondervan et al., 2001)

CPP is the most common indication for referral to gynaecology clinics. According to one study, CPP is responsible for 40% of referrals for diagnostic laparoscopy and about 50% of these referrals are found to have no apparent underlying pathology. (Howard, 2000)

In the UK, CPP is estimated to affect over one million women. (Davies et al., 1992) In a postal questionnaire survey, 74% of a randomly selected cohort of 3916 women aged 18 to 49 responded. (Zondervan et al., 2001) Of these, 24% had experienced CPP in the last three months. One third of these women reported that they had had CPP for more than five years and a quarter of them did not have a diagnosis for three to four years. Forty-one percent (41%) of the women in the study had not visited a healthcare provider in the previous year, implying that the prevalence was probably higher and that they were coping with the problem by themselves. An updated review of the prevalence of CPP in women world-wide ranged from 5.7-26.6%. (Ahangari, 2014)
Table 1.1 Estimates of the Prevalence of CPP

<table>
<thead>
<tr>
<th>Types of studies</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK community based population (Zondervan et al., 2001)</td>
<td>24%</td>
</tr>
<tr>
<td>UK national general practice database (Zondervan et al., 1999b)</td>
<td>3.7 to 4.1%</td>
</tr>
<tr>
<td>UK Hospital based population (Mahmood et al., 1991)</td>
<td>39% (incident rate)</td>
</tr>
<tr>
<td>USA Survey of households, women aged 15-50 (Mathias et al., 1996)</td>
<td>14.7%</td>
</tr>
<tr>
<td>Outpatient gynaecology (Reiter, 1990)</td>
<td>2-10%</td>
</tr>
<tr>
<td>Systematic review (Latthe, 2006)</td>
<td>2.1 to 24%</td>
</tr>
<tr>
<td>Systematic review (Ahangari, 2014)</td>
<td>5.7-26.6%</td>
</tr>
</tbody>
</table>

### 1.3 Management of CPP

Although the underlying pathophysiology of CPP in the majority of cases is unclear, we can hypothesise on the underlying neurobiological mechanisms of the pain. These are likely to be any combination of visceral, neuropathic, and musculoskeletal and or myofascial pain, in an individual patient. The role of an inflammatory process is always questioned. Treatments are, of course, dependent on what is thought to be the underlying cause. For example, for endometriosis associated pain empirical treatment with analgesics and hormonal medication can be used before a diagnosis is made. If treatment results are unfavourable, a diagnostic laparoscopy can be performed to exclude or diagnose endometriosis. (Dunselman et al., 2014)

The use of analgesia is based on the World Health Organisation (WHO) analgesic ladder for chronic pain starting with non-opioid e.g. salicylates, paracetamol, non-steroidal anti-inflammatory drugs (NSAIDS), progressing to a weak (e.g. codeine, co-codamol), then stronger opioid (e.g. oxycodone) if necessary. (Vargas-Schaffer, 2010) However, chronic pain practices are often not based on strong evidence and change over time as a result of emerging side effect issues and/or the preferences of the patients or the treating physicians.
Currently strong opioids have fallen out of favour in many chronic pain practices. Like most medications, non-opioid and opioid analgesics have unwanted side effects such as nausea, dry mouth and constipation. An understanding of the opioid side effect profile is evolving and in some patients may include endocrine and immune side effects. (Ballantyne and Mao, 2003)

Ideally and if available, patients with CPP should have a multi-disciplinary approach. However, currently the only centre in Scotland that offers a multi-disciplinary approach is the Edinburgh Centre for Pelvic Pain and Endometriosis Care and Treatment (EXPPECT) at the Royal Infirmary of Edinburgh (RIE). Most women with CPP are managed by a single healthcare professional, for example the general practitioner, gynaecologist or gastroenterologist.

Independent from pain management programmes or a multi-disciplinary approach, counselling, cognitive behavioural therapy (CBT) and psychotherapy are other options, although these can be time consuming, which may deter women from using such services. In a systematic review and meta-analysis of RCTs of 25 controlled trials of cognitive behaviour therapy for chronic pain, the authors concluded that active cognitive behaviour treatments are relatively effective compared to waiting list. CBT resulted in significant changes in pain, mood or social functioning. (Morley et al., 1999)

1.4 Management of Conditions Associated with CPP

In this section, I will give an overview of the management of the most common conditions that are associated with CPP. These include endometriosis, adhesions, musculoskeletal pain and myofascial pain syndrome (MPS), PBS and IBS and CPP of unknown aetiology.

1.4.1 Endometriosis

Endometriosis is an oestrogen-dependent chronic inflammatory disease and is defined as the presence of endometrial-like tissue outside the uterus. (Kennedy et al., 2005, Mounsey et al., 2006) It is estimated to affect one in ten women of reproductive age which equates to 176 million women worldwide. (Adamson et al., 2010) A high proportion (96.9%) of these women were reported to become pain free after menopause. (Fagervold et al., 2009) The underlying cause is unknown and it is characterised by debilitating pelvic pain (see Table 1.2 page 5) and subfertility. Endometrial glands can also be found in the myometrium and this is also associated with chronic pain and especially dysmenorrhoea. This condition is called adenomyosis.
**Table 1.2 Types of Pain and Endometriosis Lesions.**

<table>
<thead>
<tr>
<th>Types of Pain Associated with Endometriosis</th>
<th>Types of Endometriosis Lesions</th>
</tr>
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<tbody>
<tr>
<td>Dysmenorrhoea</td>
<td>Superficial peritoneal endometriosis</td>
</tr>
<tr>
<td>Painful sexual intercourse</td>
<td>Deeply infiltrating lesions (DIE)</td>
</tr>
<tr>
<td>Non-menstrual pain</td>
<td>Ovarian (cystic) endometriosis</td>
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<tr>
<td>Painful bowel movement</td>
<td></td>
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<tr>
<td>Pain on micturition</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
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</table>

About a third of the women with CPP who undergo a diagnostic laparoscopy are found to have endometriosis. (Howard, 2000) Table 1.2 (page 5) presents the different types of endometriosis and the associated pain. The types of endometriosis are superficial peritoneal endometriosis, deeply infiltrating endometriosis (DIE) and ovarian (cystic) endometriosis. (Brosens et al., 1993, Nisolle and Donnez, 1997) Endometriosis is often associated with conditions such as PBS, migraine and IBS. The constellation of pain experienced by women with endometriosis includes dysmenorrhoea, pain during intercourse, defecation and urination as well as non-menstrual pain and chronic pelvic-abdominal pain. (Mirkin et al., 2007) The severity of pain associated with endometriosis is poorly correlated with the location or extent of endometriosis lesions. (Vercellini et al., 2007, Parazzini, 2001)

Endometriosis is a significant burden to health services as women with endometriosis have the highest mean number of visits to the gynaecologist in one study. (Mathias et al., 1996) The burden of endometriosis is also seen to reduce economic and personal productivity as well as quality of life. (Simoens et al., 2012)

There is no cure for endometriosis at the present. Medical approaches and surgery are the main strategies for managing the symptoms associated with endometriosis. The main summary of the updated European Society of Human Reproduction and Embryology (ESHRE) guideline for the optimum management of women with endometriosis is presented in Sections 1.4.1.1 to 1.4.1.5 (Dunselman et al., 2014)

**1.4.1.1 Empirical Treatment of Pain**

As presented in Section 1.3, non-steroidal anti-inflammatory drugs (NSAIDs) and hormonal therapies are recommended for women with CPP prior to a diagnosis. Although there is no
convincing evidence to support the use of NSAIDs for endometriosis, NSAIDs reduce pain on primary dysmenorrhoea and are thus widely used as a first line treatment of endometriosis-associated pain. (Marjoribanks et al., 2010) However, the risks with the frequent use of NSAIDs include inhibition of ovulation, gastric ulceration and cardiovascular disease. (Bata et al., 2006) If patients do not respond well to these treatments, laparoscopic surgery is recommended as the next step to exclude or diagnose endometriosis. (Dunselman et al., 2014)

1.4.1.2 Hormonal Therapies
Hormonal therapies such as the combined oral contraceptive pills (OCPs), progestogens (steroid hormones) and anti-progestogens, gonadotrophin releasing hormone agonist (GnRH) are used for endometriosis-associated pain with effect. There is no significant evidence to support the use of one over the other and thus it is up to the clinician and patient preferences. (Dunselman et al., 2014)

OCPs are widely used for endometriosis-associated pain. OCPs are generally well tolerated and symptom relief may be achieved in 75-100% of women with endometriosis. Combined OCPs are effective in reducing endometriosis-related dyspareunia, dysmenorrhoea and non-menstrual pain. (Vercellini et al., 1993, Moghissi, 1999) Besides OCPs, the vaginal contraceptive ring or a transdermal (oestrogen/progestin) patch is another option for endometriosis-associated dyspareunia, dysmenorrhoea and non-menstrual pain. (Vercellini et al., 1993)

1.4.1.3 Progestogens and Anti-Progestogens
Progestogens are a class of steroid hormones that bind to and activate the progesterone receptor. The ESHRE Guideline recommended the use of progestogens (e.g. medroxyprogesterone [oral or injection], dienogest or danazol), or anti-progestogens such as gestrinone but cautioned the side effects of such therapies especially irreversible ones like thrombosis and androgenic effects. (Dunselman et al., 2014)

Progestogens like dienogest and provera can be given orally or as injection (Depo-provera) or as a T-shaped intra-uterine device that can remain in the uterus for up to five years. (Schweppe, 2001, Ferreira et al., 2010). However, a small study (n=37) by Lookhat and colleagues, showed that 15 (41%) women had to have the coil removed by month 23 because of side effects such as weight gain and persistent abdominal pain. (Lookhat et al., 2005)
Danazol is a synthetic testosterone. It induces amenorrhea and is helpful with pain reduction although less so with dyspareunia. (Moghissi, 1999) The associated side effects are for example, hirsutism, weight gain, hot flushes and oily skin. Since the introduction of GnRH, Danazol is used less because of its side effects.

1.4.1.4 Gonadotropin Releasing Hormone Agonist (GnRH)

GnRH agonists, (goserelin or buserelin) “a medical oophorectomy”, induce an artificial menopause and are usually given three monthly or daily by injection, alternatively there is a nasal spray. (Ihara et al., 2001) Endometriosis generally recurs within 9 to 12 months once GnRH has stopped. Women on prolonged GnRH are recommended to use hormone replacement therapy (HRT) to prevent bone density loss, a potentially serious problem. Other side effects include mood swings, dry vagina and low libido. Although GnRH is recommended as another option, the ESHRE Guideline (Dunselman et al., 2014) stressed that there is no evidence that GnRH is effective for endometriosis-related pain. (Brown et al., 2010)

1.4.1.5 Surgery

Laparoscopic surgical removal via excision or ablation (drainage and coagulation) or both is considered effective in managing endometriosis related pain. (Jacobson et al., 2009) RCTs have not demonstrated that excision is more effective than ablation, although the consensus is to excise lesions where possible especially deep lesions. (Healey et al., 2010, Wright et al., 2005) Importantly it has been shown that the first definitive surgical intervention delivers the greatest benefit with pain improvement at six months at around 83%, compared to 53% for the second operation. (Abbott et al., 2004) Although laparoscopic removal of endometriosis is recommended as another option for endometriosis related pain, intervention with surgery largely depends on the severity and what other organs are affected. For women with mild or moderate endometriosis, surgical treatment is found to be better than a “wait and see” approach. (Sutton et al., 1997) Women who had the excision experienced fewer symptoms 12 months (Abbott et al., 2004) and 18 months (Sutton et al., 1997, Sutton et al., 1994) after surgery compared with those who had a laparoscopy without excision. For ovarian endometriosis laparoscopic excision (cystectomy) is recommended instead of ablation. (Hart et al., 2008)

Surgery for DIE can be recommended to reduce pain and improve quality of life. (De Cicco et al., 2011) However, surgery is complex because of the extensive disease and there is no evidence as to which is the best strategy. Incomplete resection may reduce symptoms
and radical interventions may have major complications such as ureteric and rectal injuries. (Koninckx et al., 1996) Because of these factors, it is recommended that it should only be undertaken in a highly specialised surgical centre. (Johnson et al., 2013)

The role of hysterectomy and oophorectomy is still being debated, as there is little evidence to inform practice. Observational studies have suggested that women experience pain relief after hysterectomy and some improvement in the quality of life, although it will not necessarily cure the symptoms or disease. (Ford et al., 2004)

Laparoscopic utero-sacral nerve ablation (LUNA) is no longer recommended as considerable evidence has demonstrated that LUNA is not effective in decreasing dysmenorrhoea, dyspareunia or non-cyclical pain. However, in an individual patient meta-analysis of RCTs on the effectiveness of LUNA in CPP, Daniels and colleagues found that common to all trials, was a marked improvement in pain scores in both LUNA and no LUNA groups following laparoscopy. (Daniels et al., 2010) Arguably, this improvement might be due to placebo effect associated with the reassurance provided by the procedure or regression to the mean. (Daniels et al., 2009) If indeed the improvement in pain scores were due to the placebo effect, there could be great value in harnessing the power of this effect in clinical practice, although I am not advocating subjecting women to unnecessary surgery.

Pre-sacral neurectomy is not widely used because of its associated high incidence of constipation. (Daniels et al., 2009, Daniels et al., 2010)

Although surgery can remove endometriosis lesions, it is generally acknowledged that even after expert removal of lesions, endometriosis can recur. The recurrence rates of symptom and endometriosis lesions vary from 10%-55% within 12 months and highest among women in the twenties. (Vercellini et al., 2003) This group of women may need repeated surgical intervention or other form of management.

Complications from laparoscopic surgery for endometriosis are significantly correlated with the complexity of the procedure and the experience of the surgeon. In a multi-centre study (n=29,966), any increase in the surgeons’ experience correlated, for example, with a statistically significant drop in the number of bowel injuries (p=0.0003). (Chapron et al., 1998) Complications could vary from mild (nausea, shoulder pain, fatigue) to severe such as rectal perforation and recto-vaginal fistula.
1.4.2 Adhesion

Adhesions are abnormal bands of scar tissue that cause organs to connect together leading to the distortion of the pelvic anatomy. Adhesions were found to have nerve fibres where the tissue from 17 patients with chronic pain was examined using immunohistochemistry. (Kligman et al., 1993) Having nerve fibres in the adhesion tissue may explain why some adhesions cause pain. The risk factors for pelvic adhesions include endometriosis, a history of pelvic inflammatory disease (PID) and surgeries. (Brill et al., 1995) Between 70-85% of adhesions are estimated to occur after surgery. (Peters, 2008) For example, trapped ovarian syndrome and ovarian remnant syndrome are thought to cause pain. Ovary syndrome is when a piece of ovary becomes trapped in dense adhesions post-hysterectomy. Ovarian remnant, as the name suggests, is when a piece of ovary is unintentionally left behind and trapped in adhesions at oophorectomy. (Vincent, 2009) Adhesions can be vascular or avascular, transparent or dense and may play a major role in CPP, although there are disagreements as to whether adhesions cause CPP. (Alexander-Williams, 1987, Thornton et al., 1997) According to one study, adhesions are responsible for almost 24% of CPP. A meta-analysis of over 300 women with CPP showed that adhesions are present in 36% of women compared with 15% of the 2000 controls. (Saravelos et al., 1995) A Cochrane review on the interventions for CPP, found that surgical treatment (adhesiolysis/division/excision) of severe adhesions appears to be beneficial. (Stones and Mountfield, 2000) In an updated Cochrane Review the authors concluded “there is still uncertainty about the place of adhesiolysis among patients presenting to gynaecologists and the conclusion of this review is that there is no evidence of benefit, rather than evidence of no benefit”. (Stones W, 2005)

1.4.3 Musculoskeletal Pain and Myofascial Pain Syndrome

The terms musculoskeletal pain and myofascial pain syndrome (MPS) are often used interchangeably and can be associated with CPP. Musculoskeletal pain is felt at the muscular level, whereas myofascial pain refers to a specific syndrome caused by the presence of trigger points. Musculoskeletal pain is an important but much neglected topic in the discourse of CPP. It is estimated that musculoskeletal pain is responsible for 22% of CPP in women. (Tu et al., 2005) Examples of painful musculoskeletal conditions are pelvic floor spasm, trigger point in the myofascia of abdominal wall, muscular strains and sprains. In a study of 177 women with CPP, 74% had abdominal wall trigger points, 71% had focal pain in the vaginal wall involving the levator ani, obturator internus and piriformis muscles. (Slocumb, 1984) Of course, any pain can give rise to secondary musculoskeletal pain and it is a common accompaniment.
MPS is one example of musculoskeletal pain. There is no universally accepted diagnostic criterion for MPS. (Giamberardino et al., 2011) Travell defined MPS as a “complex of sensory, motor and autonomic symptoms” that are caused by trigger points. (Travell, 1993) Trigger points (TPs) are a discrete, tight and tender taut band of skeletal muscle. If sufficiently hypersensitive, they refer pain to other areas of the body. (Travell, 1993)

Women with CPP that is associated with musculoskeletal disorder, typically have pain in the low back that radiates to the sacrum, gluteal, groin, leg, vagina, rectum or lower abdomen. The pain is described as aching, throbbing, heaviness or as pelvic pressure. In some women, the pain can be severe and acute.

Pelvic floor spasm refers to disorders related to hypotonus or hypertonicity which can cause dyspareunia, low back pain, constipation alternating with diarrhoea, gas, painful defecation, frequency and urgency or nocturia. Pelvic floor spasm generally responds well to physiotherapy and injection of botulinum toxin (BOTOX) into the pelvic floor muscles. (Jarvis et al., 2004) However, another study (n=40) by Porta and colleagues evaluated patients with chronic MPS in the piriformis and iliopsoas muscles following BOTOX injections. Patients received either 13 BOTOX or four steroid injections. At 30 days and 60 days pain reduction in the BOTOX group was significantly lower than those in the steroid injection group. (Porta, 2000)

In a systematic review of existing therapies for musculoskeletal causes of CPP, the authors reported that only one study used control groups. This study (n=44) evaluated the effect of exercise on peri-partum pelvic pain. It compared diagonal trunk exercises, with longitudinal trunk exercises and no exercise. This study failed to observe a difference in mean VAS score between groups. (Mens et al., 2000) The remainder were uncontrolled case series. The authors concluded that well designed RCTs are urgently needed to determine the effectiveness of treatments of pelvic musculoskeletal pain. (Tu et al., 2005)

**1.4.4 Painful Bladder Syndrome**

PBS also known as interstitial cystitis is characterised by pain in the bladder and pelvic area. Other symptoms include urinary frequency, urgency, pain when the bladder is full or during urination, menstruation or sexual intercourse. PBS is ten times more common in women than in men and it is often associated with other conditions such as fibromyalgia and IBS. PBS is a poorly defined and understood condition. It is also difficult to treat. Possible causes of PBS are infection, inflammation, IBS, damage to the bladder lining and the presence of trigger points in the pelvic floor muscles. (Fall et al., 2010) There is no

TPs in the pelvic floor muscles can act as triggers for PBS and can aggravate CPP and dyspareunia. In a small study (n=52) by Weiss, pelvic floor manual therapy helped ameliorate the symptoms of PBS. The participants received manual therapy to the pelvic floor once or twice a week for about 8 to 12 weeks. Outcomes were measured by self-scored symptom sheets. However, in this study there was neither a randomisation nor a control group. (Weiss, 2001)

A systematic review on the management of PBS showed that the most frequently used treatment is oral pentosan polysulfate and botulin A toxin injections. (Giannantoni et al., 2012) However, a double blind RCT (n=369) in a 67 multi-centre trial involving the USA and Canada in adults aged 18 or over with PBS found no statistically significant difference between pentosan and placebo. Participants were randomised to pentosan 100 mg 3 times a day, pentosan 100 mg daily or placebo. The primary endpoint was the number of participants with at least 30% reduction in the interstitial cystitis score.

In a comprehensive review of the treatment for PBS the authors concluded that the knowledge on PBS was “fragmentary and insufficient” and that there is some evidence for the use of oral pentosan polysulfate sodium, amitriptyline and cyclosporin A. (Fall et al., 2010)
Table 1.3 (page 12) shows the list of treatment recommendations for PBS made by The European Association of Urology (EAU).

### Table 1.3 Medical Treatment of PBS
(Fall et al., 2010)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesia</td>
<td>Limited to cases that are awaiting further treatment</td>
</tr>
<tr>
<td>Hydroxyzine (anti-histamine)</td>
<td>Used as a standard treatment, even though there are limited efficacy shown in RCT</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>Standard treatment</td>
</tr>
<tr>
<td>Pentosan polysulfate sodium (PPS)</td>
<td>Standard treatment, data is contradictory</td>
</tr>
<tr>
<td>Cyclosporin</td>
<td>RCT showed that it is superior to PPS but has more side effects</td>
</tr>
</tbody>
</table>

#### 1.4.5 Irritable Bowel Syndrome

IBS is a chronic, relapsing condition of unknown aetiology and significantly diminished the quality of life. (Agrawal and Whorwell, 2006) It is characterised by abdominal discomfort with alternating loose stool and constipation. Other co-morbidities include PBS, back pain, dysmenorrhea, depression and anxiety. IBS affects 10% to 20% of the general population in developed countries (Jones and Lydeard, 1992) and accounts for just over 10.4% of all digestive system diagnoses. IBS is one of the most common syndromes associated with CPP and it is estimated to affect 20%-79% of women with CPP. (Zondervan et al., 1999a, Walker et al., 2009, Longstreth et al., 1990) Hypersensitivity, low-grade inflammation and gastrointestinal infection can contribute to IBS. As in PBS and CPP there is no cure for IBS. Treatments are aimed at symptom management. IBS is generally managed in gastroenterology clinics, however, may present initially to gynaecology clinics.

NICE guidelines for the management of IBS are summarised in Table 1.4 (page 13). (Dalrymple and Bullock, 2008) Lifestyle changes include increase physical activity, an appropriate intake of soluble fibre such as oats (12g dietary fibre a day) and avoidance of insoluble fibres such as bran as these have been found to aggravate IBS. (Francis and Whorwell, 1994) In patients who are sensitive to milk or lactose intolerance, a trial period of low lactose diet is recommended. (McKenzie et al., 2012) The use of single or combination drug therapies are recommended as first line management, such as antispasmodics, anti-motility for diarrhoea and laxatives for constipation. In a systematic review and meta-analysis of the effect of fibre, antispasmodics and peppermint oil, the authors concluded that
these were more effective than placebo for the treatment of IBS. (Ford et al., 2008) The use of tricyclics antidepressants (e.g. imipramine) is recommended as second line treatment. Psychological intervention such as CBT is also considered helpful. Evidence is not robust in the routine use of psychological therapies such as CBT, relaxation therapy or hypnotherapy. (Ford et al., 2009)

Table 1.4 NICE Guidelines for IBS Management
(Dalrymple and Bullock, 2008)

<table>
<thead>
<tr>
<th>Management Strategies</th>
<th>Advice to patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet and lifestyle changes</td>
<td>Increase physical activity&lt;br&gt;Use of soluble fibre e.g. oats&lt;br&gt;Avoid insoluble fibre e.g. bran&lt;br&gt;May try probiotic for at least four weeks&lt;br&gt;Referral to a dietician</td>
</tr>
<tr>
<td>Laxative or anti-motility agent</td>
<td>Dose titration according to stool consistency</td>
</tr>
<tr>
<td>Tricyclic antidepressants</td>
<td></td>
</tr>
<tr>
<td>Psychological interventions</td>
<td>Cognitive behaviour therapy or psychological therapy may be helpful</td>
</tr>
</tbody>
</table>

1.4.6 CPP of Unknown Aetiology

CPP of unknown aetiology can stem from different conditions in which the pathogenesis is poorly understood. (Latthe et al., 2006) Like endometriosis, CPP of unknown aetiology is often associated with conditions such as irritable bowel syndrome, fibromyalgia and painful bladder syndrome. (Howard, 2000, Daniels et al., 2009) CPP of unknown aetiology is most commonly associated with CPP, followed by endometriosis and pelvic adhesions. Of the 40% that are referred for diagnostic laparoscopy, 35% (Howard, 2000) to 55% (Daniels et al., 2009) are found to have no apparent underlying pathology. CPP that has no known aetiology is also referred to as idiopathic chronic pelvic pain. (Daniels, 2010)

There is no consensus as to the best management strategies for women with CPP of unknown aetiology. For this group of women, a multidisciplinary approach has been recommended as best practice. (Cheong, 2006) A study (n=106) by Peters et al., comparing standard treatment with an integrated approach showed a positive outcome in self-rating, daily activity but not in pain scores in the integrated group. In an integrated approach attention was paid to diet, psychological factors, possible organic cause and environmental causes of pain. (Peters et al., 1991) However, a multidisciplinary team approach is not always possible because of the lack of financial resources and professional with the appropriate skills.
In ending this section, I would like to pose the question of whether CPP should be considered as a whole or different entity. Given that CPP is associated with different conditions in which the pathogenesis is poorly understood, it is perhaps more useful to take a pragmatic approach, rather than adopting an either/or stance. It is essential, although not always possible, to try to obtain an initial differential diagnosis through careful history taking, physical examination and appropriate investigations. Management of CPP based on differential diagnosis or the lack of it, could be tailored to the patient.

1.5 Burdens of CPP

1.5.1 Cost to Society

Table 1.5 (page 15) presents the economic cost of CPP to society. In the UK, the annual healthcare costs were estimated at over £150 million in 1992. (Davies et al., 1992) In the USA, the annual direct medical costs for outpatient visits are approximately £673.5 million (over US$800 million). The estimated total indirect cost of CPP due to time lost from work was US$555.3 million. (Mathias et al., 1996) The financial burden of CPP in both these countries is likely to be much higher now. The latest systematic review on the prevalence of CPP found no update of the cost of treating CPP. (Ahangari, 2014)

Reflecting the financial burden of endometriosis-associated symptoms is a study that involved 12 tertiary care centres in ten countries. (Simoens et al., 2012) This study demonstrated that the total average cost per woman per year was €9579 (£8,253.55). This total cost was accounted for primarily by surgery (29%), monitoring tests (19%), hospitalization (18%) physician visits (16%) and medications (10%).
Table 1.5 Financial Burden of CPP to Society

<table>
<thead>
<tr>
<th>Study</th>
<th>Estimated healthcare cost</th>
<th>Productivity loss</th>
<th>Other non health care cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom (Davies et al., 1992)</td>
<td>£150 million/annum (likely to be much higher now)</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>USA (Mathias et al., 1996)</td>
<td>Over $800 million/annum direct medical costs for outpatient visits (likely to be much higher now)</td>
<td>US $ 555.3 million</td>
<td>No data</td>
</tr>
<tr>
<td>12 tertiary centres 10 countries (Simoens et al., 2012)</td>
<td>€3113/woman/annum (95% of direct cost) Most costly were: Surgery (29%) Monitoring test (19%) Hospitalization (18%) Physician visits (16%) Medication (10%)</td>
<td>€6298 per woman/annum</td>
<td>€168</td>
</tr>
</tbody>
</table>

1.5.2 Impact on Daily Lives and Wellbeing

CPP exerts a high economic toll not only on society but also on the sufferers and their families. CPP can have a significant and negative impact on daily lives and wellbeing (Nolan TE, 1993, Wiener, 1994, Zondervan et al., 1998), as well as work attendance and productivity. (Sundell et al., 1990)

Studies have demonstrated that women who suffer from CPP, experience poorer health and high frequency of sleep disturbances. (Mathias et al., 1996, Zondervan et al., 2001) Furthermore, a significant number of women who have CPP experience a myriad of other physical symptoms, the most common being fatigue/lethargy and inability to carry out activities without taking pain medications. (Grace and Zondervan, 2006, Zondervan et al., 2001) The inability to participate fully in their daily activities, due to pain, is consistent with the findings of a study undertaken in the USA (Mathias et al., 1996), as well as an international study on women with endometriosis. (De Graaff et al., 2013, Simoens, 2012 #898)

The impact on the daily lives and wellbeing of women with CPP is shown in another study that involved 12 tertiary centres and ten countries, 16% of 3216 women reported mobility problems, 3% reported problems with self-care, and 29% reported problems participating in their normal activities. (Simoens et al., 2012) There was also a 19% reduction in the quality
of life when compared with someone who was in the best of health. At the extreme end, two participants considered their health status to be worse than death!

1.5.3 Impact on Work Lives and Loss Productivity

CPP has been shown to impact on work attendance. A community based study shows that 18% of the women in the study had at least one day of absence from work in the previous 12 months, related to CPP. (Zondervan et al., 2001) In a USA study, 26% of the women reported at least one day in bed in the past month due to CPP. (Mathias et al., 1996) CPP not only affected their work attendance but work productivity.

Further evidence of CPP affecting the sufferers’ work lives come from an international cross-sectional questionnaire based survey. (De Graaff et al., 2013) Of the 931 women surveyed, 51% reported that their pain had had a negative impact on their work. The direct productivity loss was estimated to be twice the cost of direct health care cost. (Simoens et al., 2012)

1.5.4 Depression, Anxiety and Sexual Problems

It is well documented that women who have CPP experience a higher rate of depression, anxiety and emotional distress compared with control groups. (Simoens et al., 2012, Sepulcri and Amaral, 2009) In the Simoens study, 36% of the women surveyed reported that they experienced anxiety and depression.

CPP is also reported to interfere with the women’s sex lives as they experience pain during and after sexual intercourse. (Mathias et al., 1996, Savidge and Slade, 1997) CPP may be associated with and co-evolved with marital dysfunction. De Graaff and colleagues found that of the 931 women surveyed, 50% reported that their CPP affected their relationships at some time during their life and a significant number of these women experienced dyspareunia. (De Graaff et al., 2013) All the women surveyed had endometriosis.

1.6 The Need to Find a Satisfactory Approach to CPP

The main approaches to managing CPP and its associated conditions such as endometriosis, IBS or PBS are medical and surgical. Almost all the medical approaches to managing CPP have significant side effects. Surgical interventions do not always provide a permanent relief in pain and are not themselves without complications. The cost of CPP on a personal and society level is significant. There is an urgent need to find an acceptable approach and thus I propose that acupuncture treatment might be helpful in the management of CPP associated
symptoms. In the following sections I will review the key research literature on acupuncture and chronic pain conditions and develop my argument for my proposal.

1.7 Acupuncture for Chronic Pain Conditions

Animal (Peets and Pomeranz, 1978) and human (Zhang et al., 2004) studies have shown that acupuncture has analgesic effects. Studies on the mechanisms of electro-acupuncture (EA) in both animals and humans suggest that endogenous opioid peptides in the central nervous system mediate its analgesic effect (Han, 2003). It has also been shown that EA of 2Hz selectively stimulates the release of encephalin, β-endorphin and endomorphin, while that of 100Hz selectively increase the release of dynorphin. (Han, 2003) (Pomeranz and Chiu, 1976) (Hamza et al., 1999) Other studies by Han and colleagues suggest that frequency is one of the central parameters in EA and alternating 2Hz with 100 Hz frequencies gives the optimal therapeutic effect as it stimulates the release of these four opioid peptides; EA at 2-10Hz gave a longer effect than that of 100Hz. This is because 2-10Hz has greater inflammatory inhibition. (Han, 2004). Both low (2-4Hz), (Cheng and Pomeranz, 1979) and high frequency (100 Hz) EA (Han et al., 1984) induced analgesia were shown to be blocked by the opioid antagonist naloxone (Mayer et al., 1977b), suggesting that endorphin was involved in the clinical effect.

In a recent review of the mechanisms of acupuncture/electro-acupuncture on chronic pain, the authors made several interesting conclusions. (Zhang et al., 2014) Acupuncture may work by 3 main mechanisms: peripheral, spinal and supraspinal. In EA, periphery release of opioids appears to play a central role in inflammatory pain reduction. Studies using rats showed that inflammatory pain was reduced through opioids released by lymphocytes, monocytes/macrophages and granulocytes. Opioids released into inflamed skin, (Cabot et al., 1997, Rittner et al., 2001) activated peripheral nerve to suppress pain. EA has also been shown to activate the sympathetic nerve fibres to inhibit pain, although the exact mechanism is unclear. (Kimura et al., 2006). In a study by Goldman et al. (Goldman et al., 2010), manual acupuncture reduced pain significantly by increased local adenosine (a nucleotide that plays a role in the regulation of blood flow to various organs via vasodilation) that act on the receptors in sensory afferents of ascending nerve tracks.

At the spinal level, several animal studies have demonstrated, EA reduces pain via norepinephrine, serotonin and glutamate (Chang et al., 2012, Lao et al., 2004) and spinal opioids. (Han, 2003) In a study, Li et al. reported that EA reduced pain by activating the
serotonin-containing nucleus raphe magnus neurons and norepinephrine-containing locus coeruleus neurons that project to the spinal cord.

At the supraspinal level, pain reduction of EA worked via certain parts of the brain. In a review of the neural mechanism underlying acupuncture analgesia, Zhao (Zhao, 2008) summarised a number of animal studies that showed the involvement of the nucleus raphe magnus, periqueductal gray (PAG), locus coeruleus, arcuate, amygdala and preoptic nerve. Opioid peptides and their receptors in the arcuate-PAG-nucleus raphe magnus-spinal dorsal horn pathway play a fundamental role in acupuncture analgesia. (Takeshige et al., 1992)

However, there has been very little research of acupuncture for the treatment of CPP in women specifically. Studies led by Wayne, Rubi-Klein and de Sousa suggested that acupuncture is effective in managing endometriosis related pain. (Wayne et al., 2008, Rubi-Klein et al., 2010, de Sousa et al., 2016) In one intervention review undertaken by Zhu and colleagues, auricular acupuncture was found to be fairly effective for endometriosis associated pain. (Zhu et al., 2011) (Table 1.6, page 19) The results of the most recent RCT by de Sousa (de Sousa et al., 2016) were promising, although the sample size was small (n=46). This study compared acupuncture (n=23) with placebo acupuncture (n=23) (needles not inserted in the real acupuncture points). A statistically significant difference (p=0.0001) in VAS pain score for dyspareunia and CPP were reported in both groups. In the acupuncture group, CPP was reduced by 66% after treatment while the placebo group CPP was reduced by 17%. At two months follow-up, the effects were observed only in the acupuncture group.
Table 1.6 Acupuncture and Endometriosis Related Pain Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Design</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Rubi-Klein et al., 2010)</td>
<td>Evaluate if acupuncture treatment is an effective adjunct to standard care for endometriosis</td>
<td>RCT cross-over trial (n=101) Women aged 20-40 years Group 1 (n=47) Specific acupuncture points, 10 acupuncture treatment, cross-over after 2 menstrual cycles Group 2 (n=51) Non-specific acupuncture points</td>
<td>Acupuncture treatment: specific acupuncture points appeared effective for endometriosis related pain. Acupuncture treatment with specific points achieved a statistically difference in VAS score compared to treatment with non-specific points Group 1: (p=0.0001) Group 2: (p=0.0001)</td>
</tr>
<tr>
<td>(Wayne et al., 2008)</td>
<td>Evaluate feasibility of a future sham controlled RCT on effectiveness of Japanese style acupuncture for endometriosis in young women (aged 13 to 22 years)</td>
<td>RCT sham controlled (n=5) Japanese style acupuncture (n=9)</td>
<td>Significant pain reduction (p=0.004) in acupuncture group compared to sham group</td>
</tr>
<tr>
<td>(de Sousa et al., 2016)</td>
<td>Determine the effects of an acupuncture protocol on dyspareunia, CPP, quality of life in women with endometriosis</td>
<td>RCT placebo (n=23) compared with real acupuncture (n=23) Fix points based on Chinese medicine</td>
<td>VAS pain for dyspareunia (p=0.0001) in both groups. Effects at 2 months follow-up only observed in acupuncture group. EHP-30- social, sexual relationships improvement (p=0.0001)</td>
</tr>
</tbody>
</table>

A number of systematic reviews (Ernst and White, 1998, Ezzo et al., 2000, Madsen et al., 2009), meta-analyses, and RCTs on the effect of acupuncture on other chronic pain conditions, such as chronic headache, migraine or osteoarthritis of the knee (See GERAC and ART studies, Section 1.9, page 23) have shown conflicting results. The systematic reviews conducted by Madsen et al concluded that the analgesic effect of acupuncture is too small to have any clinical relevance. (Madsen et al., 2009) Similarly, Ezzo et al concluded that there is limited evidence that acupuncture is more effective than no treatment or sham acupuncture or standard care. (Ezzo et al., 2000) In contrast to these two systematic reviews, in a meta-analysis of acupuncture RCTs for back pain the authors concluded that acupuncture is superior to various controls, although the evidence was inconclusive with regards to whether it is superior to sham acupuncture. (Ernst and White, 1998)
The most recent and important review was an individual patient data meta-analysis on acupuncture for four chronic pain conditions: neck and back pain, osteoarthritis, headache and shoulder pain. (Vickers et al., 2012) This review analysed 29 RCTs with a total of 17,922 patients. The authors made several clinically relevant conclusions. Firstly, acupuncture is effective for chronic pain conditions. Secondly, significant differences between acupuncture and sham acupuncture, although small, are more than a placebo. Thirdly, besides the specific effects of acupuncture needling, other contextual factors contributed to the analgesic effect of acupuncture. (Kaptchuk, 2002, Kaptchuk et al., 2006, Liu and Yu, 2011) Fourthly, the total effects of acupuncture experienced by the patients is observed and considered important in a real clinical setting, but not usually evaluated or considered important in most RCTs.

The sum of the results of these reviews and studies is contradictory and their conclusions underscore the contentious debate and some of the key issues surrounding acupuncture research.

1.8 Key Issues in Acupuncture Research

1.8.1 Acupuncture Treatment: A Simple or Complex Intervention?

In the literature, the term “acupuncture” is used mostly to denote, and is understood as, a single and simple act of inserting acupuncture needles into the skin at specific chosen points. The quotes below amply demonstrate this point:

*Acupuncture is a treatment derived from ancient Chinese medicine in which fine needles are inserted at certain sites in the body for therapeutic or preventative purposes* (www.nhs.uk)

*Acupuncture is the stimulation of special points on the body, usually by the insertion of fine needles.* (Vickers and Zollman, 1999)

However, the practice of acupuncture that draws on Traditional Chinese Medicine (TCM) or Classical Chinese Medicine (CCM) (See Section 1.11, page 27) is multi-faceted and complex. (Langevin, 2010)

Acupuncture as a complex intervention is based on the Medical Research Council’s (MRC) new guideline for complex interventions (Craig et al., 2008) as well as the distinction drawn between simple and complex interventions by Rogers in her work on evaluation. (Rogers, 2008) The MRC document described a complex intervention as one that contains “several interacting components” and has “several dimensions of complexity”. Some of these
dimensions include the interactions between the different components in a study, the degree of flexibility or tailoring the intervention, and difficulty of standardising the behaviours of those delivering and receiving the intervention.

Table 1.7 (page 21) shows the distinction between a simple and complex intervention. (Rogers, 2008)

Table 1.7 Acupuncture as Simple and Complex Intervention
Adapted from (Rogers, 2008)

<table>
<thead>
<tr>
<th>Simple Intervention Following a Recipe</th>
<th>Complex Intervention Affect Changes in Complex Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture treatment as a simple intervention: fixed acupuncture points prescriptions as in the ART or GERAC studies</td>
<td>Acupuncture treatment as a complex intervention: As in my pilot study where the intervention was performed to reflect the real world clinical setting</td>
</tr>
<tr>
<td>No particular expertise is required except knowing where to insert the needles as per the prescriptions</td>
<td>Expertise contributes but does not assure success as other variables may influence the outcome e.g. fluctuation in pain levels</td>
</tr>
<tr>
<td>Recipes need to be tested for replication</td>
<td>The process of acupuncture treatment can be replicated, but acupuncture point selections vary according to the patient’s condition</td>
</tr>
<tr>
<td>Recipes produce standardised results</td>
<td>Each acupuncture treatment is tailored to the needs of the individual and thus outcomes vary</td>
</tr>
<tr>
<td>The best recipes may give good results each time</td>
<td>Outcomes are uncertain</td>
</tr>
</tbody>
</table>

1.8.2 Three Components of Acupuncture Treatment

Figure 1.1 (page 23) presents the three components of acupuncture treatment.

1.8.2.1 Specific Factors: Acupuncture Needling

The insertion of acupuncture needles on specific points is only one aspect of this complex process. Acupuncture needling includes how the points are chosen, depth of needle insertion, size of the needle and mode of needle stimulation. These specific factors are unique to acupuncture needling, are theoretically based and believed to have an impact on therapeutic outcome. These specific factors relate to what my study calls the meridian BMEA acupuncture style.
1.8.2.2 Non-needling Specific Factor

The second component of an acupuncture encounter is the TCM health consultation that is based on Chinese medicine theory. This component relates specifically to what my study reported in this thesis calls TCM HC (see Chapter Three, Section 3.14, page 59). This component of an acupuncture treatment typically involves questioning, talking, listening and tongue diagnosis. These factors are specific to and an integral part of acupuncture treatment and might have a therapeutic effect. (Paterson C and Dieppe P, 2005) (Paterson and Britten, 2008, Kaptchuk, 2000) The concern here is to organize the information into an accurate assessment to reflect the whole person: the interconnection of the mind, body and spirit. (Benfield, 1991) Here I define “Spirit” as the very essence of the individual and does not have a religious meaning.

1.8.2.3 Contextual Factors

The third component is the context in which the intervention takes place, which is known as contextual factors. These are an integral and inevitable part of clinical encounters, including that of my study. (Kaptchuk, 2008) They consist of a variety of factors such as beliefs and expectations of the patient (Vase et al.) and the healthcare provider, the therapeutic setting, the nature of the patient-healthcare provider relationships time and attention. (Kaptchuk, 2008) These contextual factors are complex and are inseparable (Paterson C and Dieppe P, 2005), but nonetheless may be clinically meaningful. (Miller and Kaptchuk, 2008, Miller and Rosenstein, 2006, Avins et al., 2012)

As concluded by Vickers and colleagues, this third component is often not considered in most acupuncture RCTs. (Vickers et al., 2012). Thus implicitly acupuncture treatment is treated as a simple intervention in acupuncture research whereas in fact it is a complex intervention according to the MRC definition.
1.9 Problems with Sham and Pre-Prescribed Acupuncture Points

The “Acupuncture Research Trials (ART)” and the “German Acupuncture Trials” (GERAC) employed a sham acupuncture control to compare acupuncture and standard care. These consisted of eight RCTs conducted in Germany between 2000 and 2006. The ART studies consisted of four parallel RCTs that investigated migraine (Linde et al., 2005), tension type headache (Melchart et al., 2005), chronic low back pain (Brinkhaus, 2006) and osteoarthritis of the knee (Witt et al., 2005). The key features of these four studies are shown in Table 1.8 (page 25). The GERAC studies were similar in design to those of the ART. The GERAC studies investigated migraine (Diener et al., 2006), tension type headache (Endres, 2007), chronic low back pain (Haake M and et al., 2007) and knee osteoarthritis. (Scharf et al., 2006) The key features of these studies are summarized in Table 1.9 (page 26).

Past sham controlled studies have employed techniques such as shallow needling, and needling with a retractable needle or toothpick. (Kleinhenz et al., 1999, White et al., 2003) Such techniques create a sensation similar to light touch which has some data to show that it has physiological effects. (Lund and Lundeberg, 2006, Lundeberg et al., 2012) It is also conceivable and probable that shallow needling and needling with a retractable needle elicit similar physiological effects as deep needling.
In a systematic review of sham-controlled acupuncture studies the author pointed out two important observations. (Moffet, 2006) Firstly, some sham-controlled studies are based on an unreliable premise. These studies used non-acupuncture points which are against TA theories to obliterate the specific effects of needling. If sham acupuncture is physiologically active, and it calls into question how valid TA theories really are. Secondly, some sham-controlled studies were performed by researchers who were ignorant of how acupuncture was practised in a real clinical setting.

Returning to problems of the ART and GERAC studies’ methodology is the less obvious issue of pre-prescribing a set of acupuncture points. This is akin to a physician prescribing a medication before the patient’s condition has been evaluated. Even more problematic in the ART and GERAC studies is that these points were used throughout the whole study period that consisted of 10-12 acupuncture sessions. Prescribing points and then not varying them based on the patients’ condition or progress, contradicts the theory of Chinese medicine and thus is a very serious flaw in these studies.
### Table 1.8 Key Features of “Acupuncture Research Trials” (ART)

Acupuncture as a simple intervention that follows a recipe

<table>
<thead>
<tr>
<th>Art Study</th>
<th>Design: RCT 3 Arms</th>
<th>Description of Point Selections</th>
<th>Primary Outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine (Linde et al., 2005) (18 outpatients centres)</td>
<td>Acupuncture n= 145; 12 sessions over 8 wks</td>
<td>Semi standardized; needles manually stimulated Superficial needling Semi-standardized sites not near recognised points; no needle stimulation Acupuncture post study</td>
<td>No. of days with moderate to severe headache between 4 wks before randomisation &amp; wks 9-12 after randomisation</td>
<td>Significant short term difference between acupuncture &amp; waiting list</td>
</tr>
<tr>
<td></td>
<td>Sham acupuncture n=81; 12 sessions over 8 wks</td>
<td>Waiting list N=76</td>
<td></td>
<td>No significant difference between sham &amp; acupuncture &amp; waiting list</td>
</tr>
<tr>
<td>Tension-type headache (Melchart et al., 2005) (28 outpatient centres)</td>
<td>Acupuncture n= 132; 12 sessions over 8 wks Sham acupuncture n=63. Same as above</td>
<td>Semi standardized Same strategy as Migraine study Acupuncture post study</td>
<td>Same as migraine study</td>
<td>Same as above</td>
</tr>
<tr>
<td></td>
<td>Waiting list n=75</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic low back pain (Brinkhaus, 2006) (30 outpatient centres)</td>
<td>Acupuncture n= 147; 12 sessions over 8 wks Sham acupuncture n=75; Same as above</td>
<td>Semi standardized Same as Migraine study Acupuncture post study</td>
<td>Change in low back pain intensity from baseline to wk 8 after randomisation by at least 60% reduction in pain (VAS)</td>
<td>Same as above</td>
</tr>
<tr>
<td></td>
<td>Waiting list n=79</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee Osteoarthritis (Witt et al., 2005) (28 outpatient centres)</td>
<td>Acupuncture n= 150; 12 sessions over 8 wks Sham acupuncture n=76; Same as above</td>
<td>Semi standardized Same strategy as Migraine study Acupuncture post study</td>
<td>Change: Western Ontario &amp; McMaster University osteoarthritis Index (WOMAC) between baseline &amp; wk 8 after randomisation by a decrease of at least 50%</td>
<td>Significant short term pain relief, acupuncture more than sham or waiting list; A significant difference between sham &amp; acupuncture</td>
</tr>
</tbody>
</table>
### Table 1.9 Key Features of the “German Acupuncture Trials” (GERAC)

Acupuncture as a simple intervention that follows a recipe

<table>
<thead>
<tr>
<th>The GERAC Trials</th>
<th>Design: RCT 3 Arms</th>
<th>Description of Points selection</th>
<th>Primary outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine (Diener et al., 2006)</td>
<td>Acupuncture n=313, 10 sessions over 6 wks Sham acupuncture n=339, 10 sessions over 6 wks Standard care n = 308</td>
<td>Semi-standardized: needles manually stimulated Superficial needling, semi-standardized sites not near points; needles not stimulated Drugs prophylaxis</td>
<td>Difference in migraine days between 4 wks before randomisation &amp; wks 23-26 after randomisation; reduction in number of migraine days by at least 50%</td>
<td>Treatment outcomes did not differ in patients treated with acupuncture or sham acupuncture or standard care</td>
</tr>
<tr>
<td>Tension type headache (Endres, 2007)</td>
<td>Acupuncture n=209 10 sessions over 6 wks Sham acupuncture, n=200, Same as above Standard care n = 400</td>
<td>Same as migraine study Same as migraine Discontinued. Unwilling to take Amitriptyline</td>
<td>Over 50% reduction in number of headache days per 4 wks from baseline to 6 months</td>
<td>TCA:33% responded Sham; 27% responded TCA was superior to sham for most secondary outcomes</td>
</tr>
<tr>
<td>Chronic low Back pain (Haake M and et al., 2007)</td>
<td>Acupuncture n=387 10 sessions over 6 wks Sham acupuncture n=387, Same as above Standard care n = 388</td>
<td>Same as migraine study Same as migraine study Drugs, physical therapy &amp; exercise</td>
<td>At least 33% improvement on 3 pain-related items on: Von Korff Chronic Pain Grade Scale; Hanover Functional ability Questionnaire</td>
<td>6 months response: TCA: 47.6%, Sham, 44.2%. Standard Care: 27.4%. The Difference between TCA &amp; Sham:3.4% TCA vs Standard care: 20.2%</td>
</tr>
<tr>
<td>Knee osteoarthritis (Scharf et al., 2006)</td>
<td>Acupuncture N=330; 10 sessions over 6 wks Sham acupuncture, n=367, Same as above Standard care n = 342</td>
<td>Same as migraine study Same as migraine study Physio, visits to practitioner, drugs &amp; exercise</td>
<td>Pain &amp; Function: WOMAC Score; change of at least 36% from baseline</td>
<td>Success rates: TCA: 53.1% Sham: 51.9% TCA had higher success rates than conservative therapy groups; there was no statistically difference between TCA &amp; sham</td>
</tr>
</tbody>
</table>
1.10 Differentiating Contextual Factors from Placebos

In clinical practice, a placebo is an “inert” substance or intervention given to patients in the hope of making them feel better. RCTs using a placebo as a control to evaluate if the intervention is superior, or not, to the placebo are generally considered the gold standard. Such placebos are given or used within a clinical encounter context. What is now clear is that the response is not due to the inertness of the placebo rather it is the context that plays a vital role in influencing clinical outcomes. (Benedetti, 2002, Finniss et al., 2010, Miller and Kaptchuk, 2008) This is a very critical distinction as the focus is shifted onto the context in which an intervention is given and not exclusively on the inert placebo. This shift has important clinical and research implications.

Because the placebo terminology is so ingrained in the clinical setting and scientific literature, I would like to make a distinction between “placebo” and “contextual factors”. Accordingly, my thesis will use “context factors” to denote the context in which the interventions were given, wherever possible.

1.11 Choice of Meridian BM Acupuncture

In the UK and USA, professional education and practice of acupuncture are well established. The acupuncture profession in the UK is self-regulated by professional associations such as the British Acupuncture Council (BAcC) and the British Medical Acupuncture Society (BMAS), although there is not a licensing body. In the USA, where I was trained, professional education and the practice of acupuncture are well regulated. Most states issue licences and require certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM).

Over the past 2,500 years, the practice of acupuncture has evolved and continues to develop. There are several acupuncture styles practised globally, such as Traditional acupuncture (TA), Japanese style acupuncture, Five Elements acupuncture, Korean acupuncture and the meridian balance method acupuncture styles. I am trained in and continue to use TA, Five Elements acupuncture, Japanese style acupuncture and the meridian BM acupuncture style in my practice and I am NCCAOM certified.

The meridian BM acupuncture style, popularized by the late Dr Richard Tan is primarily indicated for pain management (Tan, 2003). This is the acupuncture style that is used in my
study and is based on my significant clinical experience. As alluded to earlier, no study has been undertaken for CPP in women using the meridian BM acupuncture style. However, it has been well described in the Huang Di Nei Jing, (Unschuld, 2003) a seminal publication as well as modern classical Chinese medicine (CCM) text. (Twicken, 2012, McCann, 2013, Tan, 2003) CCM is a deep repository of literate and scholarly knowledge before it morphed into Traditional Chinese Medicine (TCM). TA is an important part of TCM. Thus both acupuncture styles share the same theoretical root. The meridian BM acupuncture utilizes one meridian to balance another in the treatment of pain and has a systematic approach to acupuncture point selections (see Methods Chapter Three, Section 3.15 page 62). TA uses pattern identifications/diagnoses (see Glossary) to formulate a treatment plan and acupuncture point selections. Both acupuncture styles adopt a whole person approach where treatment is focused not on the disease but the whole person. (Benfield, 1991, Kaptchuk, 2000, Paterson and Britten, 2008)

1.12 First Clinical Encounter: Meridian BM Acupuncture

In my early days as a practitioner of Chinese medicine, it would be true to say that I did not have much confidence in treating patients with pain. My first encounter using the meridian BM acupuncture treatment came as a pleasant surprise. I used the meridian BM acupuncture treatment on a patient who was diagnosed with breast cancer. Her clinical status was post mastectomy with tram flap breast reconstruction (a flap of skin, fat, and all or part of the underlying rectus abdominus muscle were used to reconstruct the breast). This reconstruction resulted in her experiencing a significant amount of pain that was not responding to pain medications. When I first met her I observed that she was in pain by her facial expression and in her slow movements. She had difficulty getting up on the acupuncture couch, removing her outer garments, or bending to take her shoes off. I treated her pain according to the steps outlined in the Chapter Three, (Section 3.15 page 62). We both agreed to aim for a 50% reduction in her pain scale. However, we were astounded at the excellent result when upon getting up, she reported that her pain level was reduced by 75%. I noted that she got up from the acupuncture couch with no difficulty, and she did not have problems in putting on her shoes or outer garments. She was very pleased with the result. She needed three more follow-up treatments to manage her pain. This is a typical case study of my work using the meridian BM acupuncture treatment.

I have used the meridian BM acupuncture treatment to treat painful conditions in many cancer patients over 15 years. I have witnessed the instantaneous pain relief once the
acupuncture needle is inserted into the appropriately chosen acupuncture point(s). My experience was limited to treating pain in cancer patients in New York. I have had no clinical experience treating CPP with this acupuncture style. Before I conduct a study, I felt more comfortable to first determine if the patient population with CPP in RIE were receptive to acupuncture. Thus within EXPPECT in NHS Lothian I undertook a ten-month (Oct 2013 to July 2014) project to determine the utilization rate of the meridian BMEA treatment as described below.

1.13 The Meridian BMEA Treatment Project: Utilization

The meridian BMEA Project offered a once a week service to women with CPP. Over the ten-month period, 218 appointments were sent to patients with CPP. Of the 218 appointments sent, six women “Did Not Attend” (2.88%) with no reason given, and 18 were “Cancellations due to sickness or conflict with work or medical appointments” (8.26%). The uptake rate of the service was 88.86%.

1.14 Patients’ Testimonials

The meridian BM acupuncture project received very positive feedback from the patients. Below are the examples of the comments provided by the patients about their experience of the meridian BM acupuncture service:

Electro-acupuncture is particularly effective in treating my pain...it appears to lessen the pain quickly and allows me to remain pain free/at low pain level for longer.

It has been my saviour over this past year and has helped manage my pain. It has benefitted me in a way nothing else has done in relation to managing the symptoms of endometriosis.

Non invasive, relaxing. Made a huge difference to constant chronic pain levels. Great to get practical advice on pain management...better option & advice/guidance than my physiotherapist. Given me instant relief on occasion from chronic pain.

Great alternative to relying on medication alone. Helps not only physically but mentally too having someone understand your symptoms & other parts of the anatomy it can ultimately affects...

Electro-acupuncture has helped me so much with my pain and emotions is not sore but very relaxing.
I have received hundreds of treatments for my depression/anxiety and endometriosis. Only thing that has helped is acupuncture. I am a true believer in its work.

The patients’ response to this ten-month project supported my desire to utilise the meridian BM acupuncture treatment and resulted in my pilot study.

1.15 Hypothesis and Objectives

Reflecting on the complexities in the management of CPP in women, the key issues in acupuncture research on chronic pain conditions, and the complexity of acupuncture treatment, the fundamentally important next step was to find the right methodology to evaluate the impact of the meridian BM acupuncture. If it were true that acupuncture analgesia was the result of the specific physiological effects of needling and the contextual factors, then it seemed appropriate to isolate the TCM HC component from the acupuncture treatment (acupuncture needling + TCM HC) to evaluate its respective therapeutic benefits. Therefore I have undertaken a three arm pilot RCT using a mixed methods research design, comparing the impact of the meridian BMEA treatment (BM acupuncture needling + TCM HC) with TCM HC and National Health Service standard care (NHS SC). The choice of three focus group discussions was embedded into my study and the data were thematically analysed.

The first arm included acupuncture needling with electro-stimulation (specific effects of needling) and specific non-needling components of acupuncture treatment (TCM HC). The second arm included the TCM HC alone. The third arm received the National Health Service standard care (NHS SC). Implicit in this design was the present of contextual factors in all three groups. To evaluate the outcomes of the interventions validated assessment tools were used rather than TCM outcome measures which have not validated or standardised.

1.16 Research Aim

The aim of my thesis is to assess the feasibility of a future large scale RCT to determine the effectiveness of the meridian balance method (BM) electro-acupuncture (EA) treatment on CPP in women.

1.17 Research Hypothesis

My hypothesis is that it is feasible to conduct a large-scale definitive study on the effectiveness of the meridian BMEA treatment for CPP in women.
1.18 Research Questions

- Is it possible to recruit and retain the required number of participants in a pilot study to inform a future large-scale RCT?
- Is the meridian BMEA treatment effective in reducing CPP in women?

1.19 Research Objectives

1.19.1 Primary Objective
To determine the recruitment and retention rates in NHS Lothian within the defined inclusion/exclusion criteria.

1.19.2 Secondary Objectives
To determine the acceptability to participants of the methods of recruitment, randomisation, assessment tools, interventions as well as the effectiveness of the interventions.

1.20 Endpoints/Outcomes

1.20.1 Primary outcomes

- Recruitment rate: assessed by the proportion of eligible participants randomised into the study.
- Retention rate: assessed by the proportion of randomised participants who returned questionnaires at the follow-up weeks 4, 8 and 12.

1.20.2 Secondary outcomes

- Acceptability to the participants of the method of recruitment and randomisation: assessed using data from recruitment history and semi-structured telephone interviews
- Acceptability to the participant of assessment tools: assessed by data completion and patterns of missing data in the questionnaires and semi-structured telephone interviews
- Acceptability of interventions: assessed by the proportion of treatment interventions completed by participants in the BMEA treatment and TCM HC groups and semi-structured telephone interviews
- Effectiveness of the interventions on CPP: assessed by the Visual Analogue Scale (VAS), Brief Pain Inventory (BPI), Short Form -12 (SF-12), Hospital Anxiety and Depression Scale (HADS), Pain Castastrophising Questionnaire (PCQ), Work Productivity and Activity Impairment Questionnaire (WPAIQ), Sexual Activity Questionnaire (SAQ) and data from the focus group discussions.
Chapter Two  Methodology

2  Introduction

Chapter One presented two central issues of my thesis: the gaps in research and treatment for CPP as well as the key issues in acupuncture research for chronic pain conditions. It also proposed that the meridian BMEA treatment might be effective in the management of CPP in women and outlined the primary and secondary objectives of my study. The present chapter considers the underlying logic of enquiry that best addresses these objectives, and is in contrast to the following chapter (Chapter Three Methods and Materials), which refers to the tools used, the types of data collected and techniques employed in analysing the data.

Finally, in the interest of rigour and openness, the study interventions were audio recorded and a reflective journal was kept throughout the study. For confidentiality reason, my reflective journal is not included in the thesis. 1

2.1  Evolution of My Study Design: Year One and Beyond

2.1.1  Does acupuncture work or it is just a placebo?

When I first started my studies, I expect like most PhD students, I was confronted with the question of how best to explore my research topic. This was made more complex as systematic reviews, meta-analyses and some RCTs on the effectiveness of acupuncture for some chronic pain conditions yield mixed results (Chapter One, Sections 1.7- 1.9, pages 17 - 23). Furthermore, published strongly held views (Colquhoun and Novella, 2013, Pandolfi, 2012) often clashed radically with my many years of acupuncture clinical experience of treating cancer patients who were in pain. This experience informed me that my patients reported less pain and enjoyed an enhanced sense of wellbeing following acupuncture treatment. I thought and believed that was an outcome worth having. Yet the current, contentious debates about the effectiveness of acupuncture in managing certain chronic conditions between sceptics and supporters were unsettling. Sceptics often dismiss acupuncture in a derogatory manner as a mere placebo. (Colquhoun and Novella, 2013, Pandolfi, 2012)

1  My reflective journal is available upon request.
The questions of whether acupuncture works and how it works as well as its clinical significance are, of course excellent questions and they are to be taken very seriously. How gratifying it would be, if these could be answered in a satisfactory manner for all interested parties, including our patients who come to us because they want to feel better. The conflicting evidence and hotly contentious debates on the effectiveness of acupuncture, coupled with my clinical experience alerted me to the challenges of this area of scholarship. It was against this backdrop that I started my thesis.

2.2 In Search of “The” Study Design

Figure 2.1 (page 35) shows the evolution of my study design. My first year PhD thesis proposal was a two-armed parallel study comparing the impact of acupuncture in women with CPP of unknown aetiology and women with CPP due to a malignancy. As I settled into, and learned more about, my new work environment and the patient population, I realized that it was difficult to recruit patients with CPP due to a malignancy.

Furthermore, from the information gleaned from my literature search, I learned my first two important lessons which were to inform my final proposal: first, sham acupuncture used in research was very problematic. Second most acupuncture RCTs on chronic pain conditions mainly regard acupuncture treatment as a simple intervention in which only the acupuncture needling was main area of enquiry. (Chapter One Section 1.8.1, page 20). These discrepancies in acupuncture research raised a fundamental question as to whether they are consistent with how acupuncture is practiced in clinical settings. I ended my first year with a new proposal.

This new proposal was two-armed pilot RCT, comparing an electro-acupuncture intervention with standard care, using a ‘waiting list’ approach. This seemed like a good study design to me, but I later realized that I really needed to unpick the different components of the acupuncture treatment already discussed in the Chapter One (Section 1.8.2 page 21). The defining moments came when I attended a “statistical consultancy workshop” at the University of Edinburgh (UoE). This workshop gave me an opportunity to present my study proposal and ask statistical questions. The two-armed RCT proposal was criticized for not having a placebo-controlled group. It was pointed out that by using a waiting list as a control group in a two-armed study, I was in fact comparing acupuncture with nothing. This presented me with a dilemma because the use of placebo (i.e. sham acupuncture) is problematic and one of the key problems in acupuncture research (Chapter One, Section 1.8, page 20). But I took the criticism very seriously.
Eventually with a significant amount of work and re-thinking, I emerged with a new proposal, “The impact of meridian BMEA on women with CPP: a three armed RCT pilot study using a mixed methods approach”. This final proposal addresses several issues: Firstly, it goes beyond the researcher’s perspective: with three focus group discussions and semi-structured telephone interviews embedded in the design, participants’ subjective experiences of the study are included. Secondly, it evaluates the different components of acupuncture treatment by comparing the meridian BMEA treatment (BMEA + TCM HC) with TCM HC and NHS SC.

Figure 2.1 Evolution of My Study Design
2.3 Rationale for a Pilot Study

The primary aim of my pilot study is to evaluate the impact of meridian BMEA treatment on CPP in women to inform a future large-scale RCT. It is thus important and appropriate to find a methodology that shows clearly if it is feasible to move forward to a large-scale RCT, especially given the complexities and the lack of satisfactory treatment for CPP.

Conducting a pilot study first, is also consistent with the Medical Research Council (MRC) guidelines on complex interventions such as acupuncture treatment. (Craig et al., 2008) The data collected from my pilot study can also be used to inform sample size calculations in the future large-scale study. (Gould, 1995)

2.4 Four Philosophical Worldviews

Philosophical or worldviews are beliefs and knowledge that guide research. Table 2.1 (page 37) presents four philosophical worldviews outlined by Creswell. (Creswell, 2011: 2-5.)

Post-positivist, unlike quantitative purist (positivist), does not claim absolute truth in knowledge about human behaviours and actions. However, they hold a deterministic and reductionist worldview where the orientation is towards an “either/or view”, for example a hypothesis is either rejected or accepted. (Creswell, 2011: 2-5.) Research is to be undertaken objectively. I do not reject outright the post-positivist view, however, used on its own in my study, I feel that it only partially explains actions and behaviours of the participants. In my opinion, there are times when it is appropriate to use either quantitative or qualitative research methods.

The post-positivist worldview is in contrast to that of the constructivist whereby each person creates his/her multiple realities based on his/her experiences. A constructivist worldview believes that there are multiple perspectives and different experiences. The constructivist way of thinking helps to generate theory from different themes that emerged from the study and thus is consistent with qualitative research for examples interviews and focus groups. (Creswell, 2011: 2-5.)

Participatory research is politically oriented to promote empowerment of the subjects under study. A participatory researcher plays an active role in the research team helping to form research questions, analyse data and implementing results in practice. (Creswell, 2011: 2-5.)
Table 2.1 Philosophical Worldviews  
(Creswell, 2011: 2-5.)

<table>
<thead>
<tr>
<th>Post positivist</th>
<th>Constructivist</th>
<th>Participatory</th>
<th>Pragmatism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determination</td>
<td>Understanding</td>
<td>Political</td>
<td>Consequences of actions</td>
</tr>
<tr>
<td>Reductionism</td>
<td>Participants hold several meanings</td>
<td>Orientation: empowerment and issue</td>
<td>Orientation: Problem centred</td>
</tr>
<tr>
<td>Empirical observation and measurement</td>
<td>Construction via social and historical</td>
<td>Collaborative</td>
<td>Pluralistic</td>
</tr>
<tr>
<td>Theory verification</td>
<td>Theory generation</td>
<td>Orientation: change</td>
<td>Orientation: Real world practice</td>
</tr>
</tbody>
</table>

Pragmatism favours more than one method of data collection to answer the problems under study. Pragmatism is a practical-outcome oriented method of research emphasizing the practicality of undertaking research and the recognition of both subjective (participants’ lived experience) and objective knowledge (outcome measures captured in predetermined instruments). (Johnson and Onwuegbuzie, 2004) Pragmatism is also about translating research into action which is consistent with my professional training, practice and goals, and which is informed by study design. (Creswell, 2009)

2.5 My Philosophical and Epistemological Positions

My philosophical position is a mixed of post-positivism and pragmatism. The fact that my study is primarily driven by the experimental quantitative design would put me squarely into the post-positivist camp. By the same token, adopting an embedded MMR approach immediately highlights my position as a pragmatist.

At core I am a clinician: a professional registered nurse and a board certified practitioner of Chinese medicine. My consuming interest is to bring the best and most up-to-date research evidence to my patients to improve their health. Some researchers argue that two different worldviews as represented in MMR could not co-exist. I disagree quite strongly. I believe that they can and do and I am very comfortable holding two philosophical views at the same time. The notion that two worldviews cannot co-exist within one study, as argued by qualitative purist such as Guba, is not only fundamentally flawed but also counter-productive. (Guba, 1990) Certainly others (and I am in agreement) have promoted the argument for a unifying philosophical assumption such as pragmatism that informs both the quantitative and qualitative research. (Creswell, 2015) By adopting this stance, the often
debated and forced-choice dichotomy between quantitative or qualitative method is rendered obsolete. (Creswell, 2013). The most important criterion is to adopt a research approach that can best answer the research questions (Creswell, 2011: 2-5.) and, I believe, a mix of post-positivism and pragmatism satisfy this criterion.

### 2.6 Mixed Methods Research (MMR)

MMR is a relatively new research paradigm, although it is gaining in popularity and acceptance. (Tashakkori, 2010) At the very fundamental level, MMR involves the collection and integration of qualitative and quantitative data in order to provide a better understanding of the subject being studied. Creswell (Johnson et al., 2007) defined MMR as:

> Mixed methods research is a research design (or methodology) in which the researcher collects, analyzes, and mixes (integrates or connects) both quantitative and qualitative data in a single study or a multiphase program of inquiry.

Creswell also emphasizes that the sum total of using both approaches is greater than using either qualitative or quantitative alone. (Creswell, 2011: 2-5.) This view lends support to the idea that an MMR promotes more effective research (Johnson and Onwuegbuzie, 2004) and it exploits the best of what quantitative and qualitative methods have to offer. (Tashakkori, 2003)

### 2.7 The Embedded Design

There are different types of MMR designs. These include the convergent, explanatory, exploratory, transformative and multiphase and embedded designs. (Creswell, 2011: 2-5.) The one design that is most suitable for my pilot study is the embedded design.

The embedded design is an MMR approach where the collection and analysis of the quantitative and qualitative data is undertaken within a quantitative or qualitative research design. (Greene, 2007) In my study, semi-structured telephone interviews and three focus group discussions were embedded into a predominantly quantitative research design firstly, to address the secondary objectives outlined in Chapter One. (see Section 1.19.2 page 31). Secondly, an embedded design also helped to enhance and explain the quantitative results. (Greene, 2007) Thus the purpose of embedding the semi-structured interviews and three focus group discussions were related to but different from the primary objectives of my pilot study (see Chapter One, Section 1.19.1, page 31). This distinguishes the embedded design
from the convergent design whereby both the quantitative and the qualitative methods are used to address one single overarching research question. (Creswell, 2011: 2-5.)

The implementation of an embedded design is quite flexible in that one can combine the data collection and analysis in sequences that suits the study. (Creswell, 2011: 2-5.) In my pilot study, the quantitative data were collected first followed by the collection of the focus group discussions and semi-structured interviews. (Creswell and Zhang, 2009) The analyses of these datasets were performed separately. By adding the semi-structured interviews and focus group discussions to the study, the primary experimental quantitative design could be improved by giving the study better interpretative power. (Creswell and Zhang, 2009)

2.7.1 Focus Group Discussions

Focus groups are characterised by a series of group discussions among different participants who do not know one another, and are facilitated by a researcher. (Morgan, 1997: 47-48) Focus groups have also been described as “somewhere between a meeting and a conversation”, (Agar and MacDonald, 1995) or a form of group interview that utilised the discussions among participants to generate data. This makes the interaction among the participants a very important feature of a focus group dynamic. Focus groups are especially useful for exploring participants’ knowledge, attitudes or experiences. (Kitzinger, 1995) Historically, focus group research was used by market research. However, focus group research is now used more frequently in academia, (Bloor and Wood, 2006) and it has a history dating back at least 50 years. (Kidd and Parshall, 2000) A group of six to eight participants is considered ideal. (Bloor, 2001, Morgan, 1997: 47-48)

Since a focus group is especially suitable for exploring knowledge or experiences, (Gregory and McKie, 1991), I have chosen to embed three focus groups in the primary experimental quantitative strand to capture participants’ experience of my study. Group interactions and dynamic in a focus group can help to produce data that would not otherwise have been possible in a one to one interview. For example, in a focus group discussion, participants can express feelings and experiences that are common to the group, thus providing mutual support. Studies have also found that focus group discussions generated more critical comments than individual interviews. (Geis et al., 1986)

My choice of focus groups over semi-structured interviews was influenced by issues of time and finance. The advantages of focus groups were summed up by Fontana et al as inexpensive, data rich and flexible. (Fontana, 1994) Focus groups are also less time-consuming than individual semi-structured interviews. However, the choice of focus groups
is by no means an easy option as they can generate a huge amount of data, which at once can be viewed as an advantage and disadvantage. A large amount of data can be cumbersome and complex to manage and analyse. Nevertheless in the context of my study I considered this the best choice.

2.7.2 Semi-Structured Telephone Interviews

The attendance in the focus group discussions did not reach optimum size (six to eight participants). It is difficult to sustain a discussion below six and above ten difficult to control. (Bloor, 2001, Morgan, 1997: 47-48) Thus a semi-structured telephone interview, a later amendment to my pilot study was conducted for completeness of data collection. These interviews were conducted to ask specific questions about the acceptability to the participants of the methods of recruitment, randomisation and questionnaire.

2.8 Dominance of RCT Studies Using Quantitative Methods

With a few exceptions, effectiveness studies of acupuncture are dominated by RCTs. (Diener et al., 2006, Endres, 2007, Haake M and et al., 2007). This seems unsatisfactory because in RCTs, predefined outcomes measures are decided by the researchers underscoring the dominance of quantitative over qualitative methods, i.e. the opinions of the patients are not explored. A MMR approach with the semi-structured interviews and focus groups embedded in the study design is the way forward to capture the richness and complexities of the participants’ experience of a complex intervention such as acupuncture treatment. This approach is also consistent with the Medical Research Council (MRC) guidelines on complex interventions. (Craig et al., 2008)

In contrast to the over-abundance of RCTs, only a few studies have been conducted that assessed acupuncture effectiveness from the patients’ perspectives. One study conducted in the US, analysed structured questionnaire responses, and 460 hand-written stories from patients who received acupuncture treatment. (Cassidy, 1998b) Cassidy showed that what patients valued most, among others, were the relief from their chief complaints, enhanced energy levels, improvement in coping skills and a holistic approach. Another two studies from the United Kingdom using questionnaire and interviews with patients shared similar conclusions. (Gould and MacPherson, 2001, Paterson and Britten, 2003) In the Gould study, three themes emerged from the data which demonstrated what patients valued most: changes in emotional and mental wellbeing; a holistic approach especially a close patient-practitioner relationship; and acupuncture treatment offered them the chance for general health maintenance. In the Paterson study, the perceived effects of acupuncture interventions were
improvement in presenting symptoms, enhanced energy and strength as well as self-confidence.

By giving voice to the patients, these three studies captured the subjective and undoubtedly invaluable data that would certainly have been missed by a quantitative method alone. They also illustrated the important role of qualitative methods in acupuncture research.

2.9 Reflective Journal

In any studies the researchers bring with them their own beliefs and epistemological approach. As a healthcare professional who has worked in the field of acupuncture for a significant number of years, I have brought with me a certain amount of subjectivity. As a researcher who delivered the two interventions in my study, there is an even greater need to account for myself in the research process by making my actions, thoughts and feelings transparent to myself as well as to others. (Scheurich, 1997) Thus I kept a reflective journal throughout the study.

2.10 The Meridian BM Acupuncture Style

I have used the meridian BM acupuncture style for many years for patients with cancer pain. I have found this acupuncture style to be very effective. This experience informed me that my patients obtained instantaneous pain relief as they are supposed to do so. Additionally, there has been no study on acupuncture that utilised the meridian BM acupuncture for either acute or chronic pain. Thus it was very important to carry out this pilot study to evaluate if there are indications of effectiveness in women with CPP.

2.11 Administering the Interventions Myself

One of the options was to train several acupuncturists for my study to administer the meridian BM acupuncture style. However, since no study has been undertaken to evaluate the effectiveness of this style of acupuncture, I felt that it was more prudent for me to be the practitioner to administer the intervention in a pilot study. This will enable me to assess potential problems and take corrective steps in a future definitive study. The disadvantage of administering the interventions myself is the risk of bias which I am acutely aware of, and hence the audio-recording and keeping a reflective journal. The other potential problem is in the replication of the study. However, the meridian BMEA has very clear and systematic protocol in formulating treatment strategies and thus should be easy to replicate by others who are trained in this method.
2.12 Separating TCM HC from BMEA Treatment

Separating the TCM HC component from the BMEA treatment was primarily based on the supposition that the non-needling component of acupuncture treatment has therapeutic benefits. This might enable us to determine which component of acupuncture treatment is responsible for its analgesic effect.

2.13 Choice of Micro-Current Stimulation

Manual stimulation (MA) or micro-electric current (EA) stimulation of acupuncture needles may be used to optimise treatment effect. EA is a technique in which electric current is passed between two acupuncture needles that are inserted into the chosen points of the patient’s body. Although the meridian BM acupuncture typically uses MA, I have chosen to use EA in my study for reasons outlined below.

The release of endogenous opioids in the central nervous system can be achieved via MA (Mayer et al., 1977a) or EA (Cheng and Pomeranz, 1979) of acupuncture needles. The analgesic effect of EA has been demonstrated to be greater than MA. (Ulett, 1998) (Wayne et al., 2008) With EA one can set both parameters precisely at every intervention. EA may be measured objectively and is easier to control and standardize than MA. Also it is impractical and difficult to be consistent when manually stimulating the needles for 20-30 minutes. Thus EA became the method of choice for my study.

2.14 Concluding Comments

In this chapter I have reported on the logic underpinning the methodology used to answer the study’s research questions. I presented the different philosophical worldviews that guide research and my epistemology position. The rationale for an embedded MMR approach was also outlined. The issues of rigour and transparency were discussed with special emphasis, as a healthcare professional and researcher, on the need to account for others and myself by making my actions, thoughts and feelings transparent. Chapter Three focuses on the methods and materials that were used in my study.
Chapter Three Methods and Materials

3 Introduction

The present chapter presents the methods and materials used to meet the study’s primary and the secondary objectives. Three focus group discussions and semi-structured telephone interviews were embedded to answer the secondary objectives of the study. (see Chapter One, Section 1.19.2, page 31) My study began with the implementation of the two intervention arms (BMEA treatment and TCM HC), quantitative data collection, followed by data analyses. Semi-structured telephone interviews and three focus group discussions were implemented post completion of questionnaire collection and the results are presented in Chapter Five.

The protocol for this study has been published in BMJ Open (Chong et al., 2015) (see Appendix 6, page 240).

3.1 Ethical Approval

Ethical approval was obtained from the South East Scotland Research Ethics Committee 02 (14/SS/1022) in August 2014. (Appendix 7, page 249). The initial application for ethical approval in June 2014 was unsuccessful. The application was revised with less Chinese medicine terminologies and was subsequently approved.

Trial registration number: NCT02295111

3.2 Study Design

This was a single centre, three-armed pilot RCT using an embedded MMR design. Participants were recruited from the Edinburgh EXPPECT Centre for Pelvic Pain and Endometriosis Care and Treatment (www.exppectedinburgh.co.uk) at the Simpson Centre for Reproductive Health (SCRH) at the Royal Infirmary of Edinburgh (RIE). Participants were randomised into one of the following three arms:

- The meridian BMEA treatment (BMEA + TCM HC)
- Traditional Chinese Medicine health consultation (TCM HC)
- National Health Service standard care (NHS SC)

Figure 3.1(page 44) presents participants’ flow through the study.
Identify women with CPP with known and unknown aetiologies

Eligible women with CPP

Consent

Screening

Randomisation

Baseline questionnaires administered, week 0 (Baseline)
- Visual Analogue Score (VAS), Short Form (SF12)
- Brief Pain Inventory (BPI)
- Pain Catastrophising Questionnaire (PCQ)
- Work Productivity and Activity Impairment Questionnaire (WPAIQ)
- Hospital Anxiety and Depression Score (HADS)
- Sexual Activity Questionnaire (SAQ)

BMEA treatment group n=10
TCM HC group n=10
NHS SC group n=10

Questionnaires repeated at weeks four, eight and 12

Focus group discussions x three
Semi-structured telephone interview

Primary Outcomes: retention and recruitment rates
Secondary Outcomes: effectiveness and acceptability of methods of recruitment, randomisation, questionnaires and interventions

Number of ineligible patients: fall into the exclusion criteria

Reasons patients not enrolled: fall in the exclusion criteria

Screen failures

Adverse events

Reasons for withdrawal

Experience of study

Figure 3.1 Participants’ flow through the study
3.3  Delivery of Interventions

The study interventions (Chong et al., 2015) reported below are consistent with the guidelines recommended in the “Revised Standards for Reporting Interventions in Clinical Trial of Acupuncture (STRICTA): Extending the CONSORT Statement”. (MacPherson et al., 2010)

I delivered all eight interventions to the BMEA treatment and TCM HC groups within the same setting, SCRH, RIE, NHS Lothian. The step-by-step interventions are described in Sections 3.15- 3.15.2 of this chapter.

3.4  Participants

My study required 30 participants, aged eighteen (18) years or over, with a history of CPP.

3.5  Sample Size

For a pilot study a sample size of 30 participants have been recommended by the statistician. The sample size of 30 allowed estimation of the rates of recruitment and retention to within a Standard Error (SE) of at most 10%.

3.6  Inclusion Criteria

To be eligible, potential participants had to meet the following inclusion criteria:

- Be female, aged eighteen (18) years old or over
- Have a history of chronic pelvic pain for longer than six months duration
- Have an average numerical pain score of at least four (4) out of ten (0-10) in the previous week
- Be able and willing to comply with the interventions

3.7  Exclusion Criteria

Potential participants were excluded from the study if they met the following criteria:

- Were pregnant at the time of recruitment
- Had a history of malignancy, seizures, had severe bleeding disorders (e.g. Type 2 or Type 3 Von Willebrand disease)
- Were taking regular anticoagulant medications
- Had severe needle phobia
- Had a pace-maker in-situ
• Were suffering from moderate to severe psychiatric illness (under the care of a psychiatrist at the time of recruitment)
• Had received meridian BMEA treatment within the last 6 months.

3.8 Recruitment of Potential Participants

From 14th October 2014 to 15th June 2015, women aged 18 years and above with CPP who attended the EXPPECT at SCRH, RIE, were approached and asked by their Consultant Gynaecologists if they were interested in participating in the study. The gynaecologists’ decisions to refer patients were based on their knowledge of the inclusion/exclusion criteria. These were emailed to them at the start of the study and made available to them in all of the outpatient areas. During the recruitment period, the total number of patients who attended EXPPECT was 135. Out of these, 59 (44%) patients were referred to the clinical research team. These patients were approached by the clinical research nurse and given a patient information sheet (PIS) (Appendix 1, page 169) to review at home. Potential participants had at least 24 hours to review the PIS, ask questions and make an informed decision as to whether they wished to participate. After the potential participants had reviewed the PIS, and expressed an interest in participating in the study, they were given an appointment to meet with a member of the research team at SCRH and be screened for eligibility based on the inclusion/exclusion criteria.

3.9 Screening for Eligibility

Having had time to read the patient information leaflet and ask any questions, participants confirmed they were happy to volunteer for the study by signing the consent form. They were informed that they could withdraw from the study at any time without having to give any reasons, and their care would not be compromised. At this point the participants were tested for pregnancy. (MEDI. Pasante Healthcare. CE is 0086) (Screening CRF in Appendix 1, page 186). If negative, the participants were given a questionnaire to complete prior to randomisation.

During the screening process, each participant was invited to take part in the focus group discussions. It was made very clear to each participant that taking part in the focus group discussions was not mandatory. If the participant agreed to take part, permissions and consents were obtained to audiotape the discussions among the participants and facilitator. Participants were informed that the reason for the audio-recording was to ensure standardisation of procedures and techniques.
3.10 Randomisation Procedure

Eligible women were randomised to one of the following three groups:

1. Meridian BMEA treatment group (BMEA treatment group)
2. TCM health consultation group (TCM HC group)
3. National Health Service standard care group (NHS SC group)

Block randomisation was used to reduce bias and achieve balance in the allocation of participants as well as to increase the probability that each arm would contain an equal number of participants. This was achieved by sequencing participant assignments by block. Each participant had an equal likelihood of being assigned to any one of the three groups. (Efird, 2010)

My pilot study used a block size of six. Thirty (30) random numbers were generated by Statistical Package for Social Sciences (SPSS), a software package for statistical analysis. There were 30 sealed envelopes numbered one to 30, each with a card inside giving the randomly allocated intervention. At the start of the study, the first participant who passed the screening received envelope number one; and the second received envelope number two and until all 30 envelopes were used. For transparency, each envelope was opened in front of each participant at the time of randomisation. Participants who were randomised into the BMEA treatment and TCM HC groups, received the appropriate first intervention on the same day. Participants who were randomised into NHS SC group were instructed to continue with NHS standard care.

3.11 Data Collection

3.11.1 Screening

Eligible participants were consented and screened by a member of the research team. The number and reasons for screen failures were recorded on a screening log and were transferred to a user-name and password protected database at the UoE.

3.11.2 Assessment Tools

The following questionnaires were used to collect the quantitative data:

- Visual Analog Scale (VAS scale) (Freyd, 1923, Hayes and Patterson, 1921, Huskisson, 1974)
- Short Form SF-12 (SF 12) (Ware Jr et al., 1996)
- Brief Pain Inventory (BPI) (Cleeland and Ryan, 1991)
• Pain Catastrophising Questionnaire (PCQ) (Sullivan et al., 1995)
• Work Productivity & Activity Impairment Questionnaire (WPAIQ) (Reilly et al., 1993)
• Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)
• Sexual Activity Questionnaire (SAQ) (Thirlaway et al., 1996)

3.11.2.1 The VAS
The VAS was first used for the evaluation of pain in 1966. (Bond and Pilowsky, 1966) The VAS instrument (Appendix 1, page 176) used in this study is a combination of a graphic rating scale (GRS) and numeric rating scale (NRS). The GRS has descriptors of “no pain, moderate pain to worst possible pain”, placed along a horizontal line for evaluating subjective pain intensity. Similarly, the NRS has a continuous numeric rating scale starting from “0” at one end which represents “no pain” and at the other end, a “10” representing “worse possible pain”. The combinations of the two descriptors have been shown to be helpful for patients in deciding where the pain score lies. (Scott and Huskisson, 1976)

The VAS is self-administered and it is used to rate subjective pain, although it was originally designed for use by raters for the evaluation of individuals. The VAS has also been used to measure several other phenomena such as mood, (Folstein and Luria, 1973), sleep (Herbert et al., 1976) and cigarette cravings (Steuer and Wewers, 1988)

3.11.2.2 The BPI
The BPI (Appendix 1, page 178) is a tool for pain assessment. There are two dimensions to the pain evaluation: pain intensity and interference. Severity or intensity reports on the “sensory” and the interference captures the “reactive” dimensions of pain. The BPI asks patients to rate their pain at the time of completing the questionnaire and also pain at its worst, least and average over the past 24 hours. Each of these parameters is measured on a 0-10 scale (0=no pain, 10=worst pain).

The BPI asks the patient to rate how much their pain interferes with their general activity, mood, walking ability, normal work, relationships with other people, enjoyment of life and sleep. Each of these parameters is measured on a 0-10 scale (0=does not interfere, 10=completely interferes).

The BPI was developed by the Pain Research Group of the World Health Organization (WHO) to evaluate pain severity and associated interference in patients with cancer. (Cleeland and Ryan, 1994, Daut et al., 1983) The BPI has been recommended by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) to
evaluate pain intensity and physical function. (Dworkin et al., 2005) It has been extensively validated in cancer pain (Harris et al., 2007, Bennett, 2009) as well as non-malignant chronic pain. (Bann et al., 2004, Tan et al., 2004)

3.11.2.3 The SF-12
The SF-12 (Appendix 1, page 176) is a health and wellbeing survey. It consists of twelve (12) items and it evaluates the health of the patient from their perspective. The SF-12 has summary scores: the physical component status (PCS) and the mental component status (MCS). (Ware Jr et al., 1996) The PCS asks the patient to rate (“yes, limited a lot”, “yes limited a little” and “No, not limited at all”) for example, how much their pain limit their daily activities such as climbing stairs, pushing a vacuum cleaner or playing golf. The MCS component asks the patient to rate if they had any emotional problems that interfered with their daily activities or normal work, during the past four weeks.

The SF-12 was originally developed for the Medical Outcomes Study of patients with chronic conditions in the United States in order to provide a shorter and easier alternative to the SF-36. (Ware et al., 1995, Ware Jr et al., 1996) The SF-12 has been validated repeatedly for the quality of life measure. (Gandek et al., 1998, Jenkinson and Layte, 1997)

3.11.2.4 The HADS
The HADS (Appendix 1, page 183) is a screening and not a diagnostic tool. It is a self-administered tool that was developed for use in non-psychiatric patients to screen for: anxiety and depression. (Zigmond and Snaith, 1983, Bjelland et al., 2002, Herrmann, 1997) There are a total of 14 items: seven depression items which measure the cognitive and emotional aspects of depression and seven anxiety items that focus on the cognitive and emotional aspects of anxiety.

The HADS has also been endorsed by NICE for use in primary care to measure baseline depression and responsiveness to treatment. (Smarr and Keefer, 2011)

3.11.2.5 The PCQ
It is well documented that catastrophic thinking heightens the pain and distress experienced by the catastrophiser. (Sullivan et al., 1995, Chaves and Brown, 1987, Rosenstiel and Keefe, 1983, Spanos et al., 1979) Catastrophising is defined as “an exaggerated negative mental set brought to bear during actual or anticipated painful experience”. (Sullivan et al., 2001) The development of the PCQ (Sullivan et al., 1995) (Appendix 1, page 180) represents a comprehensive tool to capture the three different aspects of catastrophising: rumination (“I
can’t stop thinking about how much it hurts”), magnification (“I worry that something serious may happen”) and helplessness (“It’s awful and I feel that it overwhelms me”).

The PCQ is a thirteen-item (13) instrument which has been shown to have excellent internal consistency, is a term used to describe a tendency to expect the worse and to exaggerate or ruminate on pain. By using the PCQ, the study set out to identify a sub-set of the participants who were catastrophisers and if catastrophising influenced the outcome of the interventions in this subset of catastrophisers.

3.11.2.6 The WPAIQ
The WPAIQ (Appendix 1, page 181) has four summary statistics: absenteeism, presenteeism, work productivity loss and activity impairment. The WPAIQ is a self-administered questionnaire, which aims to elicit the impact of CPP on impairment and work loss and whether the interventions reduce the number of impairment days and days lost to work. The WPAIQ is an instrument that measures impairments in both paid and unpaid work as well as absenteeism, presenteeism during the past seven days. The WPAIQ has been validated in numerous chronic conditions such as irritable bowel syndrome (Reilly et al., 2004), Crohn’s disease (Reilly et al., 2008) and in rheumatoid arthritis. (Zhang et al., 2010)

3.11.2.7 The SAQ
The SAQ (Appendix 1, page 184) was developed to evaluate the impact of tamoxifen in a chemoprevention trial on the sexual functioning of women at high risk of developing breast cancer. (Thirlaway et al., 1996) The SAQ asks patients to rate their sexual pleasure (desire, enjoyment and satisfaction), discomfort (dryness and pain) and habit (habitual sexual behaviour) during the past month. The SAQ consists of 10 items and it has been shown to be a valid, reliable and acceptable measure of sexual functioning in patients with cancer. (Thirlaway et al., 1996) The SAQ is reported to have good feasibility and a satisfactory response rate. (Stead et al., 1999, Ganz et al., 2002)

3.11.2.8 Questionnaire Schedule
In addition to the questionnaires, at baseline (Week 0) participants’ demographic and relevant clinical information were recorded. The questionnaires were posted to all participants at weeks 4, 8 and 12 with a stamped addressed envelope enclosed.
3.11.3 Focus Group Discussions Procedure

Three focus group discussions were conducted post week twelve (12) questionnaires completion. (Morgan, 1997: 47-48) The discussions were audiotaped, transcribed and thematically analysed.

3.11.4 Recruitment and Consent

At recruitment as well as at screening, participants were invited to take part in their respective focus group discussions. They were given information about the focus groups (Appendix 3, page 200). Additionally, they were informed that participation was not mandatory. Permissions and consents were obtained to audiotape the discussions among participants and facilitator.

Each participant from the BMEA treatment, TCM HC and NHS SC groups was sent a letter of invitation detailing the venue, time, day and date of their respective focus groups (Appendix 3, page XX). Participants were informed that snacks and beverages would be provided and that their travel expenses would be reimbursed. To ensure a high turnout, a week before the designated date of each respective focus group discussions, each participant was contacted by telephone to remind them of the time and venue of their focus group. I was responsible for ensuring that the letters of invitation were sent out on a timely fashion, and that there were beverages and snacks on the day of the discussions.

3.11.5 Content Guides for Focus group discussions

The content guides (Appendix 3, page 204) for the BMEA treatment, TCM HC and NHS SC groups were developed to capture the participants’ perceived benefits and experience of the study. I developed the content guides with input from Dr. G Highet, who is one of the research team (UoE) and has had many years’ experience in qualitative research.

3.11.6 Facilitation of Focus group discussions

Dr. G Highet facilitated the focus group discussions. Because I administered all the interventions to the BMEA treatment and TCM HC groups, I did not take part in the discussions in order not to bias the discussions.

The encrypted audio-taped discussions were downloaded into the user-name and password protected database of the UoE and were sent via email to “1st Class Secretarial” (https://transcription.1stclass.uk.com/) for verbatim transcription. “1st Class Secretarial” is a professional and reputable company that specialises in transcription and is based in Edinburgh.
3.11.7 Thematic Analysis

The datasets from the three focus groups’ discussions were analysed thematically. I undertook the analysis manually following the steps and iterative processes provided by Braun and Clarke (Braun and Clarke, 2006). Figure 3.2 (page 52) outlines the steps of thematic analysis.

Figure 3.2 Thematic Analysis Steps and Process (Braun and Clarke, 2006)

<table>
<thead>
<tr>
<th>Steps to thematic analysis</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.  Familiarisation and organisation of data</td>
<td>Reading the data repeated, noting initial thoughts and ideas</td>
</tr>
<tr>
<td>2.  Generating Initial Codes</td>
<td>Coding relevant and interesting features of the data systematically and collecting data relevant to each code</td>
</tr>
<tr>
<td>3.  Searching For Candidate Themes</td>
<td>Gathering codes into candidate themes and data relevant to each theme</td>
</tr>
<tr>
<td>4.  Reviewing themes</td>
<td>Evaluating if the themes are consistent to coded extracts and the entire data set and generating an initial thematic map</td>
</tr>
<tr>
<td>5.  Defining and naming themes</td>
<td>Refining each theme so that it fits in with the overall story the analysis</td>
</tr>
<tr>
<td>6.  Producing the report</td>
<td>Critically select the most compelling themes and extracts and relating back to the research question and literature.</td>
</tr>
</tbody>
</table>

Step 1: Familiarization and organization of data

This iterative phase required me to “immerse” in the dataset to familiarize myself with the data. The immersion involved reading the dataset repeatedly and actively engaging with it while searching for meanings, patterns and making notes or ideas. This process also enabled me to organise the data, and was repeated several times until a list of data was prepared for the generation of codes in Step 2.

Step 2: Generating initial codes

Step 2 is a coding process, which is also part of the analysis. Figure 3.3 (page 53) demonstrates the initial steps of coding process using the data extracts, which were organized into meaningful groups (Tuckett, 2005). The highlighted text showed the coding using data extracts. Generating the initial codes was helpful for identifying interesting features of the data and formed the most fundamental element of the raw data (Braun and Clarke, 2006).
Data Extracts

\begin{tabular}{|l|l|}
\hline
**Data Extracts** & **Coded for** \\
\hline
‘Cos one thing it done for me was help me sleep at night. It helped me…I went through…I went through about four years, eh, either pacing the floor at night time…or having broken sleep. When I started on my acupuncture, I could sleep through the night. Even just getting four solid hours…was just like a full night’s sleep for me. That was the best bit… It was just the…getting the…like the night’s sleep…So getting that sleep…even for the solid four hours or that…(Carmen) & Helped her sleep at night \\
I found it a godsend. It took my pain away for a day, two days after the treatment…which I hadn’t had in over six years, so…it made a big difference, I felt I had energy…the following day…(Sam) & Pain free for a day or two …a godsend
Big difference to energy \\
…and I’ve got a two year old daughter… I’m knackered from working…but when you got the acupuncture…it was so different…it was…go home for three, four hours before she went to bed, and…had a conversation with her…I painted with her…I did things with her that I hadn’t done before. I couldn’t think…time for that at all, it was…(Sharon) & Spent more quality time with daughter \\
\hline
\end{tabular}

---

**Figure 3.3** Step 2: Initial Steps Of Coding Using The Data Extracts

The yellow highlight is to show how data are extracted.

**Step 3: Searching for main themes**

The search for themes in Step 3 was another iterative process. I had to go back to the dataset, steps 1 and 2 repeatedly to ensure that the data were in context and represented what the participants said. When all the data were coded and collated, the initial codes from step 2 were re-analysed and combined into different themes. This essentially meant sorting out the codes into candidate themes and sub-themes. Some codes were parked as miscellaneous themes to be reviewed later if they did not appear initially to fit into the main themes. A thematic map in Figure 3.4 (page 54) shows an example of the three main candidate themes...
and sub-themes of participants talking about their “experience of acupuncture treatment”. Step 3 concluded with a list of candidate themes and sub-themes.

Figure 3.4 Step 3 Thematic map showing three main candidate themes and sub-themes

**Step 4: Reviewing themes**

In step 4, I reviewed the list of main candidate themes and sub-themes to ensure that they reflected the essence of the coded data and that they fitted in with one another. Again, that required me to re-read the entire data set. For example, Figure 3.4 (page 54) shows the sub-themes of “help me sleep at night” and “had 4 hours solid sleep” hang well together under the main candidate theme of “Enhanced Sleep”. Each candidate theme, for example, “pain relief”, is clearly different and identifiable from “enhanced sleep” and “more energy”.

**Step 5: Defining and naming themes**

In the final step of the analysis, I named and defined the three main candidate themes (Figure 3.5, page 55) by collapsing them into one overarching theme: “whole person effects”. Braun and Clarke (2006) clarified “defining” to mean the identification of the essence of each theme by returning to the collated data extracts for each theme to ensure a coherent and consistent narrative.
3.11.8 Semi-Structured Telephone Interview

I conducted a semi-structured telephone interview post focus group discussions to address the secondary objectives of the study (Chapter One, Section 1.19.2, page 31). Table 3.1 (page 56) presents the complete interview questions which consist of 4 main parts: acceptability of recruitment and randomisation methods, acceptability of questionnaires as well as their overall experience of the study. The participants were asked to rate these questions from 1 to 5 on a 5-point scale from positive to negative or acceptable to unacceptable.

At the initial call, participants were informed of the purpose of the telephone interview, that they could decline to participate, and the interview would last 10-15 minutes. None of the participants whom I contacted declined the interview. Participants whom I had been unable to contact were left a telephone message explaining the intent of my call and requesting a return call. No further calls were made if participants did not take further action.
### Table 3.1 Semi-Structured Telephone Interview Questions

#### Acceptability of Recruitment methods
On a scale of 1-5: … with 1 being (acceptable) and 5 being (not acceptable)

<table>
<thead>
<tr>
<th>Acceptable</th>
<th>Not Acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

a. …how acceptable were the manner in which you were approached about taking part in the trial?
b. … how acceptable was the way in which the study was explained?
c. …how acceptable were the methods of contacting you e.g. phone, text, face to face acceptable

#### Acceptability of Randomisation techniques
On a scale of 1-5: … with 1 being (acceptable) and 5 being (not acceptable)

<table>
<thead>
<tr>
<th>Acceptable</th>
<th>Not Acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

a. …how acceptable to you is the idea of randomisation?
b. … was the way you were randomised in the study acceptable to you?

#### Acceptability of Questionnaires

<table>
<thead>
<tr>
<th></th>
<th>Acceptable</th>
<th>Not Acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Were the instructions for completing the questionnaires clear &amp; easy to understand?</td>
<td>Yes/No</td>
<td></td>
</tr>
<tr>
<td>b. Do you feel that there were too many questionnaires or the right amount?</td>
<td>Too many/Right Amount</td>
<td></td>
</tr>
<tr>
<td>c. Did you understand why you were completing each the questionnaire</td>
<td>Yes/No</td>
<td></td>
</tr>
<tr>
<td>d. Was it easy or difficult to return the paperwork after completion?</td>
<td>Difficult/Easy</td>
<td></td>
</tr>
</tbody>
</table>

#### Overall Participants Experience of the study
Please could you rate your experience of the study? 1 being positive and 5 being negative.

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall has the study experience been a positive or negative one?</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruitment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomisation method</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Other Comments:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.12 Statistical Analyses

Data from the questionnaires were entered into an Excel data sheet and were appropriately coded in SPSS ready for analysis. For quality control, two other members of the research team checked the data entered. Estimates and confidence limits were calculated for recruitment and retention as well as relevant outcome measures from the questionnaires. The recruitment rate was calculated based on the number of women referred and the number who passed screening and proceeded to randomisation.

Confidence intervals were calculated for the estimates of rates of recruitment and retention.

3.12.1 Differences Between Groups and Per Group

Although my pilot study was not powered to allow comparisons between the randomised groups, differences between the three groups and per group were statistically analysed using a one-way analysis of variance (ANOVA). Differences between baseline and subsequent time points (weeks 4, 8 and 12) were calculated and then analysed per group as well as for differences between the three groups: BMEA treatment, TCM HC and NHS SC.

3.12.2 Clinical Significance

Differences from baseline within each group were also tested for significance. Where a clinically relevant fall was achieved, the data was reduced to a binary variable (VAS, BPI). Fisher’s Exact Test was used to test for differences in rates between the groups. Due to the small sample size, a clinically significant response is not expected. Clinical significance is defined as a drop of $\geq 30\%$ or $\geq 2$ points in the relevant score from baseline to weeks 4, 8, and 12. A one-point drop from baseline to weeks 4, 8 and 12 in the BPI-sleep is considered clinically significant.

As this was a pilot study, no additional adjustments for multiple testing were made.

The statistician was blinded to the groups at the time of analysis.

Additional information on effectiveness and acceptance of study methods not covered in the questionnaires was captured in the focus group discussions and semi-structured telephone interviews. The appropriateness of assessment tools was assessed by examination of data completion and patterns of missing data and semi-structured telephone interviews.
3.13 Planned Intervention Schedule

Table 3.2 (page 58) shows the planned intervention schedule for the BMEA treatment and TCM HC groups. Each participant in both the groups shared the same approach to TCM health consultation, the details of which are described in Section 3.14 (page 59) of this chapter. The BMEA treatment and TCM HC groups were scheduled to receive two interventions per week for four weeks, a total of eight interventions. The duration of the first interventions for both groups was scheduled for approximately 60 minutes. The TCM HC group did not receive the meridian BM electro-acupuncture. The subsequent seven interventions for both groups were anticipated to last no longer than 40 minutes. (Table 3.3, page 58).

Table 3.2 Intervention Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>BMEA Treatment Group</th>
<th>TCM HC Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>BMEA treatment</td>
<td>TCM health consultation</td>
</tr>
<tr>
<td>1 Week</td>
<td>2 X Week</td>
<td>2 X Week</td>
</tr>
<tr>
<td>2 Week</td>
<td>2 X Week</td>
<td>2 X Week</td>
</tr>
<tr>
<td>3 Week</td>
<td>2 X Week</td>
<td>2 X Week</td>
</tr>
<tr>
<td>4 Week</td>
<td>2 X Week</td>
<td>2 X Week</td>
</tr>
<tr>
<td>Total</td>
<td>4 Weeks</td>
<td>8 Interventions</td>
</tr>
</tbody>
</table>

Table 3.3 Duration of First and Subsequent Interventions

<table>
<thead>
<tr>
<th></th>
<th>First Intervention</th>
<th>Subsequent Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMEA treatment group</td>
<td>60 minutes</td>
<td>No longer than 40 minutes</td>
</tr>
<tr>
<td>TCM HC group</td>
<td>60 minutes</td>
<td>No longer than 40 minutes</td>
</tr>
</tbody>
</table>

To ensure the standardisation of procedures and techniques, interventions were audiotaped with prior permission from participants in the meridian BMEA treatment and TCM HC groups. The contents of the audio recordings of the interventions were encrypted and secured in a database of the UoE. All intervention data from the BMEA treatment and TCM
HC groups were recorded on a case record form (CFF Appendix 1, page 206) and kept in a secure locked office.

3.14 TCM Health Consultation

The BMEA treatment and the TCM HC groups received the same patient-centred approach to TCM health consultation. (Kaptchuk, 2008)(See Chapter One, Section 1.8.2, page 21, for a full description of the three components of acupuncture treatment)

3.14.1 A Warm and Supportive Environment

Based on my clinical experience, achieving a supportive environment would require me to be respectful of each participant’s experience of pain, cultural, psychosocial, emotional status and her belief system. These were demonstrated in attentive and careful listening, showing care, compassion, kindness and understanding by acknowledging with appropriate verbal and body language responses. A clinical encounter provides golden opportunity to establish a therapeutic liaison between the participant and myself. (Mitchell, 1998)

3.14.2 Observation

I observed and noted the participant’s general appearance including the manner, facial expression, the way she behaved during the intervention, and the quality of our interactions for examples; did she respond to my requests or questions, was the tone of her voice flat, or did she have eye contact with me? Further, the participant’s manner might reflect her emotional state, for example I aimed to note if she appeared to be agitated, irritable or passive, inward and quiet. (Kaptchuk, 2000)

As part of my reflective practice, I would make a mental note if I observed that I was nervous or anxious during the consultation. At an appropriate time, I would reflect upon my nervousness or anxiety to gain better insight of myself as well as my interaction with the participant.

3.14.3 Tongue Examination

Examination of the tongue was undertaken in a room that had natural light. I followed a well-established method of working based on many years of my clinical experience. I offered the participant a hand held mirror and we both examined her tongue together. The prompting questions I posed to the participants were based on my observations of the tongue at the time of the examination.
Tongue inspection (Kaptchuk, 2000, Maciocia, 2000 #878) was performed systematically by instructing the participant to examine with me, the tongue from the tip to the root. The following were aspects of tongue examination:

- **Tongue body**: When I observe the presence of clinically relevant features, I would prompt the participant. For example, if an ulcer were present, I would ask if there were any ulcer on the sides of the tongue?
- **Tongue colour**: I would prompt the participant by asking, “What colour do you think your tongue is: pink, dusky or strawberry red?” What is the colour of the tongue tip and are there any fine red grains on the tip?
- **Tongue coat**: With regards to the tongue coat, I would ask, “Tell me what you think the colour of tongue coat is: yellow or white? Is the coat thin or thick?
- **Tongue moss/material**: I would look for the degree of moisture, peeled patches on the tongue.
- **Tongue shape**: I would ask the participant if the tongue was thin, swollen, normal, trembling, stiff or contracted or deviated, long or short.

Figure 3.6 (page 61) shows the result of a tongue examination using the above steps. The left side of the tongue had an ulcer, as indicated by the arrow. The tongue colour was strawberry red with a redder tip with fine red grains. The coat was yellow and thick: thicker at the root (Lower Heater) than at the middle (Middle Heater). (See Glossary). The coat began to thin out at the Upper Heater. The tongue was moist and slightly puffy.

The most significant of the above observations was that the tongue coat was thick and yellow and the colour of the tongue was strawberry red with a redder tip that had fine red grains. Utilising the 8 principles (See Glossary) to interpret the result, the owner of the tongue would appear to have damp heat in the lower and middle burner (symptoms might include bloating, gas, foul smelling stool), disturbed sleep; either she was experiencing difficulty in falling or staying asleep or not feeling rested in the morning, probably as a result of emotional agitation. (Maciocia, 2000).

Based on the tongue findings, dietary advice was given, such as to minimise fast foods such as “McDonalds” and “Kentucky Fried Chicken”, and to increase intake of fruits and vegetables. The participant was also advised to practise mindful breathing in and out to promote calmness and relaxation. (Benson, 1975, Grossman et al., 2004)
3.14.4 Enquiry

I would enquire about the participant’s medical history and personal background at the first intervention, for example when and how the pain started, what made it better or worse, its quality and location. At subsequent interventions the participant would be asked about how she felt about the previous intervention, her pain level at the time of the consultation, sleep, energy level and emotional status. If the participant had a pressing need to talk about her emotions or any aspects of her pain, the consultation would be led by this need. There would always be a dialogue between the participant and myself. The goal here would be to create a partnership where the consultation would be participant centred.

Using the above example again, I would ask about her dietary habits as there were signs in the tongue examinations that led me to believe that the yellow thick coat and the strawberry red tongue were probably due to sub-optimal diets. I would also enquire about her emotional status as the fine red grains on the red tip tongue indicated to me that she was experiencing emotional agitation. (Kaptchuk, 2000, Maciocia, 1989)

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For confidentiality reason, permission letters from the owners of the photos will be furnished upon request.
3.14.5 Listening
I listened carefully to what the participant had to say or tried to communicate to me. I “listened” and observed her body language, facial expression and the tone of her voice. When appropriate I gave the participant the opportunity to do most of the talking and I the listening. (Kaptchuk, 2000, Maciocia, 1989)

3.14.6 Palpating
Palpation was mainly performed along the balancing meridian for ashii points (tight and tender points) for participants in the BMEA treatment group. This was to identify the therapeutic points for needle insertion and treatment (Figure 3.11, page 68). (Tan, 2003)

Participants in the TCM HC group received palpation when appropriate and indicated. For example if the participants’ pain characteristics included low back pain that radiated to the gluteal, groin, leg or lower abdomen) and the pain was described as aching, throbbing and a heavy sensation, I would palpate the appropriate areas (e.g. the abdominal and the guteal muscles) to evaluate for trigger points. If trigger points were found, I would advise accordingly.

3.14.7 Recommendations
In the example given earlier in this chapter, the recommendation was to eat less of fast foods and to include vegetables and fruits of different colours in her diet. (Benfield, 1991) To address her emotional agitation, I taught the participant simple skills such as mindful breathing and advised her to increase her physical activities such as walking to manage stress and emotional agitation. Mindful breathing techniques involved requiring the participant to focus her attention and intention on each breath in and breath out. (Twicken, 2012 page 15, Shapiro et al., 2003, Grossman et al., 2004) The participant’s intention might be to feel calm or less anxious after each complete full breath. However, the participants always chose the intention.

3.15 Algorithms For Acupuncture Points Selection
After the participants in the BMEA treatment group had received the TCM health consultation, they proceeded to receive the meridian BMEA (acupuncture needling component). Table 3.4 (page 63) presents algorithm for the five systems for balancing meridians. Acupuncture points selection for each participant in the BMEA treatment group was based on the algorithm developed by Tan (Tan) and was outlined in Chong (Chong et al., 2015). This section outlines the two algorithms for choosing the therapeutic points using
the Image and Mirror Method (Tan, 2003). The Image Method uses the limbs to balance the body and vice versa. (Table 3.5, page 67). The Mirror Method utilizes the upper limbs to balance the lower limbs and front to balance the back and vice versa.

Table 3.4  Five Systems of Meridian Balance Method (Tan, 1996)
(From: https://lotusinstitute.com. 2007)

<table>
<thead>
<tr>
<th>Sick Meridian</th>
<th>System 1</th>
<th>System 2</th>
<th>System 3</th>
<th>System 4</th>
<th>System 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name sharing</td>
<td>Branching/ Bie Jing</td>
<td>Interior/ exterior Biao Li</td>
<td>Clock opposite</td>
<td>Clock neighbour</td>
</tr>
<tr>
<td>LU/Hand Taiyin</td>
<td>SP</td>
<td>UB</td>
<td>LI</td>
<td>UB</td>
<td>LR</td>
</tr>
<tr>
<td>LI/Hand Yangming</td>
<td>ST</td>
<td>LR</td>
<td>LU</td>
<td>KI</td>
<td>ST</td>
</tr>
<tr>
<td>ST/Foot Yangming</td>
<td>LI</td>
<td>PC</td>
<td>SP</td>
<td>PC</td>
<td>LI</td>
</tr>
<tr>
<td>SP/Foot Taiyin</td>
<td>LU</td>
<td>SI</td>
<td>ST</td>
<td>TH</td>
<td>HT</td>
</tr>
<tr>
<td>HT/Hand Shaoyin</td>
<td>KI</td>
<td>GB</td>
<td>SI</td>
<td>GB</td>
<td>SP</td>
</tr>
<tr>
<td>SI/Hand Taiyang</td>
<td>UB</td>
<td>SP</td>
<td>HT</td>
<td>LR</td>
<td>UB</td>
</tr>
<tr>
<td>UB/Foot Taiyang</td>
<td>SI</td>
<td>LU</td>
<td>KI</td>
<td>LU</td>
<td>SI</td>
</tr>
<tr>
<td>KI/Foot Shaoyin</td>
<td>HT</td>
<td>TH</td>
<td>UB</td>
<td>LI</td>
<td>PC</td>
</tr>
<tr>
<td>PC/Hand Jueyin</td>
<td>LR</td>
<td>ST</td>
<td>TH</td>
<td>ST</td>
<td>PC</td>
</tr>
<tr>
<td>TH/Hand Shaoyang</td>
<td>GB</td>
<td>KI</td>
<td>PC</td>
<td>SP</td>
<td>GB</td>
</tr>
<tr>
<td>GB/Foot Shaoyang</td>
<td>TH</td>
<td>HT</td>
<td>LR</td>
<td>HT</td>
<td>TH</td>
</tr>
<tr>
<td>LR/Foot Jueyin</td>
<td>PC</td>
<td>LI</td>
<td>GB</td>
<td>SI</td>
<td>LU</td>
</tr>
</tbody>
</table>
3.15.1 Image Method Algorithm: Points Selection

Step 1: Diagnose the affected/sick meridian(s)

At this fundamental and very important step, the participant was instructed to indicate with one finger where the pain was located so that the affected meridian(s) could be diagnosed accurately. (For the 12 Meridians, see Appendix 2, page 194) For example Figure 3.7 (page 64) demonstrates the patient identifying the Kidney meridian (The Foot Shaoyin meridian) as the affected meridian i.e. where the most pain was located. Figure 3.8 (page 65) shows the Kidney meridian traversing the body from the foot and ending at the top of the chest.

![Image of a finger pointing to an area of pain]

**Figure 3.7 Step 1. Identifying the sick meridian.**
Patient pointed to location of pain with one finger. The affected meridian was the Kidney meridian (Foot Shaoyin) (Written permission obtained from owner)
Step 2: Identification of the balancing meridian(s) based on the five systems of meridian balancing.

The five systems of meridian balancing are shown in Table 3.4. (page 63). With this system, there are five meridians to balance the Kidney meridian (Foot Shaoyin):

- Heart meridian (Hand Shaoyin)
- Triple Heater meridian (Hand Shaoyang)
- Urinary Bladder meridian (Foot Taiyang)
- Large Intestine meridian (Hand Yangming)
- Pericardium meridian (Hand Jueyin)

Based on my extensive experience and feedback from participants, the Heart meridian (Hand Shaoyin) (Figure 3.10, page 66) was the meridian of choice to balance the Kidney meridian (Foot Shaoyin). Figure 3.9 (page 66) shows the Heart meridian (Hand Shaoyin) traversing the body starting from the little finger and ending in the chest.
Figure 3.9  Step 2: Identifying the Heart Meridian as the balancing meridian.
(Written permission obtained from owner)

Figure 3.10 The Heart Meridian (Hand Shaoyin)
The heart meridian starts from the little finger and ends in the chest.
Downloaded from: http://www.geocities.ws/altmedd/images/mer_r.gif

Step 3: Acupuncture point(s) selection for treatment

Once the balancing meridian(s) was identified and selected, step 3 involved locating the therapeutic points along the balancing meridian by using the Image Method (Table 3.5,
which shows that the forearm images the lower abdomen and lower back. Figure 3.11 (page 68) shows the Heart Meridian of the left forearm being palpated for ashii points. These points were the therapeutic points if upon pressing, the participant reported the most pain relief. If the participant reported inadequate pain relief, it was important to re-palpate along the next choice of meridians which was the Triple Heater or the Urinary Bladder meridians. The points along the chosen meridian that gave the most pain relief were the therapeutic points.

<table>
<thead>
<tr>
<th>Needled Area</th>
<th>Sick Area (Image)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finger</td>
<td>Testicles &amp; anus</td>
</tr>
<tr>
<td>Hand</td>
<td>Genitals, coccyx, sacrum</td>
</tr>
<tr>
<td>Wrist</td>
<td>Bladder area, lumbo-sacral area</td>
</tr>
<tr>
<td>Forearm</td>
<td>Lower abdomen, lower back</td>
</tr>
<tr>
<td>Elbow</td>
<td>Umbilicus level, lumbar 2, waist</td>
</tr>
<tr>
<td>Upper arm</td>
<td>Upper abdomen, rib cage, chest, mid-upper back</td>
</tr>
<tr>
<td>Shoulder</td>
<td>Neck, jaw, base of skull</td>
</tr>
<tr>
<td>Top of shoulder</td>
<td>Top of head</td>
</tr>
</tbody>
</table>
Step 4: Insertion of Needles

Once the therapeutic points were identified, acupuncture needles were inserted into these points as demonstrated in Figure 3.12 (page 68). Thus acupuncture point(s) selection was based on the location of the participants’ pain and the steps outlined and not on TCM pattern diagnosis (see Glossary).
**Step 5: Connecting Stimulator to the acupuncture needles.**

When all the needles were inserted into the appropriate acupuncture points and satisfactory pain relief was achieved, the AS SUPER 4 Digital stimulator (CE 0197, Germany. Four AAA batteries) was connected to the acupuncture needles (Figure 3.13, page 69) The negatively charged, black lead (to stimulate) was connected to the acupuncture needle inserted in the point that gave the most pain relief (therapeutic point), while the positively charged lead (red) was connected to another needle inserted distal to the therapeutic point. The electro-stimulator emitted a square wave of low frequency (2 Hz) for 3-second alternating with high frequency (100 Hz). Program 2 was selected and the duration of treatment was no shorter than 20 minutes and no longer than 30 minutes. These parameters were based on the work of Han and his group. (Han and Terenius, 1982) The intensity of the electrical stimulation was adjusted based on the participant’s feedback, to produce a strong sensation without pain or discomfort.

![Figure 3.13 Step 5: Acupuncture needles connected to the AS SUPER 4 Digital stimulator.](image)

White arrows showed the needles were connected to the stimulator. (Written permission obtained from the owner of this image).
3.15.2 Mirror Method Algorithm: Points Selection

Table 3.6 (page 70) shows the Mirror and Reverse Methods.

<table>
<thead>
<tr>
<th>Mirror Method</th>
<th>Reverse Mirror Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finger ↔ Toe</td>
<td>Finger ↔ Top of Hip</td>
</tr>
<tr>
<td>Hand ↔ Foot</td>
<td>Hand ↔ Hip</td>
</tr>
<tr>
<td>Wrist ↔ Ankle</td>
<td>Wrist ↔ Hip Joint</td>
</tr>
<tr>
<td>Forearm ↔ Lower Leg</td>
<td>Forearm ↔ Thigh</td>
</tr>
<tr>
<td>Elbow ↔ Knee</td>
<td>Elbow ↔ Knee</td>
</tr>
<tr>
<td>Upper Arm ↔ Thigh</td>
<td>Upper Arm ↔ Lower Leg</td>
</tr>
<tr>
<td>Shoulder ↔ Hip</td>
<td>Shoulder ↔ Ankle</td>
</tr>
<tr>
<td>Back ↔ Front (Du ↔ Ren)</td>
<td>Front ↔ Back (Ren ↔ Du)</td>
</tr>
</tbody>
</table>

Step 1: The patient was instructed to point with one finger where the most pain was. See Figure 3.14 (page 70).

Figure 3.14 Step 1 Mirror Method
Identifying the location of most pain indicated by the finger and the white arrow (Written permission obtained from the owner of this image)
**Steps 2 and 3: Palpating and locating a therapeutic point.**

Figure 3.15 (page 71) shows the identification of a therapeutic point on the back that was a mirror image of the front. This was the therapeutic point (indicated by the white arrow) when palpated and pressed the patient reported a reduction of pain in the lower abdomen. This process was repeated if there were other painful areas until a satisfactory level of pain relief was achieved.

![Figure 3.15 Steps 2 and 3 combined.](image)

**Figure 3.15 Steps 2 and 3 combined.**
Palpating and location the therapeutic point on the back that mirrors the front (see white line and arrow) where the most pain was.
(Written permission obtained from the owner)
Step 4: Inserting acupuncture needles

Once the therapeutic point/s was identified, an acupuncture needle(s) was inserted as shown in Figure 3.16 (page 72)
Step 5: The needles were connected to the AS SUPER 4 Digital stimulator (Figure 3.17, page 73). See step 5 of the Image Method (Section 3.15.1) for full details of the intensities and frequencies used.

3.16 Depth of Needle Insertion

The depth of the needle insertion was adjusted to the thickness of the muscles and subcutaneous fatty tissue of each participant. For example, for the gluteal muscle, typically a 0.30 mm x 75 mm needle was inserted to a depth of between 25.4 mm to 50.8 mm. For the forearm, typically a 0.25 mm x 30 mm needle was inserted to a depth of about 6.35 mm to 19.00 mm. The number of needles inserted was individualised based on the feedback from the participants. Figure 3.18 (page 74) compares the thickness of an acupuncture needle (0.25 mm) with a sewing needle, medical syringe and matchstick.
Figure 3.18 Comparison of the thickness of an acupuncture needle (0.25mm)
The thickness of an acupuncture needle is compared with a sewing needle, a medical syringe and match stick. Downloaded on 12 April 2016 from: http://www.watertownacupuncture.com

3.17 National Health Service Standard Care Group

The NHS SC group continue to follow their standard care given by their clinicians who might be their GP or the members of EXPPECT. Standard care is defined as care and treatment that patients would normally receive at EXPPECT, RIE. These might include oral analgesics, neuromodulators such as anti-convulsants and anti-depressants, hormonal approaches, counselling, behavioural therapy or surgical interventions when indicated. The EXPPECT service consists of a Consultant Gynaecologist, a Consultant Anaesthetist specialising in pain management, a Clinical Psychologist and a Specialist Nurse. None of the participants in NHS SC group received the meridian BM electro-acupuncture treatment or the TCM HC.

3.18 Adverse Events

An adverse event is any untoward medical occurrence, which does not necessarily have a causal relationship to the intervention. Any adverse events (AEs) that occurred during the study were reported in the participant’s medical record and followed up until resolution of the event. Such events were also reported to the ACCORD Research Governance (www.accord.ed.ac.uk) and Quality Assurance Office based at the University of Edinburgh within 24 hours. Each participant in Groups 1 and 2 was instructed to contact a member of the clinical research team if they had an event that necessitated hospitalisation, or resulted in significant disability or incapacity. In addition, each participant was asked about the
occurrence of adverse effects at each of the eight visits during the study. Open-ended and non-leading verbal questioning of the participant was used to enquire about adverse events, or if they had been admitted to hospital. If there were any doubt as to whether a clinical observation was an AE, the event was recorded.

### 3.19 End of Study

The end of study was defined as the last participants’ last contact with the study, which was the end of the last semi-structure telephone call.

### 3.20 Reflective Journal

There are different models of reflective practice. (Borton, 1970) (Schön, 1983). However, the key idea is that experience without deliberate reflection on the experience does not result in learning. (Loughran, 2002) Borton’s reflective practice has its roots in education. It involved the practitioner asking the questions, “what?, so what?, now what?” in order to frame and describe a situation. This process enabled the practitioners to reflect on their reactions to situations and enhance their learning.

Schön proposed the notions of “reflection-in-action” and “reflection-on-action”. Reflection-in-action is the ability to simultaneously "think on his or her feet" while dealing with the situation and connects feelings, emotions and prior experiences. (Schön, 1983). Reflection-on-action involves thinking through one’s reaction to a situation, framing the problem and finding solutions based on past experiences.

My reflective practice closely echoed those proposed by Borton and Schon. In the context of my thesis, my reflective practice serves to make my thoughts and feelings, as well as my observations, discussions, remarks or behaviours of the participants that appeared interesting or salient to me, visible to others and myself. My reflective journal was not intended to inform or influence the research questions, but may illuminate the quantitative results and focus group discussions findings.

Entries into the reflective journal were typically completed at the end of each day of the intervention in a secure UoE computer, which was user name and password protected. However, sometimes it was a few days after the intervention when I had more time to reflect on the different aspects of the interventions, my reactions, feelings and thoughts about the participants, and myself as a practitioner or researcher. My reflective entries in my journal not only served to make visible, but heightened my awareness of how I interacted with my
participants and the process in which I experienced myself as a healthcare provider as well as a researcher. Additionally, reflective entries could aid to enhance my skills as a practitioner.

3.21 Concluding Comments

In the present chapter, I have described the detailed methods used to meet the primary and secondary objectives of my study. I have outlined the flow of participants through the study and how the data were collected as well as a step-by-step account of how the meridian BMEA and TCM HC were administered. Then the need for a reflective journal was explored. In the next chapter, the thesis will present the quantitative results of the study. The results of the semi-structured telephone interviews and key findings of the focus group discussions will be presented in a separate chapter.
Chapter Four  Quantitative Outcomes

4  Introduction

The previous chapter presented a detailed account of the quantitative and qualitative methods and materials employed to address my study’s primary and secondary objectives. The present chapter reports on the quantitative results of my study. The discussions of these results will be presented in Chapter Six. The main findings from the semi-structured telephone interviews and focus group discussions will be reported separately in the next chapter.

This is a pilot study so my sample size of 30 was chosen to give reasonably precise estimates of rates rather than having power to detect treatment effects. However, secondary analyses comparing the randomised groups and within each group were undertaken. Estimates of clinical significance for the VAS and BPI scores were also performed.

4.1  Participants’ Characteristics

The basic demographic details of the three groups (ten participants in each group) are presented in Table 4.1(page 78). The mean age of the three groups ranged from 31.4 to 34.7 years old. Of the 30 participants, 29 were White Caucasian Scottish and one participant had mixed ethnicity of Scottish and Mexican. Table 4.2, (page 79), Table 4.3 (page 79) and Table 4.4 (page 80) present the participants’ characteristics per group.

4.1.1  Deprivation Score

The majority of the participants in all three groups were in the Intermediate Depcat category (Depcat 3-4), with the affluent (Depcat 1-2), deprived (Depcat 5) and very deprived (Depcat 6-7) occupying either side of the score.

4.1.2  Marital Status

The BMEA treatment group had the highest number (n=5) of married women, while TCM HC group had the highest number (n=5) in co-habitation and the NHS SC group had the highest number (n=5) of single women.
4.1.3 Diagnosis

Eight of ten (80%) participants in the BMEA treatment group, six (60%) in TCM HC group and seven in NHS SC group (70%) had a surgical diagnosis of endometriosis. The remaining participants presented with CPP of unknown aetiology.

Table 4.1 Participants’ Characteristics – All Groups

<table>
<thead>
<tr>
<th></th>
<th>BMEA Treatment Group n=10</th>
<th>TCM HC Group n=10</th>
<th>NHS SC Group n=10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>34.7 (SD± 9.04)</td>
<td>31.4 (SD± 9.91)</td>
<td>33.5 (SD± 8.78)</td>
</tr>
<tr>
<td>Range</td>
<td>23-50</td>
<td>21-51</td>
<td>23-44</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>9 (99%)</td>
<td>10 (100%)</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Mixed (Mexican &amp; Scottish)</td>
<td>1 (1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation Score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affluent (1-2)</td>
<td>1 (10%)</td>
<td>1 (10%)</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Intermediate (3-4)</td>
<td>5 (50%)</td>
<td>6 (60%)</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>Deprived (5)</td>
<td>2 (20%)</td>
<td>1 (10%)</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Very deprived (6-7)</td>
<td>2 (20%)</td>
<td>2 (20%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endometriosis</td>
<td>8 (80%)</td>
<td>6 (60%)</td>
<td>7 (70%)</td>
</tr>
<tr>
<td>Unknown aetiology</td>
<td>2 (20%)</td>
<td>4 (40%)</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>7 (70%)</td>
<td>8 (80%)</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Secondary</td>
<td>3 (30%)</td>
<td>2 (20%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>3 (30%)</td>
<td>6 (60%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Employed</td>
<td>7 (70%)</td>
<td>4 (40%)</td>
<td>9 (90%)</td>
</tr>
</tbody>
</table>
Table 4.2 Individual Characteristics –BMEA Treatment Group

C = Caucasian, Dep/score=Deprivation Score
Endo=Endometriosis, Aden=Adenomyosis, Unknown aetiology=UA,
Ter= Tertiary, Sec=Secondary
UNE=unemployed, EM=Employed, SEM=Self Employed, MR=Medically retired

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Dep/score</th>
<th>Diagnosis</th>
<th>Education</th>
<th>Employment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
<td>C</td>
<td>6</td>
<td>Endo Aden IBS</td>
<td>Sec</td>
<td>MR</td>
</tr>
<tr>
<td>2</td>
<td>35</td>
<td>C</td>
<td>2</td>
<td>Endo</td>
<td>Ter</td>
<td>SEM</td>
</tr>
<tr>
<td>3</td>
<td>48</td>
<td>C</td>
<td>6</td>
<td>UA</td>
<td>Sec</td>
<td>UNE</td>
</tr>
<tr>
<td>4</td>
<td>34</td>
<td>C</td>
<td>3</td>
<td>Endo</td>
<td>Ter</td>
<td>SEM</td>
</tr>
<tr>
<td>5</td>
<td>27</td>
<td>C</td>
<td>5</td>
<td>Endo</td>
<td>Sec</td>
<td>UNE</td>
</tr>
<tr>
<td>6</td>
<td>32</td>
<td>C</td>
<td>4</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>7</td>
<td>30</td>
<td>C</td>
<td>5</td>
<td>Endo</td>
<td>Ter</td>
<td>Part-time</td>
</tr>
<tr>
<td>8</td>
<td>23</td>
<td>Mixed</td>
<td>4</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>9</td>
<td>27</td>
<td>C</td>
<td>4</td>
<td>UA</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>10</td>
<td>41</td>
<td>C</td>
<td>4</td>
<td>Endo IBS</td>
<td>Ter</td>
<td>SEM</td>
</tr>
</tbody>
</table>

Table 4.3 Individual Characteristics–TCM HC Group

C = Caucasian, Dep/score=Deprivation Score
Endo=Endometriosis, Unknown aetiology=UA, Ter= Tertiary, Sec=Secondary
UNE=unemployed, EM=Employed, SEM=Self Employed

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Dep/score</th>
<th>Diagnosis</th>
<th>Education</th>
<th>Employment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22</td>
<td>C</td>
<td>3</td>
<td>Endo</td>
<td>Ter</td>
<td>UNE</td>
</tr>
<tr>
<td>2</td>
<td>51</td>
<td>C</td>
<td>2</td>
<td>UA</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>3</td>
<td>29</td>
<td>C</td>
<td>3</td>
<td>UA</td>
<td>Ter</td>
<td>UNE</td>
</tr>
<tr>
<td>4</td>
<td>27</td>
<td>C</td>
<td>7</td>
<td>UA</td>
<td></td>
<td>UNE</td>
</tr>
<tr>
<td>5</td>
<td>37</td>
<td>C</td>
<td>4</td>
<td>Endo</td>
<td>Ter</td>
<td>UNE</td>
</tr>
<tr>
<td>6</td>
<td>41</td>
<td>C</td>
<td>3</td>
<td>Endo IBS</td>
<td>Sec</td>
<td>UNE</td>
</tr>
<tr>
<td>7</td>
<td>38</td>
<td>C</td>
<td>4</td>
<td>Endo IBS</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>8</td>
<td>21</td>
<td>C</td>
<td>5</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>9</td>
<td>23</td>
<td>C</td>
<td>4</td>
<td>Endo</td>
<td>Sec</td>
<td>UNE</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
<td>C</td>
<td>6</td>
<td>UA</td>
<td>Ter</td>
<td>EM</td>
</tr>
</tbody>
</table>
**Table 4.4 Individual Characteristics-NHS SC Group**

C = Caucasian, Dep/score=Deprivation Score  
Endo=Endometriosis, Unknown aetiology=UA, Ter=Tertiary,  
UNE=unemployed, Sec=Secondary, EM=Employed, SEM=Self Employed, MR = medically retired.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Dep/Score</th>
<th>Diagnosis</th>
<th>Education</th>
<th>Employment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>42</td>
<td>C</td>
<td>3</td>
<td>Endo</td>
<td>Ter</td>
<td>MR</td>
</tr>
<tr>
<td>2</td>
<td>44</td>
<td>C</td>
<td>6</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>3</td>
<td>28</td>
<td>C</td>
<td>5</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>4</td>
<td>23</td>
<td>C</td>
<td>3</td>
<td>UA</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>5</td>
<td>44</td>
<td>C</td>
<td>2</td>
<td>UA, IBS</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>6</td>
<td>43</td>
<td>C</td>
<td>4</td>
<td>Endo IBS</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>7</td>
<td>31</td>
<td>C</td>
<td>1</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>8</td>
<td>23</td>
<td>C</td>
<td>4</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>9</td>
<td>27</td>
<td>C</td>
<td>4</td>
<td>Endo</td>
<td>Ter</td>
<td>EM</td>
</tr>
<tr>
<td>10</td>
<td>30</td>
<td>C</td>
<td>5</td>
<td>UA, IBS, PBS</td>
<td>Ter</td>
<td>EM</td>
</tr>
</tbody>
</table>

**4.1.4 Education**

All ten (100%) of the participants in the NHS SC group attained tertiary education compared to 70% and 80% in the BMEA treatment group and TCM HC group respectively.

**4.1.5 Employment**

Of the 30 participants, just under 30% were unemployed; three in the BMEA treatment group and six in the TCM HC group and none in the NHS SC group.

**4.1.6 Education**

All ten (100%) of the participants in the NHS SC group attained tertiary education compared to 70% and 80% in the BMEA treatment group and TCM HC group respectively.

**4.1.7 Employment**

Of the 30 participants, just under 30% were unemployed; three in the BMEA treatment group and six in the TCM HC group and none in the NHS SC group.
4.2 Primary Outcomes

For my pilot study, a recruitment rate of 50% or more is deemed acceptable and a retention rate of 80% satisfactory. (Horne et al., 2012) An estimate of the proportion and its 95% confidence interval (CI) is provided.

Information collected from the participants’ screening log was used to determine the number of participants recruited from the group of eligible participants.

4.2.1 Recruitment Rate

Figure 4.3 (page 84) presents the recruitment history and outcomes. The proportion of eligible participants who were randomised into the study was 51% (95% CI 38%-63%). Ten participants were randomised into the BMEA treatment group, ten into TCM HC group and ten into NHS SC group. Of the 59 women referred, 31 were eligible for the study. One eligible participant failed screening due to a history of seizure and thus did not proceed to randomisation. Of the 28 (47%) women who were ineligible for the study, only four were not interested in participating and 12 were unable to commit to the twice a week intervention schedule, seven were medically ineligible and five were uncontactable.

Figure 4.1 (page 82) displays the recruitment target over 12 months versus the number of participants who were randomised into the study. It was projected that it would take 12 months, at a rate of 2.5 patients per month, to recruit 30 participants for my study. On average, three and half participants were recruited per month and 30 were randomised over eight months.
Figure 4.1 Target recruitment and number randomised
4.2.2 Retention Rates

Figure 4.2 (page 83) presents the number of follow-up questionnaires returned per group. The retention rates were 80% (95% CI 74-96), in the BMEA treatment group, 53% (95% CI 36-70) in the TCM HC group and 87% (95% CI 63-90) in the NHS SC group. There was a statistically significant difference (at 10%) in retention rates between the three groups, the retention rate being highest in the NHS SC followed by the BMEA treatment group and TCM HC group (Chi-square test, p= 0.08). Of the 30 follow-up questionnaires sent to each group over the follow-up period (weeks 4, 8 and 12), the BMEA treatment group returned 24, the TCM HC group 16 and NHS SC group 26.

Figure 4.2 Retention Rates per Group
Figure 4.3 Recruitment History and Outcomes

Number of women referred to study: n = 59

Number eligible: n = 31

Consented: n = 31

Number randomised: n = 30

BMEA treatment: n = 10
TCM HC: n = 10
NHS SC: n = 10

Not recruited for study: n = 28
Reasons:
Unable to commit: n = 12
Uninterested: n = 4
Medically ineligible: n = 7
Uncontactable: n = 5

Screen failure: n = 1
History of seizure

Adverse events not related to interventions: n = 3

Number withdrawn from study: 0
Number lost to follow-up: 2

Primary Outcomes:
Recruitment rates: 51% (95% CI 38-63%).
Retention rates:
BMEA treatment group = 80% (95% CI 74-96%)
TCM HC group = 53% (95% CI 36-70%)
NHS SC group = 87% (95% CI 63-90%)
4.3 Secondary Outcomes

4.3.1 Acceptability of Method of Recruitment and Randomisation

Acceptability of the method of recruitment and randomisation was quantitatively assessed by the recruitment history as well as qualitatively by semi-structured telephone interviews. Thirty participants (30) were recruited out of 59 eligible (51%). Only 4 out of the 29 ineligible women were ‘not interested’, suggesting that the prospect of participating, including having to complete lots of questionnaires and possibly being randomised to the control arm, was not a major deterrent to recruitment. A full qualitative assessment of the acceptability of the methods of recruitment and randomisation follows in Chapter Five.

4.3.2 Acceptability of Questionnaires

Acceptability of the questionnaires was assessed by data completion and patterns of missing data and semi-structured telephone interviews. Table 4.5 (page 86) presents the patterns of missing values in each of the questionnaire. The WPAIQ had the highest missing values 39% followed by the SAQ 31% and the VAS 7%. There were six questions in the WPAIQ.

Of the 90 possible questionnaires, 24 were not returned and thus were not available for analysis. Sixty-six questionnaires (total of 396 questions) were available for analysis. Of the 66 questionnaires available for analysis, there were 71 missing values. There were 14 questions in the SAQ. Of the 66 (924 questions) questionnaires, there were 130 (14%) missing values. A full qualitative assessment of the acceptability of the questionnaires follows in Chapter Five.
<table>
<thead>
<tr>
<th>Follow-up Questionnaire</th>
<th>Number of Questions in Questionnaire</th>
<th>Total Number of Follow-up Questions in Questionnaires (Weeks 4, 8 and 12)</th>
<th>Missing Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>30</td>
<td>2 (7%)</td>
<td></td>
</tr>
<tr>
<td>BPI</td>
<td>450</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>SF12</td>
<td>360</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>HADS</td>
<td>420</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>PCQ</td>
<td>390</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>WPAIQ</td>
<td>180</td>
<td>71 (39%) (19 missing values from those in employment and 52 from the unemployed)</td>
<td></td>
</tr>
<tr>
<td>SAQ</td>
<td>420</td>
<td>130 (31%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2,250</td>
<td>203 (9%)</td>
<td></td>
</tr>
</tbody>
</table>
4.3.3 Acceptability of Interventions

The acceptability of the interventions was evaluated by the proportion of participants who attended all interventions, and by semi-structured telephone interviews. Six (60%) of the ten participants in the BMEA treatment group attended all eight interventions. While in the TCM HC group, two (20%) of the ten participants attended all eight interventions. Reasons for missed interventions for both groups are shown in Table 4.6 and Table 4.7 (page 88).

There was a statistically significant difference (Mann-Whitney test, P=0.023) with attendance being poorer in the TCM HC group (Figure 4.4 page 87). Of the 80 interventions, the BMEA treatment group attended 72 (90%) compared to 45 (56%) in the TCM HC group. A full qualitative assessment of the acceptability of the interventions follows in Chapter Five.

![Comparison of attendance](image.png)

Figure 4.4 Acceptability of interventions
### Table 4.6 Acceptability of Interventions-BMEA Treatment Group
The number of interventions attended and missed by participants

<table>
<thead>
<tr>
<th>Number of Participants</th>
<th>Number of interventions attended</th>
<th>Number of interventions missed</th>
<th>Reasons for missed interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
<td>1</td>
<td>Caught in traffic jam</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>3</td>
<td>Went on holiday</td>
</tr>
<tr>
<td>6</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>6</td>
<td>2</td>
<td>Unwell</td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>6</td>
<td>2</td>
<td>Unwell</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>72 (90%)</strong></td>
<td><strong>8 (10%)</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Table 4.7 TCM HC: Acceptability of Intervention: TCM HC Group
The number of interventions attended and missed by participants

<table>
<thead>
<tr>
<th>Number of Participants</th>
<th>Number of interventions attended</th>
<th>Number of interventions missed</th>
<th>Reasons for missed interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>6</td>
<td>Participant and children unwell</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>4</td>
<td>Hospitalised with asthma</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>7</td>
<td>1</td>
<td>Cold</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>7</td>
<td>No Reasons given</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>3</td>
<td>Hospitalised for pain</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>7</td>
<td>Hospitalised for pain</td>
</tr>
<tr>
<td>8</td>
<td>3</td>
<td>5</td>
<td>No reason given</td>
</tr>
<tr>
<td>9</td>
<td>6</td>
<td>2</td>
<td>Work commitment, and unwell</td>
</tr>
<tr>
<td>10</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>45 (56%)</strong></td>
<td><strong>35 (44%)</strong></td>
<td></td>
</tr>
</tbody>
</table>
4.3.4 Loss to Follow-up
Two participants from the TCM HC group were lost to follow-up, which was defined as the number who attended and completed questionnaire at Week 0 (baseline) only. One did not give any reason and the other one was hospitalised for pain flare-up and acute asthma event.

4.3.5 Analysis of Adverse Events
There was no report of adverse events that were directly related to the interventions. Three participants from the TCM HC group were admitted to hospital for conditions which were not related to the interventions.

4.4 Differences Between Groups and Per Group
4.4.1 Estimates of Effectiveness of Interventions
Differences between baseline and subsequent time points (weeks 4, 8 and 12) were calculated and then analysed for differences between the three groups using a one-way analysis of variance (ANOVA).

4.4.2 Estimates of Clinical Significance
For the VAS and BPI scores, a clinically significant response (improvement in pain) was defined as a drop of ≥30% or ≥2 points in the relevant score from baseline to 4, 8, and 12 weeks. With regard to the BPI sleep interference scale, a change of one point is the lowest level which is considered clinically meaningful. (Dworkin et al., 2008) Due to the small sample size, it was anticipated that a statistically significant difference between the groups would be difficult to detect, but it would give estimates of the effectiveness of treatment for future sample size calculations.

Of the 120 possible questionnaires from the 30 participants, 96 (80%) were available for analysis. As this was a pilot study, statistically significant differences were not expected and none were achieved between the three groups at baseline, weeks 4, 8 and 12 in all scores.

A proportion of the participants in the three groups showed a clinical impact in the VAS-pain, BPI-pain severity, interference and sleep scores. Due to the small numbers of participants, there was insufficient power to show a statistically significant difference (Fisher’s Exact Test, p=1.0).

4.4.3 Visual Analogue Score (VAS)-Pain
There were two missing values (7%), one from the BMEA treatment group (week 12) and the other from NHS SC group (week 4). The VAS pain was scored from 0-10 where “0”
represented “no pain”, “5-6, represented “moderate pain” and “10” represented “worse possible pain”. (Figure 4.5, page 90)

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No pain</td>
<td>Moderate pain</td>
<td>Worst possible pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 4.5 The VAS--Pain Score**

Table 4.8 (page 90) presents the summary of pain analysis using the VAS-pain. Although no statistically significant difference was achieved, the BMEA treatment group experienced less pain when compared to the other two groups.

In clinical terms, more than half of participants in the BMEA treatment group responded to treatment at weeks 4 and 8. However, this effect had declined by week 12. Responses in the other two groups were lower at weeks 4 and 8, and changed very little at week 12.

**Table 4.8 VAS-Pain Assessment**

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>10 7.2 (2.1)</td>
<td>10 6.1 (2.0)</td>
<td>10 7.9 (1.5)</td>
<td>p=0.1</td>
</tr>
<tr>
<td>Week 4 Clinical Significance*</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>9 -2.78 (2.6)</td>
<td>6 -1.5 (2.9)</td>
<td>8 -1.1 (1.2)</td>
<td>p=0.3</td>
</tr>
<tr>
<td></td>
<td>5 (56%)</td>
<td>2 (33%)</td>
<td>3 (38%)</td>
<td>p=1.0**</td>
</tr>
<tr>
<td>Week 8 Clinical Significance*</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>7 -1.6 (1.0)</td>
<td>4 -0.8 (1.2)</td>
<td>8 -0.4 (1.5)</td>
<td>p=0.2</td>
</tr>
<tr>
<td></td>
<td>4 (57%)</td>
<td>1 (25%)</td>
<td>1 (25%)</td>
<td>p=1.0**</td>
</tr>
<tr>
<td>Week 12 Clinical Significance*</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
<td>N Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>7 -0.9 (2.0)</td>
<td>6 -0.2 (2.1)</td>
<td>9 -1.1 (1.8)</td>
<td>p=0.7</td>
</tr>
<tr>
<td></td>
<td>1 (14%)</td>
<td>2 (33%)</td>
<td>2 (22%)</td>
<td>p=1.0**</td>
</tr>
</tbody>
</table>
The Figure 4.6 (page 91) shows the VAS-pain mean difference (CI 95%) for each change in time points (weeks 4, 8 and 12) from baseline per group. The BMEA treatment group experienced a statistical significant reduction in pain from baseline to weeks 4 (p=0.01), and 8 (p=0.005). The NHS SC group also experienced a significant reduction in pain at week 4 (p=0.04) The TCM HC group showed a trend in improvement but gradually returned to baseline by week 12.

![Figure 4.6 VAS-Pain per Group](image)

Change to week 4, BMEA group p=0.01; NHS SC group, p=0.04. Change to week 8 BMEA group p=0.005
4.4.4 The Brief Pain Inventory (BPI)

There was no missing value in the BPI questionnaires. The BPI contains two summary statistics: severity and interference.

4.4.4.1 BPI-Pain Severity

Severity is the average of questions 3, 4, 5 and 6 (Table 4.9, page 92).

Table 4.9 BPI-Pain Severity is the Average of Questions 3, 4, 5 and 6

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Please rate your pain by circling the one number that best describes your pain on average.</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Please rate your pain by circling the one number that best describes your pain you have right now.</td>
<td></td>
</tr>
</tbody>
</table>

Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please rate your pain by circling the one number that best describes your pain on average.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please rate your pain by circling the one number that best describes your pain you have right now.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>
Table 4.10 (page 93) presents the summary of BPI-pain severity. More than half and just below half of participants in the BMEA treatment group achieved clinical significance at 4 and 8 weeks respectively. Responses in the other treatment groups were lower at 4 and 8 weeks. At week 12, half the participants in the TCM HC group achieved clinical significance on their pain severity.

**Table 4.10 Pain Assessment (BPI-Severity)**
At baseline to weeks 4, 8 and 12 per group

* Clinically significant improvement in pain – defined as of ≥30% or ≥2 points drop in BPI-severity score. ** Fishers Exact Test

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N Mean (SD)</td>
<td>10 5.6 (1.6)</td>
<td>10 5.0 (1.6)</td>
<td>10 6.2 (1.0)</td>
<td>p=0.2</td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinically Significant* N(%)</td>
<td>9 -1.3(2.8)</td>
<td>6 -1.0 (2.6)</td>
<td>9 -0.17(1.6)</td>
<td>p=0.6</td>
</tr>
<tr>
<td>Clinically Significant* N (%)</td>
<td>5 (56%)</td>
<td>2 (33%)</td>
<td>2 (22%)</td>
<td>p=1.0**</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinically Significant* N(%)</td>
<td>7 - 0.9 (1.6)</td>
<td>4 0.0 (1.2)</td>
<td>8 -0.3 (1.4)</td>
<td>p=0.6</td>
</tr>
<tr>
<td>Clinically Significant* N (%)</td>
<td>3 (43%)</td>
<td>0 (0%)</td>
<td>1 (13%)</td>
<td>p=1.0**</td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinically Significant* N(%)</td>
<td>8 -0.2 (2.7)</td>
<td>6 -0.6 (1.9)</td>
<td>9 -0.1 (1.7)</td>
<td>p=0.9</td>
</tr>
<tr>
<td>Clinically Significant* N (%)</td>
<td>2 (25%)</td>
<td>3 (50%)</td>
<td>2 (22%)</td>
<td>p=1.0**</td>
</tr>
</tbody>
</table>
Figure 4.7 (page 94) shows the BPI-pain severity mean difference (CI 95%) for each change in weeks 4, 8 and 12 from baseline per group. No statistically significant difference was achieved in any of the three groups. In the BMEA treatment group there was a trend in the reduction in pain severity at weeks 4, 8 and returning to baseline at week 12. While in the TCM HC there was a reduction in pain severity at week 4, returning to baseline at week 8 and dropped slightly at week 12. In the NHS SC group little change in the pain severity was observed.

**Figure 4.7 BPI-Pain Severity per Group**
There was a trend in improvement in the BMEA treatment group, some improvements in the TCM HC group and not much change in the NHS SC group.
4.4.4.2 BPI Interference: Symptom Assessment

BPI-Interference is the average of questions 9a to 9g (Table 4.11, page 95). A higher score indicates higher interference.

<table>
<thead>
<tr>
<th>Table 4.11 BPI-Interference is the Average of Question 9a-g</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:</td>
</tr>
<tr>
<td>a. General activity</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>b. Mood</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>c. Walking ability</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>d. Normal work (includes both work outside the home and housework)</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>e. Relations with other people</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>f. Sleep</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>g. Enjoyment of life</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
<tr>
<td>Does not interfere</td>
</tr>
</tbody>
</table>
Table 4.12 (page 96) presents the summary of the analysis of the BPI-interference. In clinical terms, more than half of participants and a little less than half of the participants in the BMEA treatment group responded to treatment at weeks 4 and 8 respectively. However, this effect had declined by 12 weeks. Responses in the other treatment groups were lower at 4 and 8 weeks, and changed very little.

Table 4.12 BPI-Interference: Symptom Assessment Per Group
From baseline to weeks 4, 8 and 12
* Clinically significant improvement in pain – defined as of ≥30% or ≥2 points drop in BPI-severity score. ** Fishers Exact Test

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean (SD)</td>
<td>10 5.5(3.0)</td>
<td>10 5.6(2.1)</td>
<td>10 5.9(1.4)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean (SD)</td>
<td>8 -1.3(3.9)</td>
<td>6 -1.9(3.1)</td>
<td>9 -0.3(1.3)</td>
</tr>
<tr>
<td>Clinically Significant* N (%)</td>
<td>5 (63%)</td>
<td>2 (33%)</td>
<td>2(33%)</td>
<td></td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean (SD)</td>
<td>7 -0.7(1.6)</td>
<td>4 -0.7(1.1)</td>
<td>8 -0.3 (1.9)</td>
</tr>
<tr>
<td>Clinically Significant* N (%)</td>
<td>3(43%)</td>
<td>1(25%)</td>
<td>2(25%)</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean (SD)</td>
<td>8 -0.1(2.6)</td>
<td>6 -0.5 (2.2)</td>
<td>9 0.5(2.0)</td>
</tr>
<tr>
<td>Clinically Significant* N (%)</td>
<td>1 (13%)</td>
<td>2(33%)</td>
<td>1(11%)</td>
<td></td>
</tr>
</tbody>
</table>
Figure 4.8 (page 97) gives a summary of the change in pain interference from baseline to weeks 4, 8 and 12 per group. No statistical differences were obtained in any of the groups at weeks 4, 8 and 12. There are some suggestions of improvement in the BMEA treatment and TCM HC groups, although the small sample size makes significance testing difficult. No change in interference was observed in the NHS SC group.

![Figure 4.8 BPI Interference per Group](image)
4.4.4.3 BPI Sleep Interference

Table 4.13 (page 98) presents the summary of the analysis of the BPI single item sleep interference. Clinically, more than half of participants responded to treatment, in the BMEA treatment group, at weeks 4 and 8 respectively. However, this effect had declined by 12 weeks. In the NHS SC group, over half of the participants responded to treatment at week 4. There were negligible changes in the TCM HC group.

Table 4.13 BPI-Sleep Assessment
From baseline to weeks 4, 8 and 12 per group
Clinical significance is a fall in minimum of 1 point

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
<td>10 6.4(3.1)</td>
<td>10 6.0(3.3)</td>
<td>10 6.3(2.6)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
<td>9 -2.2 (4.9)</td>
<td>6 -1.0(4.3)</td>
<td>9 -1.1(2.8)</td>
</tr>
<tr>
<td>Clinically Significance**</td>
<td>N (%)</td>
<td>6(67%)</td>
<td>2 (33%)</td>
<td>6(67%)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
<td>7 -0.4(3.2)</td>
<td>4 2.5(3.7)</td>
<td>8 -0.8(2.1)</td>
</tr>
<tr>
<td>Clinically Significance**</td>
<td>N (%)</td>
<td>4(57%)</td>
<td>1(25%)</td>
<td>2 (25%)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
<td>8 -1.0(3.0)</td>
<td>6 0.5(2.4)</td>
<td>9 0.1(2.7)</td>
</tr>
<tr>
<td>Clinically Significance**</td>
<td>N (%)</td>
<td>3(38%)</td>
<td>2(33%)</td>
<td>3(33%)</td>
</tr>
</tbody>
</table>
Figure 4.9 (page 99) shows a trend of less sleep interference in the BMEA treatment group, suggesting that the participants did better than those in the other two groups. At week 8, the TCM HC group reported higher interference at week 8. The NHS SC group had lower interference at weeks 4 and 8 but returned to baseline at week 12. There were no statistical differences in sleep interference in the three groups at weeks 4, 8 and 12.

![Figure 4.9 BPI Sleep Interference per Group](image)
4.4.5 The Short Form-12 (SF-12)

There was no missing value in the SF-12. It comprised of two summary statistics: the physical component status (PCS) and mental component status (MCS).

4.4.5.1 Physical Component Status

The SF12-PCS consisted of questions 1-5. (Table 4.14, page 100)

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>In general, would you say your health is:</td>
</tr>
<tr>
<td>2.</td>
<td>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
</tr>
<tr>
<td>3.</td>
<td>Climbing several flights of stairs</td>
</tr>
</tbody>
</table>

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Accomplished less than you would have liked?</td>
</tr>
<tr>
<td>5.</td>
<td>Were limited in the kind of work or other activities?</td>
</tr>
</tbody>
</table>

At week 4, there were some large differences from baseline between the three groups and by week 12 the change from baseline is small. (Table 4.15, page 101)

Figure 4.10 (page 101) presents the assessment of physical health per group. There was a trend in the improvement in the PCS in weeks 4 and 8, but returning to baseline at week 12 in the BMEA treatment and TCM HC groups, although no statistical difference was achieved. The NHS SC group experienced a small improvement in the PCS at week 4 but this almost dropped back to baseline at week 8 and rose again at week 12.
Table 4.15  SF-12 PCS Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th></th>
<th>Arms</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BMEA treatment</td>
<td>TCM HC</td>
<td>NHS SC</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td>10</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>33.0(11.3)</td>
<td>31.0(8.4)</td>
<td>31.0(10)</td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td>9</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>4.2 (10.0)</td>
<td>6.4(11.0)</td>
<td>2.6(4.4)</td>
<td></td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td>7</td>
<td>4</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>1.5(8.3)</td>
<td>5.5(4.7)</td>
<td>0.7(6.7)</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td>8</td>
<td>6</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>0.01(7.3)</td>
<td>1.1(9.2)</td>
<td>1.5(9.3)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.10 SF-12-PCS per Group
Assessment of physical health from baseline at weeks 4, 8 and 12
4.4.5.2 SF-12 Mental Component Status (MCS)

The SF-12 MCS comprised of questions 6 to 12. (Table 4.16, page 102)

**Table 4.16 SF-12 MCS. Questions 6-9**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Accomplished less than you would have liked?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. Didn’t do work or other activities as carefully as usual?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all ☐  A little bit ☐  Moderately ☐  Quite a bit ☐  Extremely ☐

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Have you felt calm and peaceful?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. Did you have a lot of energy?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. Have you felt downhearted and blue?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Have your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
At week 4 there was a borderline statistically significant difference between scores (p=0.05). (Table 4.17, page 103)

Table 4.17 MCS Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>N</th>
<th>Mean(SD)</th>
<th>N</th>
<th>Mean(SD)</th>
<th>N</th>
<th>Mean(SD)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>42.0(11.9)</td>
<td>10</td>
<td>43.0(10.9)</td>
<td>9</td>
<td>42.0(7.0)</td>
<td>p=0.10</td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>7.7(9.2)</td>
<td>6</td>
<td>2.9(9.0)</td>
<td>7</td>
<td>-4.0(8.2)</td>
<td>p=0.05</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>-2.0(15.0)</td>
<td>4</td>
<td>4.2(2.8)</td>
<td>7</td>
<td>-5.0(9.6)</td>
<td>p=0.4</td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>-6.3(11.0)</td>
<td>6</td>
<td>5.3(6.6)</td>
<td>8</td>
<td>-2.4(12.0)</td>
<td>p=0.1</td>
</tr>
</tbody>
</table>
Figure 4.11 (page 104), presents emotional status from baseline to weeks 4, 8 and 12 per group. The BMEA treatment group achieved a statistically significant difference ($p=0.04$) from baseline to week 4, tapering off at weeks 8 and 12. The TCM HC group achieved a borderline significance ($p=0.06$) at week 8. While that of the NHS SC group remained largely unchanged throughout the study period.
4.4.6 Hospital Anxiety and Depression Scores (HADs)
There was no missing value in the HADS. The HADS consisted of two subscores (anxiety, depression) and a total. A high score in any scale was an indicator of a problem. A negative change indicated an improvement.

4.4.7 HADS-Anxiety
The BMEA treatment and TCM HC group experienced less anxiety at week 4. Difference between the three groups from baseline at week 12 was small. (Table 4.18, page 105)

Table 4.18 HADS-Anxiety Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th></th>
<th>Arms</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BMEA treatment</td>
<td>TCM HC</td>
<td>NHS SC</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
<td>10 9.5(5.0)</td>
<td>10 9.0(4.8)</td>
<td>10 8.3(4.1)</td>
<td>p=0.8</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
<td>9 -1.9(2.7)</td>
<td>6 -2.5(6.2)</td>
<td>9 1.4(2.5)</td>
<td>p=0.1</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
<td>7 0.0(3.1)</td>
<td>4 10.5(1.0)</td>
<td>8 2.0(3.1)</td>
<td>p=0.3</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
<td>8 0.6(1.8)</td>
<td>6 0.5(1.8)</td>
<td>9 1.2(3.2)</td>
<td>p=0.8</td>
</tr>
</tbody>
</table>
Figure 4.12 (page 106) presents the change in mean score in the HADS-Anxiety at weeks 4, 8 and 12 per group. The BMEA treatment group achieved a borderline change at week 4 (p = 0.07). The TCM HC group showed a trend of experiencing less anxiety, but gradually returned to baseline at week 8. The anxiety level in the NHS SC group remained high fairly constantly throughout the study period.

![Figure 4.12 HADS-Anxiety per Group](image-url)
4.4.7.1 HADS-Depression

All groups felt less depressed at week 4. At week 8, the BMEA and TCM HC groups continued to be less depressed, while the NHS SC group became more depressed and remained so by week 12. (Table 4.19, page 107)

Table 4.19 HADS-Depression Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>7.5(5.0)</td>
<td>10</td>
<td>8.5(3.5)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7.3(4.2)</td>
<td>p=0.8</td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>-2.0(2.8)</td>
<td>6</td>
<td>-1.0(3.2)</td>
<td>p=0.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>-0.7(3.8)</td>
<td>4</td>
<td>2.0(1.6)</td>
<td>p=0.10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>1.4(2.5)</td>
<td>6</td>
<td>2.2(2.4)</td>
<td>p=0.10</td>
</tr>
</tbody>
</table>
Figure 4.13 (page 108) presents the mean change in the HADS-Depression score from baseline to weeks 4, 8 and 12. The BMEA treatment group had a borderline significant mean change at week 4 (p=0.067) i.e. the participants reported feeling less depressed at week 4. However, by week 8 the mean score returned to just below baseline and by week 12 the mean score had risen above baseline. In the TCM HC group, a trend towards feeling less depressed was observed. The NHS SC group mean score at week 4 dropped just below baseline and by week 8 (p=0.01) and week 12 (p=0.03), the participants felt significantly more depressed.

Figure 4.13 HADS-Depression per Group
Change to 4 weeks, BMEA group p=0.07 (borderline); NHS SC change to weeks 8 and 12, p=0.01 and p=0.03 respectively
4.4.8 HADS-Total

The BMEA treatment and TCM HC groups were less depressed and anxious at weeks 4 and 8. By week 12 all groups returned to baseline. (Table 4.20, page 109)

<table>
<thead>
<tr>
<th>Arms</th>
<th>N</th>
<th>Mean(SD)</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N</td>
<td>Mean(SD)</td>
<td>10</td>
<td>17(8.5)</td>
<td>10</td>
<td>17(7.2)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N</td>
<td>Mean(SD)</td>
<td>9</td>
<td>-4.0(4.5)</td>
<td>6</td>
<td>-4.7(11)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N</td>
<td>Mean(SD)</td>
<td>7</td>
<td>-0.7(5.6)</td>
<td>4</td>
<td>-1.7(3.0)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N</td>
<td>Mean(SD)</td>
<td>8</td>
<td>2(4.1)</td>
<td>6</td>
<td>0.0(2.7)</td>
</tr>
</tbody>
</table>
Figure 4.14 (page 110) presents the mean change baseline to weeks 4, 8 and 12. The BMEA treatment group achieved a significant (p=0.04) change from baseline to week 4. However, the HADS-Total mean score gradually returned to baseline by week 8 and risen above baseline by week 12. In the TCM HC group there was a trend towards feeling less depressed and anxious. In sharp contrast, the NHS SC group achieved a significant difference (p=0.04) from baseline to weeks 8, and 12 i.e. the participants in the NHS SC group reported feeling significantly more depressed and anxious.

Figure 4.14 HADS-Total per Group
4.4.9 The Pain Catastrophising Questionnaire (PCQ)

There was no missing value in the returned PCQ questionnaires. There were three summary statistics, “Rumination”, “Magnification” and “Helplessness”.

4.4.9.1 (PCQ)-Rumination

At week 4, the BMEA treatment group ruminated less when compared to the TCM HC group. By week 12, there was signal of potential difference (p=0.08) between the three groups. (Table 4.21, page 111)

Table 4.21 PCQ-Rumination Means at Baseline, Weeks 4, 8 and 12 per

<table>
<thead>
<tr>
<th>Arms</th>
<th>PCQ-Rumination Means at Baseline, Weeks 4, 8 and 12 per</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BMEA treatment</td>
<td>TCM HC</td>
<td>NHS SC</td>
</tr>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
<td>10 13(4.3)</td>
<td>10 12(4.2)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
<td>9 -2.6(4.0)</td>
<td>6 1.8(4.0)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
<td>7 -2.4(3.3)</td>
<td>4 -1.2(3.8)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
<td>8 -2.5(3.2)</td>
<td>6 -0.7(3.3)</td>
</tr>
</tbody>
</table>
Figure 4.15 (page 112) presents the mean change of the PCQ-rumination from baseline to weeks 4, 8 and 12. The BMEA treatment group achieved a borderline significant difference (p=0.06) from baseline to week 12 i.e. the participants ruminated less. There was negligible change in the other two groups.

**Figure 4.15 PCQ- Rumination per Group**
Change from baseline to week 12, BMEA treatment group, p=0.06
4.4.9.2 PCQ-Magnification

At week 8, the TCM HC group magnified their problem less when compared to the NHS SC group. (Table 4.22, page 113)

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
<td>10 6.8(2.7)</td>
<td>10 8.2(2.5)</td>
<td>10 7.1(3.9)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
<td>9 -1.4(2.0)</td>
<td>6 -1.8(2.0)</td>
<td>9 0.2(2.3)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
<td>7 -0.9(2.5)</td>
<td>4 -2.0(1.6)</td>
<td>8 1.0(3.0)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
<td>8 -1.0(2.2)</td>
<td>6 -0.7(2.2)</td>
<td>9 1.0(2.8)</td>
</tr>
</tbody>
</table>
Figure 4.16 (page 114) presents the PCQ-magnification change from baseline to weeks 4, 8 and 12 per group. The BMEA treatment and TCM HC groups achieved a borderline statistically significant difference (p=0.06) and (p=0.07) respectively at week 4, i.e. these two groups reported less magnification of their problems, while there was a trend to more magnification by weeks 8 and 12 in the NHS SC group.

**Figure 4.16 PCQ-Magnification per Group**
Change to week 4, BMEA treatment group p=0.06, TCM HC group p=0.07
4.4.10 PCQ Helplessness

There was no evidence to suggest a difference in feeling helpless between the groups. (Table 4.23, page 115)

Table 4.23 PCQ-Helplessness Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
<td>10 17(4.0)</td>
<td>10 19(6.3)</td>
<td>10 17(6.0)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
<td>9 -3.6(4.0)</td>
<td>6 -1.7(3.3)</td>
<td>9 -0.8(5.0)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
<td>7 -2.7(3.5)</td>
<td>4 -2.7(3.1)</td>
<td>8 0.5(4.2)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
<td>8 -2.7(5.3)</td>
<td>6 -2.3(4.0)</td>
<td>9 0.9(4.2)</td>
</tr>
</tbody>
</table>
Figure 4.17 (page 116) presents the PCQ-helplessness change in means from baseline to weeks 4, 8 and 12 per group. The BMEA treatment group achieved a significant difference at week 4 ($p=0.03$), i.e. the participants felt less helpless. The TCM HC group showed a trend towards an improvement throughout. In contrast, the NHS SC group reported little difference throughout the study period.

![PCQ-Helplessness per Group](image)

**Figure 4.17 PCQ-Helplessness per Group**
4.4.11 Work, Productivity, and Impairment Questionnaire

The WPAIQ comprised of four scores: absenteeism (work time missed), work impairment, work productivity loss and activity impairment (how much pain impaired normal activities).

The WPAIQ has the highest number of missing values, which may be due to high unemployment, and poor return of follow-up questionnaires in the TCM HC group. Of the 96 possible questionnaires available for analysis, there were six missing values from the BMEA treatment group, one from the TCM HC group and 13 from the NHS SC group. The group with the highest unemployment was the TCM HC group. (Table 4.24, page 117)

<table>
<thead>
<tr>
<th>Employed</th>
<th>Baseline</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMEA Treatment Group</td>
<td>7/10</td>
<td>6/9</td>
<td>5/7</td>
<td>7/8</td>
</tr>
<tr>
<td>TCM HC Group</td>
<td>4/10</td>
<td>3/6</td>
<td>3/4</td>
<td>3/5</td>
</tr>
<tr>
<td>NHS SC Group</td>
<td>10/10</td>
<td>8/8</td>
<td>8/8</td>
<td>8/9</td>
</tr>
</tbody>
</table>

4.4.11.1 WPAIQ Absenteeism

The TCM HC group had zero hour absenteeism at baseline, weeks 4 and 8. This might be due to unemployment and poor return of questionnaires, rendering the data not meaningful. (Table 4.25, page 118) The same applied to the analysis of absenteeism per group. (Figure 4.18, page 118)
Table 4.25 WPAIQ-Absenteeism Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arrows</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
<td>6 15(36)</td>
<td>4 0.0(0.0)</td>
<td>10 27(42)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
<td>5 -13.0(44)</td>
<td>2 0.0(0.0)</td>
<td>7 -3.1(5.5)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
<td>3 -20(35)</td>
<td>3 0.0(0.0)</td>
<td>7 3.5(12)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
<td>4 0.0(0.0)</td>
<td>4 25(50)</td>
<td>7 -3.1(5.5)</td>
</tr>
</tbody>
</table>

Figure 4.18 WPAIQ-Absenteeism per Group
4.4.11.2 **WPAIQ-Work Impairment**

Again small sample size made the results not very meaningful between groups (Table 4.26, page 119) and per group throughout the study (Figure 4.19, page 119)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Arms</td>
<td></td>
<td></td>
<td>P</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>N</td>
<td>Mean(SD)</td>
<td>7</td>
<td>47(29)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N</td>
<td>Mean(SD)</td>
<td>6</td>
<td>-10(20)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N</td>
<td>Mean(SD)</td>
<td>4</td>
<td>2.5(29)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N</td>
<td>Mean(SD)</td>
<td>5</td>
<td>4.0(34)</td>
</tr>
</tbody>
</table>

*Table 4.26 WPAIQ-Work Impairment Means at Baseline, Weeks 4, 8 and 12*

*Figure 4.19 WPAIQ-Work Impairment per Group*
4.4.11.3 WPAIQ-Work Productivity Loss

Results between groups (Table 4.27, page 120) or per group (Figure 4.20, page 120) were not very meaningful due to small sample sizes.

Table 4.27 WPAIQ-Work Productivity Loss Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6 32(26)</td>
<td>4 35(31)</td>
<td>8 46(20)</td>
<td>p=0.5</td>
</tr>
<tr>
<td>Week 4</td>
<td>5 -1.9(22)</td>
<td>2 5.0(7.0)</td>
<td>5 -1.6(17)</td>
<td>p=0.9</td>
</tr>
<tr>
<td>Week 8</td>
<td>3 22(20)</td>
<td>3 -3.3(5.8)</td>
<td>5 -1.3(25)</td>
<td>p=0.3</td>
</tr>
<tr>
<td>Week 12</td>
<td>4 -7.7(26)</td>
<td>4 -22(40)</td>
<td>5 7.4(29)</td>
<td>p=0.4</td>
</tr>
</tbody>
</table>

Figure 4.20 WPAIQ-Productivity Loss per Group
4.4.11.4 WPAIQ-Activity Impairment

A better sample size and a reasonable difference were observed between the BMEA treatment group and NHS SC (Table 4.28, page 121). Figure 4.21 (page 121) shows the activity impairment per group.

Table 4.28 WPAIQ-Activity Impairment Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N</td>
<td>10 Mean(SD)</td>
<td>61(27)</td>
<td>55(25)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N</td>
<td>9 Mean(SD)</td>
<td>6-6.7(27)</td>
<td>5.0(18)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N</td>
<td>7 Mean(SD)</td>
<td>4-5.0(10)</td>
<td>4.3(27)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N</td>
<td>8 Mean(SD)</td>
<td>6-8.3(19)</td>
<td>1.3(24)</td>
</tr>
</tbody>
</table>

Figure 4.21 Activity Impairment from baseline to weeks 4, 8 and 12 per Group
4.4.12 The Sexual Activity Questionnaire (SAQ)

The SAQ has the second highest number of missing values. The SAQ has four summary scores: pleasure, discomfort, habit and tired. As in the WPAIQ, there were many missing values. The SAQ comprised of four summary scores: pleasure, discomfort (sum of questions 9 and 10), habit, (question 13) and tired (question 7).

4.4.12.1 SAQ-Pleasure

The pleasure scores were derived from the following SAQ questions:

<table>
<thead>
<tr>
<th>During the past month:</th>
<th>Very much</th>
<th>Somewhat</th>
<th>A little</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was ‘having sex’ an important part of your life this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Did you enjoy sexual activity this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Did you desire to have sex with your partner(s) this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>In general, did you feel satisfied after sexual activity this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How often did you engage in sexual activity this month?</th>
<th>5 times or more</th>
<th>3-4 times</th>
<th>1-2 times</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much more</td>
<td>Somewhat</td>
<td>About the same</td>
<td>Less than usual</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Were you satisfied with the frequency of sexual activity this month?</th>
<th>Very much</th>
<th>Somewhat</th>
<th>A little</th>
<th>Not at all</th>
</tr>
</thead>
</table>

At weeks 4 and 8 the TCM HC showed a rise in sexual pleasure however, there were only five and three participants respectively. (Table 4.29, page 123).

Figure 4.22 (page 123) shows statistical significance changes at week 4 in the NHS SC group ($p=0.001$), and borderline significant at week 8 ($p=0.06$) in the TCM HC group.
Table 4.29 SAQ-Pleasure Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>N</th>
<th>Mean(SD)</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>10</td>
<td>16(5.1)</td>
<td>8</td>
<td>14(5.0)</td>
<td>p=0.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>15(5.5)</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td>5</td>
<td>-3.2(5.3)</td>
<td>5</td>
<td>-2.3(0.8)</td>
<td>p=0.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>-4.2(5.6)</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 8</td>
<td>5</td>
<td>1.2(4.5)</td>
<td>3</td>
<td>0.2(3.3)</td>
<td>p=0.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>-1.3(0.6)</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td>6</td>
<td>-0.7(2.5)</td>
<td>5</td>
<td>0.1(4.1)</td>
<td>p=0.8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>0.6(4.5)</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 4.22 SAQ-Pleasure per Group
4.4.12.2 SAQ-Discomfort

The discomfort scores were derived from the following SAQ questions:

<table>
<thead>
<tr>
<th>During the past month:</th>
<th>Very much</th>
<th>Somewhat</th>
<th>A little</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>During sexual relations, how frequently did you notice dryness of your vagina this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Did you feel pain or discomfort during penetration this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Sample size was small especially in the TCM HC group. (Table 4.30, page 124)

**Table 4.30 SAQ-Discomfort Means at Baseline, Weeks 4, 8 and 12**

<table>
<thead>
<tr>
<th>Arms</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BMEA treatment</td>
</tr>
<tr>
<td>Baseline</td>
<td>N Mean(SD)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean(SD)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean(SD)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean(SD)</td>
</tr>
</tbody>
</table>
Figure 4.23 (page 125) presents the change in means of the SAQ-discomfort from baseline to weeks 4, 8 and 12 per group. No statistically significant differences were achieved in any of the groups throughout the study period. However, there was a trend towards less discomfort in the BMEA treatment group. The TCM HC group showed some improvement at week 4 and 8 but experienced discomfort by week 12. The NHS SC group experienced relatively low discomfort returning at baseline at week 12.
### 4.4.12.3 SAQ-Habit

The SAQ-habit score was derived from this question:

<table>
<thead>
<tr>
<th>9. How did this frequency of sexual activity compare with what is usual for you?</th>
<th>Much more</th>
<th>Somewhat more</th>
<th>About the same</th>
<th>Less than usual</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Only small differences between the three groups were observed throughout. (Table 4.31, page 126)

#### Table 4.31 SAQ-Habit Means at Baseline, Weeks 4, 8 and 12

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>N Mean (SD)</td>
<td>10 3.3(0.9)</td>
<td>9 3.6(0.5)</td>
<td>8 3.2(0.7)</td>
</tr>
<tr>
<td>Week 4</td>
<td>N Mean (SD)</td>
<td>6 -0.3(0.8)</td>
<td>6 -0.7(1.0)</td>
<td>7 0.1(1.0)</td>
</tr>
<tr>
<td>Week 8</td>
<td>N Mean (SD)</td>
<td>5 -0.2(1.7)</td>
<td>4 -0.5(1.3)</td>
<td>6 -0.2(0.7)</td>
</tr>
<tr>
<td>Week 12</td>
<td>N Mean (SD)</td>
<td>6 -0.3(0.5)</td>
<td>6 -0.7(1.4)</td>
<td>6 0.2(0.7)</td>
</tr>
</tbody>
</table>

Figure 4.24 (page 127) presents the change in means of the SAQ-habit from baseline to weeks 4, 8 and 12 of the three groups. No statistical significant differences were achieved in any of the groups throughout the study period. There were some suggestions that the BMEA treatment and TCM HC groups were having sexual intercourse more often throughout the study period but not in the NHS SC group.
The SAQ-tired score was derived from this question:

<table>
<thead>
<tr>
<th>During the past month:</th>
<th>Very much</th>
<th>Somewhat</th>
<th>A little</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. In general, were you too tired to have sex?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

There was a relatively large difference in tiredness between the BMEA treatment group and the NHS SC group at week 4. In week 8, fewer than half the participants were involved. (Table 4.32, page 128)

Figure 4.25 (page 128) presents the change in means of the SAQ-habit from baseline to weeks 4, 8 and 12 per group. No statistical significant differences were achieved in any of the groups throughout the study period. The BMEA treatment group showed some improvements at week 4 and drop below baseline by weeks 8 and 12. The TCM HC group
also showed some improvements at weeks 4 and 8 and returned to baseline by week 12. While the NHS SC group showed a trend of being more tired throughout.

Table 4.32 SAQ-Tired Means at Baseline, Weeks 4, 8 and 12 per Group

<table>
<thead>
<tr>
<th>Arms</th>
<th>BMEA treatment</th>
<th>TCM HC</th>
<th>NHS SC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N Mean(SD)</td>
<td>10 2.6(1.2)</td>
<td>9 2.4(1.1)</td>
<td>7 2.6(1.3)</td>
<td>p=0.9</td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N Mean(SD)</td>
<td>9 0.7(1.3)</td>
<td>6 0.5(0.8)</td>
<td>6 -0.5(1.2)</td>
<td>p=0.2</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N Mean(SD)</td>
<td>5 -0.6(1.5)</td>
<td>4 0.5(1.0)</td>
<td>5 -0.2(1.1)</td>
<td>p=0.4</td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N Mean(SD)</td>
<td>7 -0.4(1.5)</td>
<td>6 0.0(1.1)</td>
<td>7 -0.9(1.5)</td>
<td>p=0.5</td>
</tr>
</tbody>
</table>

Figure 4.25 SAQ-Tired per Group
4.5 Summary of Outcomes

This section gives a summary of the primary and secondary outcomes of my study (see Chapter One, Introduction, Section 1.19, page 31). Estimates of effectiveness of interventions are reported by clinical significance, per group and between groups. A full discussion of the implications of these outcomes is presented in Chapter Six.

4.5.1 Recruitment, Retention Rates and Acceptability

Over a period of eight months, my study was able to randomised 30 (51%, 95% CI 38%-63%) participants to the BMEA treatment, TCM HC, NHS SC groups. The retention rates in the BMEA treatment and NHS SC groups were above 80% which is considerably higher than that of the TCM HC group (53%). Attendance to the respective interventions followed the similar pattern as the retention rates. The BMEA treatment group attended statistically significantly (Mann-Whitney test, P=0.023) more interventions (90%) compared to 56% in the TCM HC group.

The acceptability of the questionnaire was shown in data completion and patterns of missing data. Overall there were few missing data in the 66 returned questionnaires. There was two (7%) missing data in the VAS, 71 (39%) in WPAIQ 130 (31%) in the SAQ. The BPI, SF12, HADS, and PCQ were fully completed.

Two participants from the TCM HC group were lost to follow-up. Three participants from the TCM HC group were admitted to hospital for conditions unrelated to the interventions. There was no adverse event reported.

4.5.2 Estimates of Effectiveness

4.5.2.1 Estimates of Clinical Significance

A proportion of participants in the three groups showed a response clinically in the VAS=pain, BPI=pain severity, interference and sleep scores. More than half the participants in the BMEA treatment group responded to treatment at weeks 4, and 8 in the VAS, and BPI scores. The effect declined by week 12. Responses in the other two groups were lower at weeks 4 and 8 and no changes were observed at week 12. Fishers Exact test did not show a statistically significant difference.
4.5.2.2 Statistically Significant Different Outcomes Per Group

Statistical significant differences were achieved in the following scores:

- VAS-pain: a reduction in pain from baseline to weeks 4 (p=0.01) and 8 (p=0.005) in the BMEA treatment group; in the NHS SC group from baseline to week 4 (p=0.04)
- HADS-total: feeling less anxious and depressed from baseline to week 4 (p=0.04) in the BMEA treatment, while the NHS SC group felt more anxious and depressed at weeks 8 & 12 (p=0.04)
- PCQ-helplessness: feeling less helpless in the BMEA from baseline to week 4 (p=0.03)
- SAQ-pleasure: an increased in pleasure in the NHS SC at week 4 (p=0.001)

Table 4.33 (page 131) presents the summary of the scores per group that showed signals of change in the BPI-severity and interference, SF-12 PCS and MCS, HADS-anxiety and depression, PCQ rumination and magnification, WPAIQ-activity and SAQ-pleasure.
<table>
<thead>
<tr>
<th>Tool</th>
<th>BMEA Treatment Group</th>
<th>TCM HC Group</th>
<th>NHS SC Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPI-severity &amp; interference</td>
<td>Signals of improvement at week 4 &amp; 8, returned to base-line at week 12</td>
<td>Signals of improvement at week 4 and 12</td>
<td>Little change</td>
</tr>
<tr>
<td>BPI-sleep</td>
<td>Signals of improvement at week 4</td>
<td>Not much change throughout</td>
<td>Not much change throughout</td>
</tr>
<tr>
<td>SF-12 PCS</td>
<td>Signals of improvement at week 4</td>
<td>Signals of improvement at week 4 &amp; 8</td>
<td>Not much change</td>
</tr>
<tr>
<td>SF12 MCS</td>
<td>Stronger signal (p=0.054) in feeling better from baseline to week 4.</td>
<td>A trend of feeling better from baseline to weeks 4, 8 and 12</td>
<td>No change in emotions from baseline to weeks 4, 8 and 12</td>
</tr>
<tr>
<td>HADS- anxiety</td>
<td>Signals of less anxiety at week 4 but gradually feeling more anxious at weeks 8 and 12</td>
<td>Signals of feeling less anxious. Gradually increases at weeks 8 and 12</td>
<td>Signals of feeling more anxious from baseline to weeks 4, 8 and 12</td>
</tr>
<tr>
<td>HAD: depression</td>
<td>From baseline to week 4, there is almost a statistical difference in feeling less depressed</td>
<td>A trend towards feeling less depressed</td>
<td>Less depressed from baseline to week 4. More depressed at weeks 8 &amp; 12</td>
</tr>
<tr>
<td>PCQ: rumination</td>
<td>Strong signal from baseline to weeks 4, 8 12 (p=0.06) less rumination</td>
<td>No trend</td>
<td>No trend</td>
</tr>
<tr>
<td>PCQ: magnification</td>
<td>Strong signal from baseline to week 4 (p=0.06) - less magnification</td>
<td>Strong signal from baseline to week 4 (p=0.07) less magnification</td>
<td>Signal of a negative - more magnification</td>
</tr>
<tr>
<td>WPAIQ: activity impairment</td>
<td>Some improvement at week 4. Returned to above baseline by weeks 8 and 12</td>
<td>A trend towards lower activity impairment throughout but numbers were small</td>
<td>A trend towards more activity impairment</td>
</tr>
<tr>
<td>SAQ: tiredness</td>
<td>Improvement at week 4. Drop by weeks 8 and 12</td>
<td>Improvement at weeks 4 &amp; 8. Returned to baseline at week 12</td>
<td>More tired throughout</td>
</tr>
</tbody>
</table>
4.5.3 Estimates of Effectiveness Between Groups

No statistical significant differences were achieved in all scores between BMEA treatment, TCM HC and NHS groups. Table 4.34 (page 132) presents the summary of outcomes between the three groups that showed signals of changes. The WPAIQ and SAQ had small sample sizes, rendering their results not meaningful.

Table 4.34 Summary: Signals in Outcomes Between the Three Groups

<table>
<thead>
<tr>
<th>Tool</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>All groups show signals of pain reduction at week 4. The BMEA treatment has the biggest reduction throughout</td>
</tr>
<tr>
<td>BPI Pain severity</td>
<td>Signals in the drop in pain severity in all groups at week 4. NHS SC has the smallest fall</td>
</tr>
<tr>
<td>BPI Interference</td>
<td>A fall in all groups. A reasonably large fall in the TCM HC compared to baseline at week 4.</td>
</tr>
<tr>
<td>BPI-Sleep</td>
<td>Signals in all groups that pain interfered less with sleep at week 4</td>
</tr>
<tr>
<td>SF12-PCS</td>
<td>Signals in all groups of feeling better physically at week 4.</td>
</tr>
<tr>
<td>SF12-MCS</td>
<td>Strong signals (p=0.05) of physical improvement at week 4 in the BMEA treatment group</td>
</tr>
<tr>
<td>HADS-anxiety &amp; depression</td>
<td>Signals that the NHS SC group experienced more anxiety and depressed throughout compared to the other two groups</td>
</tr>
<tr>
<td>HADS-Total</td>
<td></td>
</tr>
<tr>
<td>PCQ-rumination</td>
<td>Strong signals (p=0.05) of less rumination from baseline to weeks 8 (p=0.05) and 12 (p=0.08) in the BMEA treatment group</td>
</tr>
<tr>
<td>PCQ-magnification and helplessness</td>
<td>Signals in the NHS SC group of more magnification and feeling more helpless throughout compared to the other two groups</td>
</tr>
</tbody>
</table>
Chapter Five  Qualitative Findings

5 Introduction

The previous chapter presented the quantitative results. The present chapter reports on the results of the semi-structured telephone interviews and key findings that emerged from the thematic analysis of my focus group discussions. The semi-structured telephone interviews address the secondary objectives of the acceptability to the participants of the methods of recruitment, randomisation, assessment and interventions. The focus group discussions address the secondary objective of effectiveness of the interventions. For clarity and the smooth flow of the chapter, where there were shared key findings between the groups these were reported together. The “Whole Person Effects” shared by the BMEA treatment and TCM HC groups are reported first. Similarly, the “Experience of Standard Care” and “Impact of Living with CPP” which are shared between the BMEA treatment and NHS SC groups are presented together. There were five themes in the “Experience of Standard Care” key finding that pertained only to the NHS SC group and thus reported separately. The summary of the key findings is presented in Table 5.2 (page151). Excerpts from the three focus group discussions and the actual words used by the participants are integrated into the narrative to provide an authentic account of their experiences. The full implications of these findings are discussed in this chapter. However, when appropriate, these findings will be integrated into the Chapter Six, the “Discussion and Conclusion Chapter”.

My reflective journal was recorded throughout the study.
5.1 Participants’ Characteristics

The participants’ characteristics are presented in Table 5.1 (page 134)

Table 5.1 Participants Characteristic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BMEA treatment group</th>
<th>TCM HC group</th>
<th>NHS SC group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>41.5</td>
<td>36.5</td>
<td>42</td>
</tr>
<tr>
<td>Median</td>
<td>40.7 (SD± 9.05)</td>
<td>36.5 (SD± 20.5)</td>
<td>38(SD±8.71)</td>
</tr>
<tr>
<td>Mean Range</td>
<td>27-50</td>
<td>22-51</td>
<td>28-44</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Single</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Co-habiting</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Divorced</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endometriosis</td>
<td>6</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Unknown aetiology</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medically Retired</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Self-employed</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Employed</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Unemployed</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

5.2 Semi-Structured Telephone Interviews

Of the 30 participants, 21(70%) responded to my telephone interviews: eight from the BMEA treatment group, five from the TCM HC group and eight from the NHS SC group. The remainders did not respond to my telephone messages. All the 21 participants responded favourably to the methods of recruitment, randomisation and intervention, assessment tools and rated them 1 or 2 on a 5-point scale from positive to negative. Of the five participants in the TCM HC, two participants expressed disappointment that they were not randomised into the BMEA treatment group, but they got over their initial disappointment. One participant in the NHS SC group informed me that she was dyslexic and thus the questionnaire was somewhat challenging.

5.3 Whole Person Effects: Key Finding of BMEA Treatment and TCM HC Groups

The key finding that is common to the BMEA treatment and TCM HC groups is the “whole person effects”, a term used by Paterson (Paterson and Britten, 2003) that is characterised by a several therapeutic benefits such as pain reduction, enhanced sleep, energy level and wellbeing. (See Appendix 3, page 208 for transcript)
5.3.1 Pain

The participants in the TCM HC group were tentative in their discussion about the pain. They reported a reduction in pain but were aware and careful to state that that other events such as surgery could have contributed to their experience of their pain:

... Sometimes I think, yes...and then every now and again I think, no, but...on balance I think, yeah...yes...Yeah, it...it has...it has helped...to cope with the...the pain... (Participant 2, TCM HC group)

...erm, as for my pain levels, well, I think they got better after that...for sure. They were a bit better, erm, though like you said, I have the same struggle. Like some days I’m like, yes, and some days I’m like...no. ...I did have surgery in June which...really, really helped...for a while...so...And that obviously, you know, complicates whether I can say it’s...just from the health consultation or not. (Participant 1, TCM HC group)

Almost all the participants in the BMEA treatment group reported short-term pain relief which they said was a welcomed break from the constant debilitating pain. Against the background of being in pain for over six years, participant 6 reported that the BMEA treatment made a big difference to her experience of pain and energy level. This in turn enabled her to accomplish more and spend quality time with her daughter (Figure 5.1, page 136):

...I found it a godsend. It took my pain away for a day, two days after the treatment...which I hadn’t had in over six years, so...it made a big difference, I felt I had energy...the following day...I mean, I’ve got the full time job...and I’ve got a two-year old daughter... I find myself lying on the couch, ’cos I can’t lift myself up...because I’m knackered from working. But...but when you got the acupuncture...you were going home, it was...it was so different...it was...go home for three, four hours before she went to bed, and...had a conversation with her...I painted with her...I did things with her that I hadn’t done before... (Participant 6, BMEA treatment group)
5.3.2 Sleep

Reflecting their experience of pain, a mixed pattern was reported by the TCM HC group with their sleep. Participant 2 felt that TCM HC did not contribute to her sleep as she relied on amitriptyline while participant 1 reported that sleep was enhanced after TCM HC:

*Well, I take amitriptyline now…. I slept well on that… Prior to that…my sleep wasn’t great…so I probably can’t say that…my sleep’s, er…any better because of anything…to do with the…study. (Participant 2, TCM HC group)*

*Er ..I’m pretty sure that mine is definitely improved because of that…Whether it’s staying up…half the night and not falling asleep or… I’ve…I’ve always had terrible sleeping patterns but mine has been a lot better since then actually. It’s really improved so…(Participant 1, TCM HC group)*

Similar to the pain free experience, a majority of the participants in the BMEA treatment group reported that they enjoyed better sleep. Participant 3 who was worn out by her chronic pain and sleep deprivation, reported that getting a good night sleep enabled her to have more energy and ability to complete household chores:

*I went through about four years, eh, either pacing the floor at night time or having broken sleep…. Because nobody can run on no sleeping, constantly. It just wears you out, it makes your pain worse, it just makes everything worse. Oh absolutely. Yeah…”cos one thing it done for me was help me sleep at night….When I started on my acupuncture, I could sleep through the night…That was the best bit….Happy mummy.*
5.3.3 Energy

With enhanced sleep, some participants experienced more energy. These participants recounted the impact of enhanced sleep on her energy level:

…it was helping me so I had more energy...so I just thought I was just like Wonder Woman. You know, first couple of times I was coming home and everything was getting done in the same day. Um, and then after that I was like that, no, just...just stop. [laughs] (Participant 3, BMEA treatment group)

…I felt like in my head, I felt like I had more energy, I felt more bubbly type thing...although the pain was still there, I felt more relaxed going home, and more cheerful sort of thing... (Participant 1, BMEA treatment group)

Participant 2 in the TCM HC group thought that her enhanced energy level was from learning to pace herself:

But I th...think on the...on the...longer term...I think it has. And that might be something to do with me pacing myself a bit...better. (Participant 2, TCM HC group)

5.3.4 Wellbeing

Both the TCM HC and BMEA treatment groups reported an enhanced sense of wellbeing. They spoke of being emotionally stronger and happier following their respective interventions. Participants in the TCM HC group reported that the consultation had helped them cope better and consequently felt happier. The key for the TCM HC group was timing. Participant 2 described the impact of TCM HC as long lasting and it offered what she needed most at the stage of her life. Here is the conversation between the two participants:

...You know, to have somebody working with you one to one...the impact that that can have on you...really is...immense... And I do think that it’s had a lasting effect on the way that I approach things...and...feel about myself. Hmm...Top that. (Participant 2, TCM HC group)

...definitely better, definitely feel...happier and easier to deal with stuff...really been a great help. And that I would say is absolutely down to the consultations...just feeling emotionally stronger...happier...Yeah. (Participant 1, TCM HC group)

...And we spoke about how it depends on where you are...in...in your life...and what’s happening...with you. So I think I’m more
ready now to be able to take on board some of the... advice or... or you know just working out what... used to do when I was your age I wouldn’t have been. I definitely wouldn’t have been. (Participant 2, TCM HC group)

Mmm... yeah, for me though I think it was at a right point in my life because I was, sort of, trying to finish uni and... not sure what I was gonna do next... and where I was going and didn’t... have enough confidence in it and... So for me it did come at like a turning point in my life... which was the perfect time... to have... someone give you advice and help you out... so that... was very useful. (Participant 1, TCM HC group)

Participant 1 reported that the meridian BMEA treatment did not alleviate her pain, although it made her feel better, more cheerful and relaxed. Here is what she had to say:

... on the day of the treatment, I always felt better... and then relaxed going home, and yeah, it helped me sleep... I’ve had pain for over 30 years and I’ll never get rid of it now...

...Um, well... it’s more my wellbeing OT (Practitioner) helped... Yeah, she is... she was... yeah, she’s kind of made me try and be better... nicer to myself... sometimes, and more accepting and... so it’s more emotional... (Participant 1, BMEA treatment)

5.3.5 Coping Skills

Participants in the BMEA treatment group acknowledged that because they experienced less pain, they were more positive and were able to function and cope better. Participant 5 captured the essence of the group’s discussions:

Yeah, I... was a lot more positive and a lot more pain free, and it was just... a lot easier to get through the week knowing that even if it was just a few hours of less pain... it was just so much easier to cope with everything...

Participant 4 reported that she felt more able to cope because the intervention has shifted her focus in dealing with her pain to her emotional wellbeing, consequently she felt more positive and happier:

Yeah,... I felt much more able to cope when I was having it... just looking at my emotional wellbeing and... stuff that I never considered. I’m so focused on trying to deal with the pain all the time... I always put everything else to the side. Being able to sleep and things like that... were massively helpful to me... I had it, ‘cos it
had been a month of really, really positive...great...I was a lot more happier. (Participant 4, BMEA treatment group)

Similarly, Participant 5 reported that the intervention coupled with advice on emotional wellbeing, helped her cope better:

...she actually suggested a lot of emotional stuff for me,...obviously your emotions and your pain link in really...there was actually one session I just burst into tears...which was really embarrassing...but she (practitioner) was so lovely about it,... she just suggested starting to write a journal again. And that was quite cathartic...so that helped a lot,...she was really encouraging that side of things...and that helped a lot as well...Yeah, bit more positive... Yeah, I...was a lot more positive and a lot more pain free, and it was just... a lot easier to get through the week knowing that even if it was just a few hours of less pain...it was just so much easier to cope with everything...(Participant 5, BMEA treatment)

5.4 Experience of Standard Care: Key Finding of BMEA Treatment and NHS SC Groups

The “Experience of Standard Care” is the shared by the BMEA treatment and NHS SC groups. The BMEA treatment and NHS SC groups reported a mix of experiences with the care they received. They unanimously expressed a dislike for medications and the associated adverse effects. The participants of the NHS SC group expressed a great sense of frustration at seeing different consultants at each clinical encounter and a perceived lack of communication among healthcare professionals. However some of the participants in the NHS SC group felt supported by their GP and the Pain Team

5.4.1 Unwanted Side Effects Of Medications

There was a general consensus among the participants of the BMEA treatment and TCM HC groups that many of their medications were ineffective and had significant side effects ranging from dry mouth, constipation to memory loss. Participants reported that managing the side effects was sometimes worse than managing their CPP.

Yeah, because every time you take something, you can see all the side effects...and...sometimes ...I think...just to...try to manage the pain and not take that as much and it...feels fine, so...that's what I would say...Yeah... because every time you take something, you can see all the side effects... (Participant 1, NHS SC group)

For me, some of the side effects were quite bad. It was affecting my blood pressure and my...heart rate...the drug treatment was
just...really no...no a good thing...I mean, I’ve suffered this for quite a number of years and I’ve been put on various courses o’, like, Zoladex and so forth...I finished my second round...I was on Zoladex first time for two and half years...they kept me on it. Came off it and I had the usual, sort of, painkillers and...all sorts. I was put on a second round of Zoladex. After that round I started to get even more...and my hips... (Participant 2, NHS SC group)

...but I just dinna like pain patches and don’t know if anybody else is waiting to get a pain patch...Yeah...but they can burn your nerves...um, but yeah, I’ve got Lidocaine patches on, but... (Participant 2, BMEA treatment group)

...I had Pregabalin in that as well, but I’ve had to come off of that. I’ve come off of that...That’s just knocked me nuts...On the meds you were just like...I mean, sometimes I just stagger about the place...and people go like that, on the drink again... (Participant 3, BMEA treatment group)

These participants complains of loss of memory, feeling “groggy”, dry mouth and constipation:

...with just like hip flexers and all of that, um, but then... I’m losing the plot...see this is another thing, meds, they just go boom...forgot what I was saying...Sick of popping pills, if I’m dead honest. I feel like I rattle. Like it’s the constipation, it’s the...bowel, it’s just everything, it’s just an absolute royal pain the ass. ...The other thing...the...no saliva either. Like you’re talking...Yeah you’re dry. (Participant 2, BMEA treatment group)

...and also I find when I’ve...if I’ve had to take top up painkillers, then half the time I don’t know what I’m speaking about anyway...and I can’t remember anything...I’ve got a lot of side effects going as well as the... ‘Cause the...actual problem itself...um, and I found actually,...that that seemed almost...sometimes worse...than the actual...you know, it’s trying to find...balances of things, so...no...um, and I’m just...really just wanting to try and find other things...that will help, so I don’t have to...take so many of...you know, sort of, morphine and...all the rest of it... And in the meantime, you’re getting all the new side effects...um, everything...Um...and then you have to take drugs for the side effects...All they’ve done is given me pain...er, sleeping tablets on top of...everything else...that I take. So then you end up making...you’re...even more groggy the next day. (Participant 1, NHS SC group)
5.4.2 Experience of Standard Care: Key Finding of the NHS SC Group

5.4.2.1 Frustrations at Ineffectiveness of Medications

Participants were asked if the NHS SC treatment had helped with their CPP. None of the participants had found the oral medications effective or satisfactory. The excerpts below capture their experience of the lack of effectiveness of oral medications:

Mm. Not for me. No. It’s been years like that and...there’s no improvement...Yeah for me as well...For me this treatment hasn’t changed anything...No...I’m on the contraceptive and...at first, ...it was the first year, I was in heaven...But after that year...it’s just been getting worse and worse...and I’ve been trying...I...I might have tried twenty different kind of...er, compositions on...in the contraceptives and nothing works. It’s like my body doesn’t react to it. (Participant 3, NHS SC group)

The following participants shared similar experiences of the lack of effectiveness of their medical treatment:

...even the meds, and they don’t work, it just takes over...(Participant 1, BMEA treatment group)

...none of the medications have ever worked for me now...so I’ve now just weaned myself off everything. They were...they weren’t working when I was on them, so...there’s no point in being on...(Participant 2, BMEA treatment group)

Yeah, it doesn’t help. No, um, the last one was Amitriptyline and unless I take five a day, then it’ll dose me off for a couple of hours. Or sooner, but then half an hour I’ve taken them, but if I’m only on one or two, then it doesn’t make any difference. But I actually take some more...(Participant 1, BMEA treatment group)

These participants expressed great frustration at the lack of effectiveness and the side effects of their medications:

...I couldn’t move...for the pain in my hips. And that was sore...so for me, it was quite frustrating...going down that route and I didn’t find...what I was getting was giving me much relief...if anything...as you say, I was probably going...the opposite way... (Participant 2, NHS SC group)

Well...I have to admit, I’ve been absolutely gobsmacked that there isn’t more non-drug, clinical...or intrusive thing...you know. I’ve been asking...hydrotherapy for...I mean...So I didn’t know...
what...how much I, I was going to get from the...pain team...and obviously when you first start you have the pain management group...and all of these other thing which were obviously good...I’m still seeing them and everything, but it’s still all about the drugs and managing the drugs...It’s...it’s...nothing else. And it’s very frustrating...for somebody who never took a paracetamol. (Participant 1, NHS SC group)

5.4.2.2 Frustrations at Seeing Different Consultants

Another source of frustration was not seeing the same consultant at each clinical consultation. This was from participants in the NHS SC focus group made these comments:

Um, but I think what was the most frustrating thing for me is that...as I say, I’ve been going there since about two thousand and nine...and I don’t think I’ve seen the same person twice. And I think that’s been...a frustrating thing for me...as well, because then I’ve got to sit every appointment...I’ve got to go through it all again...whereas if...I had that one or even two people...that I went to see...They knew all my case without me...having to sit and go all over it...again. You can’t go, right, let’s try...it...well we’ve already tried that...(Participant 2, NHS SC group)

Another problem that resulted from seeing different physicians was captured by Participant 3:

They started lowering one drug, went to see them the next time...and they were supposed to start me on something else, and they couldn’t remember why he’d taken me off the other one. (Participant 1, NHS SC group)

5.4.2.3 Frustrations at Perceived Lack of Communications

The third source of frustration has its roots in the perceived lack of communication among healthcare professionals:

But I just...just think you need to look at the person...I don’t feel as well that If...you have all these people...I have three different consultants and then various other people who are there...and nobody talks to each other. I work in the education system...You work with the child or the family; you have a group of people...and then somebody...is the leader...and, you know...I mean, my GP sometimes...unless I tell her, she doesn’t know what’s...going on. She doesn’t get...hospital appointments until...three months after the event...

...You know, it’s...I also tell her. I go away and the day after...my consultation...with the...you know, Doctor W...and I have to
say…right, he’s said to do this, this, this and this…and she just takes me on my word …of what I was saying. You know, go…give me some more morphine. That’s fine. Yeah. No, he said, up it right to… It’s quite slack… (Participant 1, NHS SC group)

This participant expressed her frustration at her rushed consultation with the pain team after waiting for eight months for an appointment:

Um, I mean…but it took, like, a year for me to get even on the pain team…even though…um, from when it was first mentioned, that was when…when I got, um…when I was in hospital for two weeks and I saw the in-house pain team…and then I was supposed to immediately see them out of…out of hospital…but didn’t see them for…eight months or something...So it’s…it’s…it’s...The whole...the whole thing I find quite frustrating...In and out very quickly. Because it’s always very rushed. (Participant 1, NHS SC group)

5.4.2.4 Heavy Reliant On Drugs

Participants in the NHS SC group felt that there was too much reliance on drugs to manage their CPP. They thought that complementary therapies should be included in the standard care rather than just relying on drugs:

...um, I think...they’re too heavy reliant on drugs and change...of drugs and give you more drugs and try that……injection. So we’ll do this...Whereas they should be working hand-in-hand wi’ comple...When I say ‘complementary’...I mean things like...Yes. Aromatherapy...Yes or...Reflexology...And we all, kind of, take...part of a package rather...than just the drugs...alone (Participant 2, NHS SC group)

That’s…I just do think there’s so much...emphasis...on the drugs...I have to admit, I’ve been absolutely gobsmacked that there isn’t more non-drug, clinical...you know...or intrusive thing...you know. I’ve been asking for...you know, this for...hydrotherapy (Participant 1, NHS SC group)

5.4.2.5 What Worked for the Participants

The participants were asked if they received emotional/mental support from NHS SC. Participant 3 reported that she received good support from her General Practitioner (GP) and CPN (Community Psychiatric Nurse):

And I will…I’m getting…I do get very good support from my GP...and from my CPN. And...I have to admit they have been very good and they’ve been very on the ball with...looking up things...but
Participant 3 found attending the pain team gave her a sense that she was helping herself:

*I find the pain group more helpful...than anything else. Depending on...feels like you're helping yourself...but...did you go to one of the pain management groups?  No, I did the pelvic pain...(Participant 3, NHS SC group)*

Other aspects which Participant 2 found helpful were, for example, dietary advice although it did not work:

*I found the support from the pain team good and...apart from obviously giving us the drugs and...the injections and everything I've been on. They're tried to point me in the direction...er, cutting out different things in my...diet and...changing what...which...I tried it...For me, it didna really work (Participant 2, NHS SC)*

5.5  Impact of Living with CPP: Key Finding of the BMEA Treatment and NHS SC Groups

The BMEA treatment and NHS SC groups shared a common finding of the impact of living with CPP. I have included this key finding although it does not directly address the secondary outcome (effectiveness of the interventions) of my study. This finding is interesting and unusual because the content spontaneously evolved from the focus group discussions and was not specifically asked by the facilitator. The negative impact of CPP rippled across the fabric of the women’s lives such as work, home and social lives.

5.5.1 Employment

Participants freely shared their experience of living with CPP and reported how the disrupted sleep, debilitating fatigue and pain impacted on their ability to work. Some participants were unable to hold down a full time position and had to be medically retired:

*I worked right up until 2009, so...and then I became medically retired, but I was one of the first people to be...for endometriosis...But I was...I was like...well, I worked all my life up until I was 45...and whatnot, then 2009, and my mind started to go really badly just before then, so I...And you get brain fog, so...I was doing things I wasn’t aware of for like six weeks in a row at work and I had no choice, I either got sacked or I got medically...*
...because I was working in a bank, so...transferring millions of pounds to...(Participant 1, BMEA treatment group)

I was so fit and...you know, I was running marathons and things before... two thousand and thirteen...and then, you know... I’m not able to do anything. And it’s affected...every...you know,... psychologically as well. And I’ve just...permanently medically retired...at forty-two...I was very aware that I was quite low...but I hadn’t realised that I was getting worse...and then that... um, makes it harder to deal with the pain...and also...the sleep pattern...things. I either sleep for sixteen hours or I can’t sleep at all. Um, and that’s...obviously again stops you from... functioning...(Participant 1, NHS SC group)

Some participants had to give up their jobs because of poor memory and extreme fatigue:

...like before I’ve worked in loads of clubs and stuff, and it’s like...working in a bar, you’re standing up, you’re...I mean, I have to pack in a bar job that I...and I loved my bar job... 'cos I had two jobs. I had my own job and a bar job...and I had to pack in my bar job first, and that broke my heart. Because I loved it, absolutely loved it. That’s...and then I had to stop...because I was getting to the stage where...like you would be talking to somebody. I worked in a nursery...and I’d look at a kid and go...poof, what was I thinking? What’s your name? Completely gone. On the meds you were just like...I mean, sometimes I just stagger about the place...and people go like that, on the drink again... Aye, nae bother. Twat, not had a drink for five year. (Participant 3, BMEA treatment group)

....my fatigue’s like super bad, so I’s like...it didn’t affect my sleep because I always sleep like twelve, fourteen hours a night...And I don’t work either, I can’t work...I work like an hour and a half week, so it’s about as much as I can manage just now. (Participant 5, BMEA treatment group)

For participant 2, work was a real struggle, which in turn impacted on her sleep and ability to cope with her pain:

... For me, um, like yourself, I force myself to go to my work...and there’s times that I really shouldn’t have been at my work...but I’ve got a mortgage to pay...I’ve no choice. I’ve got to go. Um, but that takes everything out of me...with it...um, and like yourself, I either sleep like... or I’m struggling to sleep...and there...there’s times you’re...you could...being asleep and you’re rolling over and it’s, like, [respondent makes a sigh as if in pain]...(Participant 3, NHS SC group)
5.5.2 Social Isolation

For many of the participants, CPP not only impacted negatively on their work lives, it impacted negatively on their ability to conduct social lives, leaving them feeling socially isolated. For Participant 1, even holding a conversation posed a challenge due to the lack of energy:

> See...see just trying even...get a conversation in, sometimes you can do it, sometimes you can’t....Because I mean, I...sometimes I don’t even want to talk to people...and like my...I’ll sit on the bus and all I can hear’s my mum talking away to me, and I’m thinking...and nothing comes out of my mouth. Nothing’s going in, is it? Because I just...I just don’t even have the energy to want to speak...and I just don’t want to speak to anybody [laughs]...so I suppose it’s...it’s one of the ways that like affects your life, you just can’t be bothered. (Participant 1, BMEA treatment group)

Participant 5 confided that because social interaction was challenging, she was losing her friends. She also found going out to the local shops a challenging experience. She felt that her whole life was put on hold:

> I find myself cancelling a lot...I do it a lot, and it’s...that’s a bit rubbish, that’s...so like...um, like I keep cancelling my friends, friends are dropping like flies...and like postponing life, like, goals and...like...and it’s just...I am a hermit at the moment...like I leave the house maybe once, twice a week...if that, and even then it’s just to go round the corner, because I live just behind the ...so I’m two minutes away from the shops...and even then I have to build myself up...to just leave the house...just to go to one shop to buy one thing. (Participant 5, BMEA treatment group)

Participant 3 was a single mother. She reported that she felt socially isolated because of her pain. She had to rely on friends to drive her to places:

> ...I expect a lot from people because I expect a lot from myself and friendships and...I don’t have a partner...but, you know, it’s definitely everything...all the pain and everything...and the way I’ve been feeling, it affects how sociable I am...You know, seeing friends, can’t drive half the time...Um, all my family are up in Aberdeen. It’s...you know, you’re relying on friends all the time to help me...Yeah....and I am very much on my own with a seventeen year old, so...I’m about as much use as a...chocolate teapot. Yeah. And it’s been hard on...I think it’s hard on a few...other people that care...as well. My son finds it really hard. You know. Yeah. (Participant 1, NHS SC group)
5.5.3 Challenged by Household Chores

Undertaking household chores posed a real challenge for some of these participants:

...I’ve been trying to redecorate one of my rooms, and it’s a tiny room, it’s like two point one metres by three point six metres or something, it’s tiny, and it’s taken me over a year just to paint it...I have had months where I just couldn’t face going up a ladder. Cos just the idea of standing upright is just insane, and so like I keep pushing off stuff, everything in life’s just been postponed...
(Participant 5, BMEA treatment group)

Participant 1 joined in the lament and had this to say:

Oh, I know that, but like...I know what it’s like to feel tired with this...it’s just when you’re wiped out...it’s like the thought of doing anything, you’re just like, oh no...It makes you miserable, though...I’ve cried trying to hoover...you know, because I...it can take me all day to do something...and I don’t work, and...but at the same time it’s like it all overwhelms me...and I’m just about in tears thinking, I’ve not done this, I’ve not done that...oh my God, it’s ten o’clock at night, and I’ve still not done the dishes. (Participant 1, BMEA treatment group)

5.5.4 Loss of Self-Worth

Participants were self-conscious about their disabilities and felt a great loss of self-worth and a deep sense of failure. This participant described her inability to cope at medical appointments:

...I have got really panicked in appointments because...they’ve said they’re going to start...that they’re wanting to reduce the amount of morphine that I take...and things and that just...and I don’t want to be on it...but I can feel myself panicking just...thinking about it...’cause I’m thinking, how am I going to be able to cope?

...I was the only one in the pain management group that...again, that wasn’t working...and I felt I...I thought I was fail...even more of a failure than...than...than I already felt.

...because of the pain and because...also my leg goes from underneath...me sometimes. So the confidence has gone...
(Participant 1, NHS SC group)

They were self-conscious and felt judged by the public. Participant 2 had this to say about her pain and perceived judgement of her by the public:
Because it’s nerves, innit? Hey ho. And this is the thing, ’cos it’s not physical, like people would see you on the crutches and think...

...they’d be like, take a seat, but if you’re there sheet white and you’re like...well, what’s wrong with you now? (Participant 2, BMEA treatment group)

Participant 1 echoed the above sentiment and went further to justify her disability. She also described using a walking stick to make visible the invisible. As a result she perceived the changed attitudes of some people and that made her feel better:

Well, I’ve just been classed as disabled now, and I’ve been fighting since 2009...but I’ve now been...and I’ve now got the...you know, the free bus pass, but I still feel...I feel that everybody’s looking at me when...I’m putting my disabled bus pass on it, and...and I think the bus driver’s maybe thinking...what’s wrong with her, do you know what I mean...you’re not walking with sticks...you’re not in a wheelchair, sort of thing. I sometimes use a stick, though, and like I’ve got a wee...got a wee like foldy uppy one, and see sometimes I do find like I’m stuck in the middle of a supermarket and think, oh my God, I can’t walk any further. And then if you’re on the bus with a stick...then people’s attitudes change. I was...I was walking in town...and people...you like it relaxes...(Participant 1, BMEA treatment group)

5.5.5 Negative Impact on Sex and Intimate Relationships

We have witnessed how CPP impacted negatively on many aspects of the participants’ lives. The negative impact of CPP on their intimate relationship is no exception. In this instance, the inability of Participant 5 to carry out some of the household chores had created tension in her relationship with her live-in partner to the point that it almost caused the breakup:

...and at that point, like the pain was so bad I couldn’t even do...sweeping in the hallway...like or change a cat litter tray...My boyfriend was total...working full time and...he was doing everything in the house...and he nearly left me because of it all. (Participant 5, BMEA treatment group)

Whereas following participants’ pain was so severe that they did not bother with sex anymore:

I...I have really bad pain with it...sometimes. Um...it...getting my Mirena taken out helped, actually, but, um, other than, no, it didn’t help. I don’t bother, I...I... (Participant 3, BMEA treatment group)
You know, because with the endometriosis being so bad...I’ve never...wanted a sex life...so, um, that’s caused a lot of problems for me in relationships...so now it’s a case of I just live on my own...and don’t...don’t bother, so...I mean, I don’t...I just can’t be bothered. (Participant 1, BMEA treatment group)

It’s not helped, no. I mean, there are issues...if there’s a lot of pain. Um, but having the treatment that I’ve had...Not helped.
(Participant 2, NHS SC group)
5.6 Discussion

Analysis of the semi-structured telephone interviews data regarding the acceptability of the methods of recruitment, randomisation and assessment tools was unanimously positive. There might be inherent bias as I conducted these interviews, although I did not recruit or randomise the participants. I also had not met any of the participants in the NHS SC group during the study. One participant from the NHS SC group found the questionnaire challenging because of dyslexia. This made me aware of the need to ask for possible barriers to completing questionnaire in the next study. Two participants from the TCM HC were disappointed for not being in the BMEA treatment group. Interestingly, telephone interviews response rate of the three groups followed similar patterns of those of the attendance and return of follow-up questionnaires, with the TCM HC group having the lowest response rate in all three categories. This may be because the characteristics of the participants in the TCM HC group were indeed different from those in the BMEA treatment and the NHS SC groups. Or that the TCM HC group did not like being randomised into a health consultation group as evidenced by the participants’ comments about being disappointed.

A summary of the key findings of the three focus group discussions is presented in Table 5.2 (page 151). The key finding the “Whole Person Effects” i.e. reduced pain, enhanced sleep, energy, coping skills and wellbeing were similar to findings of other qualitative studies in the USA (Cassidy, 1998b) and the UK. (Gould and MacPherson, 2001, Paterson and Britten, 2003) This finding was conspicuously absent in the NHS SC group. The Paterson study used a MMR approach (questionnaire and interview in-depth) to determine what the perceived benefits and problems of acupuncture in patients with chronic illness such as headache, pain in the leg or elbow. There were two categories of the “Whole Person Effects” and these were increased in energy and strength and social identity. The Gould study, also used a MMR approach, (semi-structured interviews [n=11] and questionnaire [n=72]) to determine patients’ experience of outcomes after acupuncture treatment with various physical, emotional and mental health symptoms. The “Whole Person Effects” in the Gould study included an improvement in physical, emotional and mood changes.
### Table 5.2 Summary of the Key Findings of the Three Focus Group Discussions

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The second key finding was “Experience of Standard Care” shared by the NHS SC and BMEA treatment groups. Both groups found the adverse effects of oral medications unacceptable. While the adverse effects of medical approaches to CPP are well documented (Daniels et al., 2010, Fall et al., 2010), there has been no qualitative study to document women’s attitudes to or how they cope with the side effects of medications. Similarly, there have been few qualitative studies that specifically evaluate the experiences of NHS standard care in women with CPP. One qualitative study (n=26) using semi-structured interviews examined the attitudes of women with CPP to gynaecological consultation in the UK gynaecological outpatient clinics in district and teaching hospitals. The authors identified
several themes. The women wanted personal care that they often did not get, to be understood and taken seriously, although they were often dismissed, a cure and an adequate explanation which again they often did not receive and be reassured. The study called for improvements in care. (Price et al., 2006) Three other qualitative studies on the experience of women with CPP in their medical consultations were undertaken in mid 1990’s and are somewhat out of date. The Grace study was undertaken in New Zealand. Nonetheless these studies highlighted the disappointment with the overall quality of the consultations. (Savidge et al., 1998, Selfe et al., 1998, Grace, 1995)

In the third key finding, the participants gave a detailed account of the negative impact of living with CPP. Consistent with literature on CPP, (De Graaff et al., 2013, Zondervan et al., 2001, Grace and Zondervan, 2006) the effect of living with CPP was far reaching and infiltrated almost every aspect of their lives to the extent of being biographically disruptive. This concept describes the shift away from the expected trajectory of life’s journeys. (Bury, 1982) The biographical disruptions are perhaps best captured in the employment, social and intimate history of the two groups. Of the nine participants in BMEA treatment and NHS SC groups, two were medically retired and two were unemployed. The constant lack of sleep, poor memory and severe fatigue impacted negatively on their ability to function. This in turn might have negatively impacted on their career. The negative impact of CPP on women’s employment is well documented. (Nnoaham et al., 2011, Simoens et al., 2012, Fourquet et al., 2011, Cox et al., 2003) For example, the Cox study (n=61) used focus group to learn about women’s experiences of living with endometriosis related CPP and highlighted the multiple losses women suffered: loss relationships, career and a sense of self-worth.

With regards to relationships issues (sexual and social), qualitative studies underlined a range of problems arising from the living with CPP such as breakups from the strains and stress of the illness and disruption to social activities as well as decreased in social support (Denny, 2004)

5.7 Conclusion

In conclusion, the findings of the semi-structured interview support the acceptability to the participants of the methods of recruitment, randomisation, questionnaires as well as the interventions (BMEA treatment and TCM HC). TCM HC group appears less accepting of their intervention as implicated by lowest telephone response and attendance rates in the focus group discussions and the intervention compared to the other two groups. The two
key findings “Whole Person Effects” and “Experience of Standard Care” would suggest that the BMEA treatment and TCM HC have therapeutic effects. These participants were overall dissatisfaction with standard care typified by the lack of effective treatment and the adverse effects of medications. However, it must be noted that there were only two participants in the TCM HC group discussion and four in the NHS SC group. Thus the findings might not be truly representative.
Chapter Six  Discussion and Conclusion

6  Introduction

This thesis sets out to evaluate the feasibility of a future multicentre RCT to determine the effectiveness of the meridian BMEA treatment for CPP in women. To achieve this aim, I conducted a three-arm pilot RCT using an embedded MMR approach, the rationale of which was presented in the Methodology Chapter Two. My study’s primary and secondary objectives were outlined in Chapter One (Section 1.20, page XX) and the methods used to achieve these objectives were described in Chapter Three. The quantitative results were reported in Chapter Four. In Chapter Five, I presented the results of the semi-structured telephone interviews and the key findings of the three focus group discussions. The present chapter will discuss critically the implications of the quantitative results and the qualitative findings.

6.1  Feasibility of a Future Large-Scale Study

My pilot study supports the hypothesis that it is feasible to conduct a future large-scale RCT to determine the effectiveness of the meridian BMEA treatment in managing the symptoms related to CPP in women. Feasibility is supported by my study’s ability to recruit and randomise 30 women over eight months (51% of those referred to the study) to the BMEA treatment, TCM HC or NHS SC. The study achieved completed 12 weeks follow-up in 23 participants (77%). Of note, retention rates in the BMEA treatment and the NHS SC groups were 80% and 87% respectively, which were higher than the TCM HC group at 53%.

The methods of recruitment, randomisation and interventions were overall acceptable to the participants. The recruitment history showed that only 4 out of the 59 women referred to my study were ‘not interested’ in participating. This would suggest that the prospect of participating, including having to fill out several questionnaires and possibly being randomised to the control arm, was not a major deterrent to recruitment. This is further supported by the results of the semi-structured telephone interviews whereby the participants interviewed were unanimously positive about the methods used in the study. These results were presented in Chapter Five.

The attendance rates between the BMEA treatment and TCM HC groups differed. This could be a problem if replicated in a larger trial, because it would complicate the interpretation of any differences in outcomes that might be found. The attendance rates were specifically problematic in the TCM HC group. Since the explanations for the five poor
attenders in the TCM HC group were a mixture of hospitalisation and no reasons given, it was likely that these participants would have preferred to be in the BMEA treatment group. My impression from my clinical experience of working closely with them would support this conjecture, however, it is important to note that there may also have been some baseline differences in characteristics between groups which could have impacted on attendance.

With regards to the acceptability of the questionnaires, all the questionnaires were complete in those returned questionnaires, except for the VAS, SAQ and WPAIQ. In the WPAIQ, missing data were primarily due to higher unemployment rate in the TCM HC group, another different baseline characteristic. Indeed, nearly all the non-returns occurred in just five of the 30 patients, all in the TCM HC group. In reviewing the SAQ questionnaire, I noted there are some questions that could have been confusing. This, along with the issue of having to commit to writing down very intimate aspects of their lives might have been responsible for the high frequency of missing data (see Chapter Five, Section 5.2 re completing questionnaire). Additionally, through the semi-structured interviews I was alerted to the issue of dyslexia where completing all the questionnaire posed a challenge. The VAS has only 2 missing values. There were no missing data in the BPI, SF-12, HADS and PCQ suggesting that the participants had no problem or objection to completing them.

Overall estimates of effectiveness in clinical significance, between groups and by group showed a trend that the BMEA treatment group experienced higher therapeutic benefits than TCM HC and NHS SC groups. (see Results Summary, Chapter Four, Section 4.5). These results, while not from an appropriately powered study, go some way in answering the second research question of whether the meridian BMEA treatment is effective in reducing CPP in women. I can say that there were positive signals of effectiveness and no signals of deterioration in symptoms.

There was no adverse event to acupuncture treatment reported or observed in my study, suggesting that acupuncture is safe if performed by an appropriately trained acupuncturist. This observation is consistent with most acupuncture studies. Minor side effects such as bruising, or dizziness can sometimes associated with acupuncture needling. (Wayne et al., 2008, MacPherson, 2001).

Table 6.1 (page 158) presents the key features of pilot studies in chronic pain conditions and how these compare with my study. The level of recruitment in my study fulfilled my expectation of 50% or over and is higher than comparable pilot studies undertaken by Couilliot (2013), Salter (2006) and Wayne (2008). (Couilliot et al., 2013, Salter et al., 2006,
Wayne et al., 2008) The retention rates were satisfactory in the BMEA treatment and NHS SC groups, but lower in the TCM HC group. Similar to my pilot study, these three acupuncture pilot studies showed a high recruitment, retention and acceptability rates. The study by Lewis et al, (Lewis et al., 2016) although not an acupuncture trial, is included in this discussion because its study design is similar to that of my study and both studies shared three questionnaires: VAS, BPI and HADS. Both the recruitment and retention rates of the Lewis et al study were lower than that of my pilot study and the acceptability of the Lewis study methods was favourable.

In terms of effectiveness, all three acupuncture studies showed some statistical significance and trends towards improvement in pain and quality of life issues such as feeling less anxious and having more energy. My study demonstrated statistically significant differences per group in the VAS-pain at week 4 (p=0.01) and week 8 (p=0.005) in the BMEA treatment group. However, at week 4, the NHS SC group also reported less pain (p=0.04) and in the TCM HC group there were some signals of pain reduction. Again, at week 4 the BMEA treatment group reported lower scores in the HADS for anxiety and depression (p=0.04), while the NHS SC group reported higher scores for anxiety and depression at weeks 8 and 12 (p=0.04). Clearly, in a study whose primary aim was to establish feasibility of a subsequent adequately powered trial, interpretation of effect has to be undertaken with appropriate caution. This is particularly important when we consider the effect noted in the NHS SC group at week 4. This might be due to the acknowledged benefits of being in a study, (Moore et al., 2013) a reflection of the fluctuating and random variation in pain experienced by this group of women, and to potentially biased reports that did not reflect real improvement. All these factors could explain why all three groups experienced a fall in their pain level at week 4.
Table 6.1 Pilot Studies in Chronic Pain Conditions Compared To My Study

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Tools Used</th>
<th>Objectives/Outcomes</th>
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<tbody>
<tr>
<td>My Pilot Study</td>
<td>RCT Using MMR, CPP in women, BMEA treatment n=10, TCM HC n=10, NHS SC n=10, Age: 18-60</td>
<td>VAS, BPI, SF12, HADS, PCQ, WPAIQ, SAQ, Focus Group &amp; semi-structured telephone interview</td>
<td>Recruitment rate/51%; Retention rates/ BMEA treatment 80%, TCM HC 53%, NHS SC 87%; Study methods acceptability/ Overall positive; Effectiveness/ Signals in improvement in pain, anxiety &amp; depression.</td>
</tr>
<tr>
<td>Couilliot et al (2013)</td>
<td>Open non RCT; Musculo-skeletal pain; TA n=60, Average 83 years</td>
<td>Behavioural pain scale</td>
<td>Recruitment rate/n/a; Retention rates/ 90%; Study methods acceptability /89.6% (attendance rate); Effectiveness/ Statistically significant pain reduction (p=0.01); Enhanced sleep &amp; reduction in anxiety symptoms reported.</td>
</tr>
<tr>
<td>Salter et al (2006)</td>
<td>RCT, chronic neck pain; TA n=10, SC n=14; Age: 45-51 years</td>
<td>Northwick Park Pain Questionnaire (NPQ)</td>
<td>Recruitment rate/10.5% (24 of 227 patients); Retention rate/ TA=90%, SC=86%; Study methods acceptability/ High level of acceptability; Effectiveness/Improvement in neck pain, feeling relaxed, energised when compared to SC group at 3 months but not statistically significant</td>
</tr>
<tr>
<td>Wayne et al (2008)</td>
<td>RCT Endometriosis JA Acupuncture n=10, Sham n=8; Age: 13-22 years</td>
<td>Endometriosis Health Profile, Paediatric Quality of Life, Perceived Stress</td>
<td>Recruitment rate/0.03 (18 of 550); Retention rate/ JA=9 (90%), Sham= 5 (63.5%); Study methods acceptability/ not reported; Effectiveness/Pain reduction significantly lower in JA group (p=0.004) compared to Sham group. A trend in perceived less stress in JA group</td>
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<tr>
<td>Lewis et al (2016)</td>
<td>RCT CPP in women Gabapentin (n=22), Placebo (n=25); Age: 18-50 years</td>
<td>VAS, BPI, HADS, EQ5D Quality of Life, Semi-structured telephone interview</td>
<td>Recruitment rate/34%(47 of 137); Retention rate/Gabapentin 59% (n=13), Placebo 48% (n=12); Acceptability/ Overall favourable; Effectiveness/Inconclusive: at 3 months placebo was better, at 6 months gabapentin was better. Gabapentin was statistically significantly better than placebo (HADS and BPI)</td>
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6.2 Specific Effects of Acupuncture Needling

Estimates of the effectiveness of the interventions showed that the BMEA treatment group experienced more therapeutic benefits than the TCM HC group, with the NHS SC reporting the least therapeutic benefits. The perceived benefits from the BMEA treatment focus group discussions lend support to these quantitative outcomes (see Chapter Five, Section 5.3, page 134 for “Whole Person Effects”). As this is a pilot study with small sample size, it is impossible to draw a conclusion that the specific effects of acupuncture needling alone were responsible for these effects or were due to placebo or a combination of both. Although, studies on the mechanisms of EA, on both animals and humans, support the notion that acupuncture needling has specific physiological effects. (Introduction Chapter One, Section 1.7, page 17) (Napadow et al., 2005) However, these data were challenged by other studies that showed that placebo-induced analgesia might also be mediated by endogenous opioids in some circumstances. The modern concept of placebo-induced analgesia had been proposed as early as 1978 by Levine. In this study (n=51) of the biological mechanism of placebo analgesia, all the patients received diazepam, nitrous oxide and local anaesthetic for extraction of impacted third molars. Three to four hours after surgery, naloxone an opioid antagonist, or a placebo was administered under randomised and double-blind conditions. Using the VAS-pain questionnaire, patients who received the naloxone reported significantly (p-0.05) greater pain than those given placebo. This would imply that placebo-induced analgesia was mediated by endogenous opioids. (Levine et al., 1978) Placebo-induced analgesia has also been found in studies using rats. (Nolan et al., 2012) Indeed, a systematic review of placebo analgesia concluded that placebo analgesia might exist and endogenous opioids might play a role in its mechanism. (ter Riet et al., 1998)

While the mechanisms of acupuncture treatment remains unclear, I can however hypothesise about perceived and observed effects in this small pilot study.

6.3 Specific Effects of TCM HC

TCM HC is the non-needling components of acupuncture treatment that might have a therapeutic effect. (See Chapter One, Section 1.8.2.2, page 22). In my pilot study, the group that were randomised to receive TCM HC did not experience as much therapeutic benefits as those who received BMEA treatment, but did better than those who got only NHS SC.
Again this observed trend was supported by the perceived benefits from the participants in the TCM HC focus group discussion.

### 6.3.1 Possible Reasons for Less Effect in TCM HC Group

### 6.3.2 Rituals in Acupuncture Treatment

The ritual of acupuncture treatment might explain why the TCM HC group experienced lower benefits than the BMEA treatment. Briefly, rituals are repetitive prescribed formal behaviours which have a sense of purpose. (Kaptchuk, 2011) The absence of acupuncture needling ritual might be the first explanation why the TCM HC reported less therapeutic benefits than the BMEA treatment group. The ritual of inserting the acupuncture needles into the skin of the participants together with the talking and listening might have provoked a placebo response in the BMEA treatment group.

In his paper on the placebo effect in alternative medicine, Kaptchuk argued that the rituals in alternative medicine practices might enhance the placebo effects. (Kaptchuk, 2002) Later in a nested study (n=262) that examined the different components of placebo effect in patients with IBS, Kaptchuk et al (Kaptchuk, 2008) concluded that size of placebo analgesia could be manipulated and the results were akin to dose response in pharmaceutical studies. In this study, the ritual of acupuncture treatment was incrementally added as follows: Group 1 received sympathetic general questioning; Group 2 received sympathetic general questioning + fake treatment; and Group 3 received sympathetic general questioning, + fake treatment + supportive patient-practitioner relationship. The supportive patient-practitioner engaged in highly organised ritual that included history taking, demonstration of compassion, attentive listening, thoughtful silences and expressions of confidence. The results showed that 28%, 44%, 62% of participants in Groups 1, 2 and 3 reported pain relief respectively on a validated IBS scale. This underscored the importance of a credible clinical interaction and ritual. In my study, the BMEA treatment group received interventions that were not dissimilar to Group 3 of the Kaptchuk study.

### 6.3.2.1 Beliefs and Expectations

Patients’ belief in and the expectation that acupuncture treatment works have often been proposed as the central factor for its effectiveness compared to no treatment or standard care. (Vase et al., Kong et al., 2009, Linde et al., 2007, White et al., 2012) A systematic review of the role of expectation found that studies that utilised experimentally induced pain such as the study by Kong et al (2009) were more likely to find a significant relationship, but the
authors did not discount that expectation might indeed play a role in acupuncture analgesia. (Colagiuri and Smith, 2011)

Could expectation have influenced the participants in the BMEA treatment and TCM HC groups? In my study, the TCM HC participants had not heard of a health consultation that was based on Chinese medicine theory. Most of the participants in the BMEA treatment group did not know what to expect, as almost all of them had not had acupuncture treatment before. They used words like “nervous”, “apprehensive”, “curious” and “excited” about acupuncture treatment. Nonetheless, I believe that expectation probably played a role in the therapeutic effects of the interventions. Besides, it might be that the participants hoped or want to believe that acupuncture treatment would help with their CPP when standard care appeared to have failed them. This hope or belief might have played a role in better therapeutic benefits experienced by the BMEA treatment and TCM HC groups. This finding is also reflected in the Kaptchuk study mentioned earlier. (Kaptchuk, 2008) The Kaptchuk study which interviewed 27 patients at baseline, midpoint and endpoint, found that the patients who had consulted with numerous specialists, were desperate and did not have positive expectations. However, they consistently expressed hope and were open to possibilities. Additionally, there might also be the reduced expectation associated with being randomised into the TCM HC group.

6.3.3 Possible Reasons for Less Effect NHS SC Group

6.3.3.1 Rituals and Positive Participant-Practitioner Relationship

It is important to note that only two participants attended the TCM HC focus group. The same two participants attended the intervention consistently and who reported in the focus group as having a good rapport with the practitioner. The positive relationship might have evolved through the ritual and interaction of looking at the tongue, talking, listening, and encouraging participants’ active involvement in lifestyle changes, all of which are tailored individually to the participant. The importance and quality of an interaction between patient and healthcare practitioner was also confirmed in systematic reviews and studies. Systematic reviews on pain and placebo effect concluded that the quality of patient-healthcare practitioner interaction could influence clinical outcome. (Turner et al., 1994, Di Blasi et al., 2001) There are other recent studies whereby the display of support, empathy and positive verbal suggestions also provided pain relief and enhanced outcome. (Kaptchuk, 2008, Kong et al., 2009, White et al., 2012)
In contrast the participants in the NHS SC group expressed a great sense of frustration at seeing different consultants. (see Chapter Five, Section 5.4.2, page 141). This might suggest that the opportunity to form a therapeutic alliance with their consultants was somewhat compromised.

It is interesting to note that the Huangdi Neijing, the oldest known document of Chinese medicine which was believed to have been compiled sometime between 200 BC and 800 AD, informed us that the process of getting better is not just about mechanically inserting a needle into the skin of a patient. Rather, the healing relationship between the practitioner and the patient was equally important. (Ni, 1995)

6.4 Contextual Effects and Synergy

The third component of acupuncture treatment is the contextual factors such as beliefs or expectations of the patient or practitioner, attitudes or past experiences. (Chapter One, Section 1.8.2.3, page, 22) It has been proposed that there might be a synergistic effect between the three components of acupuncture treatment that positively influenced clinical outcome such that its sum is greater than the individual components. (Paterson C and Dieppe P, 2005) If indeed there were synergism between these three components, it might explain the more promising therapeutic benefits achieved by the BMEA treatment and TCM HC groups. Additionally, to add strength to the notion of synergy, one of the key themes that emerged from the focus group discussions was the “whole person effects” experienced by both these groups, although less so in the TCM HC group. The “whole person effects” theme finding was consistent with other published findings. (Cassidy, 1998a, Gould and MacPherson, 2001, Paterson and Britten, 2003)

6.5 Strengths of my Study

6.5.1 MMR Approach

The demonstrable strength of my study was in the MMR approach in which a semi-structured telephone interview and three focus groups were embedded in a randomised controlled trial which yielded the qualitative and quantitative data. The focus group discussions captured a rich array of data that underscored the participants’ experience of their respective interventions and the impact of CPP on their lives.
6.5.2 Recognition of Context Effects

My study keenly recognised the context in which the interventions were given for example, that the patient-practitioner relationship, beliefs and expectations might all play an important role in pain reduction. Some data would suggest that such contextual factors do make a difference in clinical outcomes. (Kaptchuk, 2008)

6.5.3 Intervention Tailored to Individual Health Needs

Clearly, another strength of my study lies in the administration of the intervention. The meridian BM acupuncture treatment was administered to reflect how it was practised in a real clinical setting. The therapeutic points for needling were chosen based on a systematic protocol, and yet tailored to each participant’s exact location of pain at each treatment session. While the same procedural protocol was used, the points chosen and depth of needling varied according to each participant’s location of pain. This real world acupuncture practice approach used in my study contrasted sharply with the acupuncture RCTs discussed in the Chapter One (Section 1.9 page, 23) where a prescribed or semi-standardised set of points were used throughout the study regardless of the progress made by the participant, or the lack of it. (Diener et al., 2006, Endres, 2007, Haake M and et al., 2007) In my opinion, this was a fundamental and serious flaw in these studies, which significantly disadvantaged the performance of the acupuncture intervention arm. This flaw was one of the keys to understanding why acupuncture and sham acupuncture shared similar effect magnitudes.

6.6 Limitations of My Study

6.6.1 Inflexibility of Intervention Schedule

The twice-weekly schedule of the TCM HC and BMEA treatment of my pilot study suffered from inflexibility in that the schedule was not based on the participants’ progress or lack of it. It is difficult to imagine that patients in my practice would or could normally avail themselves for treatment twice a week. In my real world clinical practice, I would have followed-up my patients based on their progress, needs and time constraint.

6.6.2 Lacking Sham Control

It is generally acknowledged that the gold standard for effectiveness of RCTs is the use of a placebo/sham control for the study intervention. I understand that the exclusion of sham acupuncture as a control in my study might be viewed as a weakness. However, I would argue that it is a strength rather than a weakness because techniques employed in past sham
acupuncture controlled studies have shown to be problematic, e.g. sham acupuncture might produce physiological effects. (see Chapter One, Section 1.9, page 23)

### 6.6.3 The Meridian System

According to Chinese medicine theory, pain results from blocked meridians leading to an imbalance in the system. On the surface of the body is a network of 12 meridians (6 yin and 6 yang) that connect acupuncture points together. (Deadman, 2001:13-16) Theoretically, these meridians act as a pathway between the surface of the body and the internal organs. The meridian BM method acupuncture treats pain by balancing a “healthy meridian” with a “sick meridian”, for example using a “healthy” yin meridian to balance a “blocked” yang meridians. (Twicken, 2012) Thus the basis of understanding and practising the meridian BM acupuncture treatment style is to have an in-depth knowledge of the meridian system. However, employing this acupuncture style in my study where the meridian system played a central role in the diagnosis and treatment is challenging. There are considerable scepticisms and controversies surrounding the theories and existence of the meridian system and they continue to be hotly debated. (Ulett, 1998, Pandolfi, 2012) I believe that it is more useful to understand these systems as a conceptual framework that guides the clinical practice of acupuncture, rather than to debate if they exist as physical entities or not. Related to this discussion is an observation made by Langevin which leads to the possible explanation that acupuncture points and meridians are related to connective tissue and not as illustrated in Chinese medicine text. (Langevin et al., 2002)

### 6.6.4 Performance Bias

I administered all the interventions and therefore my study had the potential of performance bias. For obvious reason, I could not be blinded to the interventions. Because this is a pilot study, I wanted to personally administer the interventions to identify unanticipated issues that might arise and which could be addressed at the next large RCT. For this valid reason, I chose to administer the interventions, but again this might be problematic in a future large-scale study. To address the potential for performance bias, I kept a reflective journal throughout the study and the interventions were recorded which could be made available for scrutiny if necessary.


6.7 Lessons Learned and Future RCT

6.7.1 Managing Expectations

The TCM HC group had a much lower retention and uptake of interventions rate than the BMEA treatment group. The most important consideration for keeping the TCM HC group in the next RCT is the need to evaluate if TCM HC on its own, confers therapeutic benefits. This will give us some understanding of which component of acupuncture treatment contributes to the therapeutic effects. Corrective actions for the poor retention and uptake of interventions in the TCM HC group must however be taken. These corrective steps would aim at managing the expectations of potential participants. This might include firstly, training members of the research team to present the study as a pain rather than an acupuncture study. This would require a concise and clearly scripted information sheet. Secondly, it might be necessary to rename all the documents such as the PIS, letter to the patient to reflect that it is a pain study, rather than an acupuncture study.

6.7.2 Might a Second Set of Interventions be of Value?

Given the unpredictable nature of CPP an added 4-weeks intervention might give a more robust comparison between groups. This idea is worth considering in the next appropriately powered RCT.

6.7.3 Quantitative and Qualitative Research Tools

On reviewing what questionnaires were appropriate for my study, I chose for examples the HADS over Beck Depression Inventory (BDI) and the SF12 over SF16. The BDI was a series of questions developed to measure specifically the intensity, severity and depth of depression in patients with psychiatric diagnoses. The HADS was specifically developed to screen for depression and anxiety in patients with somatic co-morbidity. (Aben et al., 2002) Thus I felt that the HADS was an appropriate instrument to employ. I also felt that SF36 was burdensome for the participants, as they also had to complete concomitant questionnaires in the study.

In the next RCT, I would consider keeping the VAS, SF12, BPI, HADS and PCQ questionnaires but exclude the SAQ and WPAIQ due to the significant amount of missing data. However, the use of specific questionnaires for the next RCT will of course depend on its final design.
The focus group discussions and the semi-structured interview allowed me to collect a rich set of data that was useful to my pilot study. The combination of these tools served to answer both the primary and secondary objectives of my study. Although anonymised questionnaires might have been a better choice than the semi-structured interviews in evaluating the participants’ experience of the study. To ensure accuracy of the focus group transcripts, they should have been sent to the participants for verification. In the next RCT, I would keep the nested MMR design and use some of these tools as appropriate.

6.7.4 Exclusion criteria

The exclusion criteria in my pilot study needed to be more specific. For example, one of the exclusion criteria was “A history of seizure”. Some potential participants were excluded unnecessarily because they had seizures when they were children, or that a significant number of years have already passed. “Seizure within the last one year” would have been a better choice for the next RCT.

It is interesting to note that at baseline the cohort of women in my study did not appear to suffer from severe depression. Those who were severely depressed might have been excluded from the study based on the exclusion criteria. Another probable reason why this cohort of women in the study did not appear to be severely depressed was the use of antidepressants such as amitriptyline or duloxetine.

6.7.5 Audio Recording of Interventions

Initially, I was quite uncomfortable audio-recording the interventions. Permission was always sought at each intervention and no participant ever voiced any objections. It would appear that both the study participants and I soon got used to it. Eventually I did not even notice the audioRecorder anymore and I hope that was true for the participants too. However, I felt that audio-recording of the interventions might have made some difference to the behaviour of some of the participants. For example, one participant posed this question to me:

*Does Chinese medicine have anything to say about cravings for sugar?*

What was noteworthy was not the question itself but the timing, given that it was on the day that my audio-recorder had technical issues. In the past she had given me the impression that she did not wish to discuss nutrition or diet, even when prompted. She had bariatric surgery to reduce the size of her stomach to control her weight. This well-timed question made me
wondered if she might have been concerned by the recording but did not want to explicitly
voice any objection. Also, could it be that she took the opportunity of the absence of audio-
recorder to ask what she perceived as a difficult question? If so, the audio-recording was not
a good idea as it would appear to have influenced this specific participant’s ability to engage
freely in a dialogue with me. This is only a clinical impression of mine, but an interesting
one that should be considered in the future.

Another participant had asked to have the audio-recording be switched off for one session.
She asked who else would listen to the tape? I reassured her only professionals who had
anything to do with the research and of the strict confidentiality of the recording. This
brought up again the question of how wise it is to audio-record the sessions. I feel it
inhibited participants’ willingness to talk and share. In light of these observations, I might
consider excluding the audio-recording in the next RCT.

6.7.6 Training and Surveying Acupuncturists
Looking ahead, in a multi-centre RCT, it would be essential to choose carefully and train the
required number of acupuncturists. My intention is to work with the British Acupuncture
Council (BAcC), the main regulatory body for the practice of TA in the United Kingdom, to
survey the level of interest in the membership and identify suitable acupuncturists.

6.7.7 Public Involvement
Moving forward it is crucial to involve the public. Public involvement might include
patients, potential patients and people who use the health services. Involving the public
could lead to improved study design, creating interventions more acceptable for people
taking part in the study, more patient-centred data collection and outcomes as well as
making the research relevant to them.

6.8 What My Pilot Study Contributes
This is the first pilot study to utilise the meridian BM acupuncture style for CPP in women.
Most studies on the effectiveness of acupuncture generally used TA style. If the future
definitive RCT showed that the meridian BM acupuncture style is effective in managing
CPP, it could open a whole new field in pain management. It is also the first study to
separate the health consultation from the acupuncture treatment. This is important because
preliminary data suggest that TCM HC alone has therapeutic benefits, giving further insight
into which component of acupuncture treatment contribute to its analgesic effect.
As to the placebo effects of acupuncture, Avins so elegantly articulated that if patients find benefits in acupuncture or other complementary and alternative medicine (CAM) therapies, it is incumbent upon us to re-examine our attitudes and perceptions of the placebo effects. (Avins, 2012) In fact we should and must harness the contextual factors such as, the power of a positive clinician-patient relationship, compassion, listening, care and concern in improving clinical outcomes.

6.9 Conclusion

The large number of missing data in the SAQ and WPAPQ would caution me not to use these tools in the next study as indicated earlier. Nonetheless the methodology was broadly acceptable to the participants, including the requirement for randomisation and a large majority were fully prepared to fill in and return the questionnaires. The TCM HC group showed a consistent pattern in low retention, attendance to intervention and focus group discussions as well as the semi-structured telephone interviews. Corrective actions are needed if this arm is to be included in the next RCT. There were some statistically significant results and trends in improvement in pain and moods however, the sample size is too small to make a definitive conclusion on the effect of the meridian BMEA treatment and TCM HC on CPP in women.

My study has successfully demonstrated the feasibility of conducting a large-scale RCT for CPP in women. The recruitment rate achieved in my pilot study will allow me to estimate recruitment rate more accurately and determine the number of centres and the recruitment period that is required. I will also be able to utilise the information from the efficacy to inform the power calculation for a future trial.
PARTICIPANT INFORMATION SHEET (PIS)

Study Title:
The impact of meridian balanced method (BM) Electro-acupuncture (EA) treatment on women with chronic pelvic pain (CPP): A three-arm randomised controlled pilot study: The BMEA Study.

You have been asked take part in our research study because you have chronic pelvic pain (CPP). It is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before deciding whether or not you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
Chronic pelvic pain affects over 1 million women in the UK. The reason for the painful symptoms is poorly understood. It can sometimes be caused by conditions such as endometriosis, but up to 55% of women with CPP appear to have no obvious reason why they have it. The management of CPP is therefore difficult. Electro-acupuncture (EA) may be helpful in the management of CPP and we would like to see if Traditional Chinese Medicine (TCM) Health Consultation + Electro-acupuncture can contribute to improved quality of life and reduce painful symptoms. We would like to see if we can recruit successfully to a study comparing 3 potential treatment groups:

Group 1 - TCM Health Consultation + Electro-acupuncture
Group 2 - TCM Health Consultation alone
Group 3 - NHS Standard Care (SC).

What will happen to me if I take part?
We will ask you to come in to the hospital to see a member of the research team. During this visit we will ask you to sign a consent form and ask you some questions. We will also do a pregnancy test. If you are randomised to Group 1 or 2 you will receive your first consultation at this visit. Details below:

Consent
If you decide to take part, we will ask you to sign a consent form. One copy will be kept in our study file and one in your hospital notes. You should keep a copy of the consent form and this participant information sheet for your own records.

Pregnancy test
You will be asked to give a sample of your urine for a pregnancy test. We cannot give you acupuncture if you are pregnant.

Questionnaires
You will be asked questions about your health and to complete some questionnaires. You will then be randomly assigned to 1 of the 3 groups:

Group 1 - TCM Health Consultation + Electro-acupuncture
Group 2 - TCM Health Consultation alone
Group 3 - NHS Standard Care (SC).

All 3 groups will have optimal NHS standard care delivered by the chronic pelvic pain multidisciplinary team (see details below). We will ask you to complete questionnaires at weeks 4, 8 and 12. This may be done in person or via post.

Focus Group
Appendix 1  Study Forms

You will be asked to take part in a focus group at the end of the trial to discuss your experience. Focus groups are important as they tell us what we have done right in the study and where things could be improved. You can say no to taking part in this group on your consent form or at the end of the study. This discussion will be recorded and the recordings will be erased once the discussion has been put into a secure database. We will ask permission to contact your GP to let them know that you are taking part in the study.

**What will happen if I am assigned to the TCM Health Consultation + Electro-acupuncture (EA) group?**

You will be invited to come into the hospital for treatment twice a week over the next four weeks. Your first treatment will take place at your initial visit with the research team.

**TCM Health Consultation**

The acupuncturist will ask you questions about your health and examine your tongue and pulse. Based on these findings, self-care skills such as breath work and dietary advice based on Traditional Chinese Medicine might be given to better manage your pain.

**Electro-acupuncture**

The acupuncturist will ask you to locate your most painful areas and sterile disposable needles will be inserted into selected acupuncture points on your body. These points will be stimulated with electrical micro-current. Stimulating these points with electrical micro-current attached to the needles is called Electro-acupuncture.

The TCM Health Consultation and the Electro-acupuncture will take 60 minutes on your first visit. Your follow-up visits will be based on the same format as your first visit and will take about 40 minutes.

**How many TCM Health Consultation + Electro-acupuncture (EA) will I receive?**

You will receive 2 TCM Health Consultations and Electro-acupuncture per week for 4 weeks. You will receive a total of 8 treatments. With your consent, these treatments will be audiotaped. This is to ensure we are delivering the same treatment to all patients. These tapes will be stored in a locked secure place and only authorised members of the research team have access to these tapes. These recordings will be destroyed after the consultation details have been put into a secure database.

**Questionnaires**

At weeks 4, 8 & 12 you will be asked to complete a repeat of the questionnaires you completed at the beginning. Some of these will be sent to you via post with a stamped addressed envelope.

**What will happen if I am assigned to the TCM Health Consultation group?**

You will be invited to come into the hospital for treatment twice a week over the next four weeks. Your first treatment will take place at your initial visit with the research team.

During a TCM Health Consultation you will be asked questions about your health and your tongue and pulse will be examined. Based on these findings, self-care skills such as breath work and dietary advice based on Traditional Chinese Medicine might be given to better manage your pain. You will not receive any Electro-acupuncture.

The TCM Health Consultation will take 60 minutes on your first visit. Your follow-up visits will be based on the same format as your first visit and will take about 40 minutes.

**How many TCM Health Consultations will I receive?**

You will receive 2 TCM Health Consultations per week for 4 weeks. You will receive a total of 8 TCM Health Consultations. With your consent, these consultations will be audio-taped. This is to ensure we are delivering the same treatment to all patients. These tapes will be stored in a locked secure place and only authorised members of the research team have access to them. These recordings will be destroyed after the consultation details have been put into a secure database.

**Questionnaires**

At weeks 4, 8 & 12 you will be asked to complete a repeat of the questionnaires you completed at the beginning. Some of these will be sent to you via post with a stamped addressed envelope.

**What will happen if I am assigned to the standard care group?**

You will continue with standard NHS care from your doctor and the NHS Lothian Pelvic Pain Service. This multi-disciplinary team consists of a Consultant Gynaecologist, an Anaesthetist specialising in pain management, a Psychologist and a Specialist Nurse.

**Questionnaires**
At weeks 4, 8 & 12 you will be asked to complete a repeat of the questionnaires you completed at the beginning. These will be sent to you via post with a stamped addressed envelope.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part. This will not affect your care in any way.

What are the possible disadvantages and risks of taking part?

Electro-acupuncture is safe for most people. Side effects are rare. If they occur they are usually mild and short-lasting. Some people may get minor bruising, feel sick or light-headed. If you feel light-headed it is best not to drive immediately after a treatment. We also strongly advise to eat within 2 hours before each treatment as this might help prevent you feeling light-headed.

If you are worried please, contact us on 0131 242 9492.

What are the possible benefits of taking part?

The possible benefit is that you may experience pain relief.

What will happen if I don’t want to carry on with the study?

You are free to withdraw from the study at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care that you receive. If you withdraw we may still choose, with your permission, to use any anonymised data obtained as a result of your participation.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the clinical researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Contact: Freepost NHS Lothian, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Phone: 0131 536 3370. Email craft@nhslothian.scot.nhs.uk

Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. You will be allocated a unique code and your responses to the questions will be held in a coded form in a secured central database which is only accessible to the research team. Your responses and the tape recordings will not be identified when the results of the study are published. The tape recordings will be erased after the discussion has been put into the database.

What will happen to the results of the current research study?

The results of this study will be published e.g. in medical journals, reports and textbooks. The anonymised data will be stored for ten years at the University of Edinburgh and may be considered for possible use in future ethically approved projects.

Who is organising and funding the research?

The research is being organised in Edinburgh by Ooi Thye Chong, Lecturer in Integrative Medicine, University of Edinburgh and is partly funded by the Morag Robinson Legacy.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland Research Ethics Committee 02. NHS management approval has also been obtained.

Contact details:

You may contact our clinical research team directly by telephoning 0131 242 9492 for further information at any time. If you require any further information from a doctor who is not involved in any way in this study you can contact Dr. Melanie Mackean on 0131 537 3053.

Thank you for reading this information sheet.

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Additional Information That You Might Be Interested In: Acupuncture and Electro-acupuncture

What Is Acupuncture?
Acupuncture is believed to have started in China over 3000 years ago. When you have acupuncture, fine needles are put into your skin at specific points. Acupuncture can help relieve pain. It may work by causing your body to release its own pain-relieving and anti-inflammatory chemicals (e.g. endorphins and cortisol). There is some research data that supports acupuncture, though more research is still needed.

Is acupuncture safe?
- Yes, acupuncture is safe for most people.
- Some health problems mean that acupuncture is not advisable. You will be asked questions about your health to check that acupuncture is safe for you.
- If you have any risks, they will be discussed with you.
- The needles are thin, sterile and are only used once, then thrown away.
- You should eat something in the two hours before having acupuncture otherwise you may feel faint.
- You can still give blood.

Do the needles hurt?
- It may be slightly uncomfortable when the needles first go in.
- It should not be painful.
- Some people may feel a dull, warm, ache. This is a good sign.
- The needles may be put in place for only a few seconds, or they may be left in (e.g. up to 30 minutes).

Will it make me better?
Some conditions and people can be helped with acupuncture. It does not help all people and all problems. It is used to support other treatments.

Does acupuncture have side-effects?
Side-effects are rare. Some people may get these symptoms:
- Minor bleeding or bruising where the needles were. This should fade within a few days.
- Slight distending sensation in the first few hours after treatment. This will settle.
- Feeling drowsy or light-headed. This can happen as acupuncture may lower your blood pressure and blood sugar levels. For this reason, it may not be safe for you to drive straight away, and we strongly advise you to eat within two hours before your treatment.
- If you do feel tired after treatment you should rest.

What is Electro-acupuncture (EA)?
Electro-acupuncture is a method of stimulating acupuncture points with electrical micro-current attached to the needles. A typical EA treatment lasts about 30 minutes.

Why use EA?
Studies have shown that EA is helpful with chronic pain management as it helps your body to release endogenous neurotransmitters such as beta-endorphin, a natural analgesic.

Do I feel any sensation?
Typically you will feel a mild tingling sensation and/or a mild involuntary muscle twitches. These are normal sensations.

Is it safe?
Yes, it is a safe treatment for most people. However it is not recommended for people with a pacemaker or a history of seizures.
CONSENT FORM

BMEA Study: The impact of meridian balanced method (BM) electro-acupuncture (EA) on women with chronic pelvic pain (CPP): A three-arm randomised controlled pilot study.

Names of Researcher:
Ooi Thye Chong, Chief Investigator, Lecturer, Integrative Medicine, University of Edinburgh

Please initial box

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<table>
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<tbody>
<tr>
<td>1.</td>
<td>I confirm that I have read and understand the information sheet dated … Version … for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.</td>
</tr>
<tr>
<td>2.</td>
<td>I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.</td>
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<td>3.</td>
<td>I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by clinical research staff or by responsible individuals from the NHS, the University of Edinburgh or other authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.</td>
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<td>4.</td>
<td>I understand that I may not derive any direct benefit from this research.</td>
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<td>5.</td>
<td>I understand that I will be randomised into 1 of the 3 groups: electro-acupuncture treatment group, OR Traditional Chinese Medicine (TCM) consult group OR standard care group</td>
</tr>
<tr>
<td>6.</td>
<td>I agree to my General Practitioner being informed of my participation in this research and any clinically significant information derived from this study being sent to them.</td>
</tr>
</tbody>
</table>

7. I consent to be randomised in the meridian BMEA study. Yes No

8. I consent to take part in a audio-recorded focus group Yes No

9. I consent to the audio-recording of electro-acupuncture treatment/Traditional Chinese Medicine consult Yes No

Name of Participant
Date
Signature

Name of Person taking consent
(if different from researcher)
Date
Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record

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INVITATION LETTER

Date:

Dear

Re: BMEA Study: The meridian balanced method electro-acupuncture treatment study

We are writing to you because you have previously been diagnosed with ________________ and have pain associated with this condition. A study is being carried out in Edinburgh to investigate if the meridian balanced method electro-acupuncture helps to relieve pain. I enclose a participant information sheet about the study.

Please contact the clinical research team directly for further information by telephoning 0131 242 9492 at any time.

Yours sincerely

Consultant Gynaecologist
# QUESTIONNAIRES

<table>
<thead>
<tr>
<th>PIN</th>
<th>Initials</th>
<th>Day</th>
<th>Month</th>
<th>Year</th>
</tr>
</thead>
</table>

**Week in study**

| Baseline | 2 | 4 | 8 | 12 |

**BMEA study Questionnaires**
### VAS

Please fill in this scale:

Please circle the one number that best describes your pain.

**How severe has your pain been on average this week?**

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</table>

No pain | Moderate pain | Worst possible pain

### SF-12

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
</table>

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th></th>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3. Climbing several flights of stairs</td>
<td>□</td>
<td>□</td>
<td>□</td>
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</tbody>
</table>

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>4. Accomplished less than you would have liked?</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>5. Were limited in the kind of work or other activities?</td>
<td>□</td>
<td>□</td>
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</tbody>
</table>
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

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<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Accomplished less than you would have liked?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Didn’t do work or other activities as carefully as usual?</td>
<td></td>
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</table>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

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<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
</table>

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
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<tbody>
<tr>
<td>9. Have you felt calm and peaceful?</td>
<td></td>
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<tr>
<td>10. Did you have a lot of energy?</td>
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<tr>
<td>11. Have you felt downhearted and blue?</td>
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12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

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<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
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</table>
1. Throughout our lives, most of us have pain from time to time (such as minor headaches, sprains and toothache). Have you had pain other than these everyday kind of pain today?

Yes ☐  No ☐

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

![Diagram of human body with areas shaded and marked for pain]

3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

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<tbody>
<tr>
<td>No Pain</td>
<td>Pain as bad as you can imagine</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

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<td>Pain as bad as you can imagine</td>
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5. Please rate your pain by circling the one number that best describes your pain on average.

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6. Please rate your pain by circling the one number that best describes your pain you have right now.

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7. What treatments or medications are you receiving for your pain?
8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received?

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
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No relief  
Complete relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

a. General activity

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Does not interfere  
Completely interferes

b. Mood

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Does not interfere  
Completely interferes

c. Walking ability

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<th>3</th>
<th>4</th>
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Does not interfere  
Completely interferes

d. Normal work (includes both work outside the home and housework)

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Does not interfere  
Completely interferes

e. Relations with other people

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<th>3</th>
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Does not interfere  
Completely interferes

f. Sleep

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<th>3</th>
<th>4</th>
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<th>7</th>
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</table>

Does not interfere  
Completely interferes

g. Enjoyment of life

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<th>2</th>
<th>3</th>
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</table>

Does not interfere  
Completely interferes

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Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

<table>
<thead>
<tr>
<th>When I’m in pain …..</th>
<th>Not at all</th>
<th>To a slight degree</th>
<th>To a moderate degree</th>
<th>To a great degree</th>
<th>All the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>I worry all the time about whether the pain will end</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I feel I can’t go on</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>It’s terrible and I think it’s never going to get any better</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>It’s awful and I feel that it overwhelms me</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I feel I can’t stand it anymore</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I become afraid that the pain will get worse</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I keep thinking about other painful events</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I anxiously want the pain to go away</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I can’t seem to keep it out of my mind</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I keep thinking about how much it hurts</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I keep thinking about how badly I want the pain to stop</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>There’s nothing I can do to reduce the intensity of the pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I wonder whether something serious may happen</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
### WPAIQ

The following questions ask about the effect of your PROBLEM on your ability to work and perform regular activities. *Please fill in the blanks or circle a number, as indicated.*

<table>
<thead>
<tr>
<th><strong>1. Are you currently employed (working for pay)?</strong></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[ ] No, check “NO” and skip to question 6.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The next questions are about the **past seven days**, not including today.

<table>
<thead>
<tr>
<th><strong>2. During the past seven days, how many hours did you miss from work because of problems <strong>associated with your PROBLEM</strong>?</strong></th>
<th>_____ hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include hours you missed on sick days, times you went in late, left early, etc., because of your PROBLEM. Do not include time you missed to participate in this study.</td>
<td></td>
</tr>
</tbody>
</table>

| **3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?** | _____ hours |

| **4. During the past seven days, how many hours did you actually work?** | _____ hours |
| (If “0”, skip to question 6.) |             |

| **5. During the past seven days, how much did your PROBLEM affect your productivity while you were working?** |
| Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If PROBLEM affected your work only a little, choose a low number. Choose a high number if PROBLEM affected your work a great deal. Consider only how much PROBLEM affected productivity while you were working | 0 1 2 3 4 5 6 7 8 9 10 |

No effect on my work  Prevented me from working
6. During the past seven days, how much did your PROBLEM affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If PROBLEM affected your activities only a little, choose a low number. Choose a high number if PROBLEM affected your activities a great deal.

Consider only how much PROBLEM affected your ability to do your regular daily activities, other than work at a job.

<p>| | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
</tbody>
</table>
This questionnaire helps your physician to know how you are feeling. Read every sentence. Place an “✓” on the answer that best describes how you have been feeling during the LAST WEEK. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important.

<table>
<thead>
<tr>
<th>I feel tense or “wound up:”</th>
<th>I feel as if I am slowed down:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of the time</td>
<td>Nearly all the time</td>
</tr>
<tr>
<td>A lot of the time</td>
<td>Very often</td>
</tr>
<tr>
<td>Occasionally</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Not at all</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I still enjoy the things I used to enjoy:</th>
<th>I get a sort of frightened feeling like “butterflies” in my stomach:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely as much</td>
<td>Not at all</td>
</tr>
<tr>
<td>Not quite as much</td>
<td>Occasionally</td>
</tr>
<tr>
<td>Only a little</td>
<td>Quite often</td>
</tr>
<tr>
<td>Hardly at all</td>
<td>Very often</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I get a sort of frightened feeling as if something awful is about to happen:</th>
<th>I have lost interest in my appearance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very definitely and quite badly</td>
<td>Definitely</td>
</tr>
<tr>
<td>Yes, but not too badly</td>
<td>I don’t take as much care as I should</td>
</tr>
<tr>
<td>A little, but it doesn’t worry me</td>
<td>I may not take quite as much care</td>
</tr>
<tr>
<td>Not at all</td>
<td>I take just as much care</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I can laugh and seethe funny side of things:</th>
<th>I feel restless and have to be on the move:</th>
</tr>
</thead>
<tbody>
<tr>
<td>As much as I always could</td>
<td>Very much indeed</td>
</tr>
<tr>
<td>Not quite as much as now</td>
<td>Quite a lot</td>
</tr>
<tr>
<td>Definitely not so much now</td>
<td>Not very much</td>
</tr>
<tr>
<td>Not at all</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Worrying thoughts go through my mind:</th>
<th>I look forward with enjoyment to</th>
</tr>
</thead>
<tbody>
<tr>
<td>A great deal of the time</td>
<td>As much as I ever did</td>
</tr>
<tr>
<td>A lot of the time</td>
<td>Rather less than I used to</td>
</tr>
<tr>
<td>From time to time, but not often</td>
<td>Definitely less than I used to</td>
</tr>
<tr>
<td>Only occasionally</td>
<td>Hardly at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I feel cheerful:</th>
<th>I get sudden feelings of panic:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>Very often</td>
</tr>
<tr>
<td>Not often</td>
<td>Quite often</td>
</tr>
<tr>
<td>Sometimes</td>
<td>Not very often</td>
</tr>
<tr>
<td>Most of the time</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I can sit at ease and feel relaxed:</th>
<th>I can enjoy a good book or radio/TV programme:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely</td>
<td>Often</td>
</tr>
<tr>
<td>Usually</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Not often</td>
<td>Not often</td>
</tr>
<tr>
<td>Not at all</td>
<td>Very seldom</td>
</tr>
</tbody>
</table>
Occasionally, some women notice hormonal changes which may affect their sexual relationship. Although the following questions are sensitive and personal, they are important in determining how treatment affects this part of your life. Please be assured that your responses to these questions will remain confidential.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you currently married or having an intimate relationship with someone?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Have you changed your sexual partner in the last six months?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Do you engage in sexual activity with anyone at the moment?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If ‘yes’ please go to next page If ‘no’ please answer the remaining questions on this page</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I am not sexually active at the moment because …..(please tick as many of these items as apply)

<table>
<thead>
<tr>
<th>Reason</th>
<th>☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I do not have a partner at the moment</td>
<td>☐</td>
</tr>
<tr>
<td>b. I am too tired</td>
<td>☐</td>
</tr>
<tr>
<td>c. My partner is too tired</td>
<td>☐</td>
</tr>
<tr>
<td>d. I am not interested in sex</td>
<td>☐</td>
</tr>
<tr>
<td>e. My partner is not interested in sex</td>
<td>☐</td>
</tr>
<tr>
<td>f. I have a physical problem which makes sexual relations difficult or uncomfortable</td>
<td>☐</td>
</tr>
<tr>
<td>g. My partner has a physical problem which makes sexual relations difficult or uncomfortable</td>
<td>☐</td>
</tr>
<tr>
<td>h. Other reasons (please describe)</td>
<td>☐</td>
</tr>
</tbody>
</table>

Please read each of the following questions carefully and tick the box that best indicated your sexual feeling and experiences during the past month.

**During the past month:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Very much</th>
<th>Some what</th>
<th>A little</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was ‘having sex’ an important part of your life this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Did you enjoy sexual activity this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. In general, were you too tired to have sex?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Did you desire to have sex with your partner(s) this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. During sexual relations, how frequently did you notice dryness of your vagina this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Did you feel pain or discomfort during penetration this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. In general, did you feel satisfied after sexual activity this month?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
### Appendix 1 Study Forms

**8. How often did you engage in sexual activity this month?**

<table>
<thead>
<tr>
<th></th>
<th>5 times or more</th>
<th>3-4 times</th>
<th>1-2 times</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**9. How did this frequency of sexual activity compare with what is usual for you?**

<table>
<thead>
<tr>
<th></th>
<th>Much more</th>
<th>Somewhat more</th>
<th>About the same</th>
<th>Less than usual</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**10. Were you satisfied with the frequency of sexual activity this month?**

<table>
<thead>
<tr>
<th></th>
<th>Very much</th>
<th>Somewhat</th>
<th>A little</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
## CRF-SCREENING

<table>
<thead>
<tr>
<th>PIN</th>
<th>Day</th>
<th>Month</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>201</td>
</tr>
</tbody>
</table>

### Demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>Postcode</th>
<th>Depcat</th>
</tr>
</thead>
</table>

*If not above 18 stop screening*

<table>
<thead>
<tr>
<th>Asian</th>
<th>Black</th>
<th>Caucasian</th>
<th>Other (specify)</th>
</tr>
</thead>
</table>

### Gynaecology History

#### Contraception (tick all that apply)

<table>
<thead>
<tr>
<th>Condoms</th>
<th>Patch</th>
<th>Copper IUD</th>
<th>Vasectomy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>COCP</th>
<th>Nexplanon</th>
<th>Mirena</th>
<th>None</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>POP</th>
<th>Depo</th>
<th>Sterilised</th>
<th>If other state what used?</th>
</tr>
</thead>
</table>

*If not using effective contraception then discuss starting or stop screening*

### Medical History *(please include dates)*

#### Have you had pelvic pain for the last 6 months?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### What has your worst pain been in the past week? 0-10

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

*If score is less than 4 then stop screening*

#### Do you have any present malignancy?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Do you have a history of bleeding disorders?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Do you have a needle phobia?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Do you have a history of seizures?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Do you have a pacemaker?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Are you currently under the care of a psychiatrist?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### Have you received acupuncture in the past 6 months?  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

*If yes then stop screening*
### Have you been diagnosed with any of the following?

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometriosis</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>Irritable bowel disease</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>Painful bladder syndrome (interstitial cystitis)</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

If “yes” please give details:

[ ]

If “no”, is there no underlying pathology for the pain?

<table>
<thead>
<tr>
<th>Other relevant past medical history</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

### Concomitant Medications

<table>
<thead>
<tr>
<th>Name</th>
<th>Dose</th>
<th>Frequency</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Indication</th>
</tr>
</thead>
</table>

### Clinical Observations

<table>
<thead>
<tr>
<th>Height</th>
<th>cm</th>
<th>Weight</th>
<th>kgs</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

Pregnancy Test

<table>
<thead>
<tr>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
</tr>
</tbody>
</table>

If positive stop screening

### Eligibility

**Inclusion Criteria**

<table>
<thead>
<tr>
<th>Chronic pelvic pain longer than 6 months duration</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average numerical pain score of at least 4 out of 10 in the previous week</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Able and willing to comply with intervention</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>
### Exclusion Criteria

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged 18 and above</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Malignancy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Severe bleeding disorders (eg Type 2, 3 Von Willebrand disease)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Taking anticoagulants</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Severe needle phobia</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>History of seizures</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>A pacemaker in situ</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Moderate to severe psychiatric illness (seeing psychiatrist)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Received acupuncture within the last 6 months</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Fulfils inclusion criteria?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Consent form signed</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Researcher’s Signature**

**Date**
## CRF-BMEA TREATMENT

### Electro-Acupuncture Intake & treatment form

<table>
<thead>
<tr>
<th>Number</th>
<th>Treatment</th>
</tr>
</thead>
</table>

**Notes**

Chief Complaint/s:

Participant’s subjective report since last treatment:

### Other symptoms

**Digestion**

<table>
<thead>
<tr>
<th>Constipation</th>
<th>Loose stool</th>
<th>Reflux</th>
<th>Nausea</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thirst</td>
<td>Hot</td>
<td>Cold</td>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

How has your energy levels been on average this week?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No energy</td>
<td>Most energy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sleep**

Difficulty falling/staying asleep

Not rested in the morning

**Tongue**

**Emotion/s**

**Pulses**

<table>
<thead>
<tr>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Si/Ht</td>
<td>Lu/Li</td>
</tr>
<tr>
<td>Gb/Liv</td>
<td>Sp/St</td>
</tr>
<tr>
<td>Bl/Ki</td>
<td>Pc/Sj</td>
</tr>
</tbody>
</table>

**Recommendations**
Please mark the area of your pain

How would you describe your pain?

<table>
<thead>
<tr>
<th>Throbbing</th>
<th>Sharp</th>
<th>Cyclical</th>
<th>Intense</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cramping</td>
<td>Shooting</td>
<td>Dull</td>
<td>Dragging</td>
<td></td>
</tr>
</tbody>
</table>

What makes your pain better?

<table>
<thead>
<tr>
<th>Movement</th>
<th>Rest</th>
<th>Heat</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold</td>
<td>Rubbing</td>
<td>Medication</td>
<td></td>
</tr>
</tbody>
</table>

What makes your pain worse?

<table>
<thead>
<tr>
<th>Movement</th>
<th>Stress</th>
<th>Heat</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold</td>
<td>Tiredness</td>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

How severe has your pain been on average this week/since your last acupuncture?

0 1 2 3 4 5 6 7 8 9 10

What medications have you taken in the last 24 hours for your pain?

Comments
<table>
<thead>
<tr>
<th>Affected meridians:</th>
<th>Balanced Meridians:</th>
<th>Therapeutic points selection:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELECTRO-ACUPUNCTURE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red to Red to Red to</td>
<td>Black to Black to Black to</td>
<td>Program Program Program</td>
</tr>
<tr>
<td>Intensity (amps) Intensity (amps) Intensity (amps)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of needles inserted</td>
<td>Removed</td>
<td></td>
</tr>
<tr>
<td>Acupuncturist signature</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### TCM HC Intake & treatment form

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Complaint/s:</td>
</tr>
<tr>
<td>Participant’s subjective report since last treatment:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digestion</td>
</tr>
<tr>
<td>Constipation</td>
</tr>
<tr>
<td>Thirst</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How has your energy levels been on average this week?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>No energy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty falling/staying asleep</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tongue</th>
<th>Emotion/s</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Pulses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
</tr>
<tr>
<td>Right</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
</table>

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### CRF-TCM HC

Appendix 1  Study Forms
Please mark the area of your pain

How would you describe your pain?

- Throbbing
- Sharp
- Cyclical
- Intense
- Other
- Cramping
- Shooting
- Dull
- Dragging

What makes your pain better?

- Movement
- Rest
- Heat
- Other
- Cold
- Rubbing
- Medication

What makes your pain worse?

- Movement
- Stress
- Heat
- Other
- Cold
- Tiredness
- Comments

How severe has your pain been on average this week/since your last acupuncture?

0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

No pain | Moderate pain | Worst possible pain

What medications have you taken in the last 24 hours for your pain?

Appendix 1  Study Forms
The 12 Primary Channels/Meridians. (Deadman, 2001:13-16)

The Lung Channel of Hand Taiyin

The Large Intestine Channel of Hand Yangming
Appendix 2 The 12 Primary Meridians

The Stomach Channel of Foot Yangming

The Spleen Channel of Foot Taiyin
Appendix 2 The 12 Primary Meridians

The Heart Channel of Hand Shaoyin

The Small Intestine Channel of Hand Taiyang
Appendix 2 The 12 Primary Meridians

The Bladder Channel of Foot Taiyang

The Kidney Channel of Foot Shaoyin
Appendix 2 The 12 Primary Meridians

The Pericardium Channel of Hand Jueyin

The Sanjiao Channel of Hand Shaoyang
2. The Liver Channel of Foot Jueyin
Focus Group Discussion: Electro-acupuncture (EA) treatment and chronic pelvic pain (CPP)-The BMEA study.

You have been asked to take part in our Focus Group discussion as you have participated in the BMEA study. It is important for you to understand why the Focus Group discussion is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether or not you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the Focus Group discussion?
Your views matter and are important to us. The purpose of the Focus Group discussion is to find out experience of the BMEA Study:

a. Electro-acupuncture to manage your pelvic pain
b. The acceptability of a twice weekly electro-acupuncture treatment
c. Solutions to overcome any barriers to a twice weekly electro-acupuncture treatment
d. The questionnaires that we plan to administer in the study on electro-acupuncture treatment and chronic pelvic pain that will take place later in 2014. In this study (BMEA Study) we would like to find out if electro-acupuncture (EA) treatment is more effective than Traditional Chinese Medicine (TCM) health consult and the standard care you receive from your doctor.

What will happen to the results of the Focus Group discussion?
The findings will help us understand your experience and meet the needs of the participants of the BMEA study. Additionally, the findings will be presented at local and national academic meetings and published in peer reviewed journals. All study findings will be fully anonymised.

Where is the Focus Group discussion going to be held?
It will be held at the Quiet Room, Palliative Care/ Spiritual and Pastoral Care, The Quiet Room is on the ground floor, South Corridor, of the Royal Infirmary of Edinburgh.

Who will be running the Focus Group discussion?
Dr. G Hight will lead the group. The Focus Group discussion will last about 60 minutes.

Ooi Thye Chong, the Chief Investigator will be there to welcome you.
With your consent, in addition to note-taking, the group discussion will be digitally recorded and transcribed to help us keep an accurate record of what is said. The recording will not be heard by anyone other than the researchers, and will be kept in a secure location. A transcript will be typed up containing no identifiable personal information and then the recording will be erased.

Will I be reimbursed for travel expenses?
Yes, we will provide a flat fee of £10.00 to cover your travel expenses. Light snacks and beverages will be provided at the Focus Group discussion.

What are the possible benefits and disadvantages of taking part?
Agreeing to take part will not be of direct benefit to you although we hope you will find the Focus Group discussion informative and interesting. However, the information we collect will help us understand and meet the needs of those participants who agree to take part in the BMEA Study. In the longer term, it will help the large number of women who suffer from chronic pelvic pain. We do not think there are any disadvantages other than the time taken to participate.

Appendix 3 Focus Groups Forms
**Appendix 3 Focus Groups Forms**

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**Will my taking part in this study be kept confidential?**
All the information will be kept confidential. All aspects of the focus group will be treated in strict confidence. The notes and recording will only be used by the researchers who are all NHS Lothian employees. Data will be kept in a locked filing cabinet and backed-up on a password-protected, encrypted computer. No person identifiable information will be attached to the stored data. Our procedures for the handling, processing, storage and destruction of data comply with the Data Protection Act 1998.

**Who is organising and funding the research?**
The Focus Group discussion is being organised in Edinburgh by Ooi Thye Chong, Lecturer in Integrative Medicine and is partly funded by the Morag Robinson Legacy.

**What if there is a problem?**
If you have a concern about any aspect of the Focus Group discussion, you should ask to speak with the clinical researchers who will do their best to answer your questions. You can contact us on 0131 242 9492.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Contact: Freepost NHS Lothian, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Phone: 0131 536 3370. Email complaints.team@nhslothian.scot.nhs.uk

**Contact details:**
You may contact our clinical research team directly by telephoning 0131 242 9492 for further information at any time.

*Thank you for reading this information sheet.*
Focus Group Invitation

Simpson Centre for Reproductive Health
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
EH16 4SA

Date:
Dear:
Re: Focus Group Discussions
Thank you for your participation in the BMEA study. The study has now ended and we are writing to invite you to our focus group discussions. The purpose of the discussions is to find out your experience of the study. Dr. G Highet who has many years of experience in focus group will be leading the group discussions. Ooi Thye Chong will be there to welcome you but will not be present during the discussions. The focus group discussions will be held on:

Day:
Date:
Time:
Place: Quiet Room, Palliative Care/ Spiritual and Pastoral Care, RIE (See directions below)

We would like to offer you £10.00 as a token of our gratitude for your time and to cover your travel expenses and parking. There will also be light refreshments.

Your participation is very important. It will contribute to our understanding and the delivery of services to patients with chronic pelvic pain. Please contact the clinical research team directly by _____ to confirm if you will be attending the focus group discussions. The number to call is: 0131 242 7904. If you need further information you can also call the same number at any time.

Thank you.

Yours sincerely

BMEA Research Team
Directions: Quiet Room, Palliative Care/ Spiritual and Pastoral Care

The Quiet Room is on the ground floor of the RIE, South Corridor.

1. Enter the hospital via the main entrance (this is the entrance with the bus hub and car parks).
2. At the Information Desk, turn left along South Corridor.
3. You will find the departments of Palliative Care/Spiritual and Pastoral Care on the right (just past the entrance to the Sanctuary).
4. Come in through the double doors, turn left and the Quiet Room is the room at the end on the right.
Focus Group Discussion Topic Guide

BMEA Treatment Group

Experience of treatment
1. Can I start by asking you about the actual treatment itself?
2. What was involved?
3. Any surprises, or was it pretty much what you expected?
4. What was it like for you coming along twice a week for the four weeks?
5. Any other comments about what it was actually like having the treatment?
6. If practical advice was given, did you find it useful in managing your pain?

Expectation and belief in acupuncture
1. Did you believe that acupuncture will help with your pain?
2. Did you expect that acupuncture will help with your pain?

Did the intervention make any difference in
1. How you feel in your day to day life? If so, could you expand on your feeling?
2. The quality of life in general? If so, can you explain how it has affected your quality of life?
3. In your pain level? If so, could you expand on that?
4. Sleep quality – get to sleep more easily? wake early less often? more likely to feel you’ve had a good night’s sleep
5. Energy levels – able to get more done? for example?
6. Sexual function – more likely to feel like it? less painful? more enjoyable?
7. Degree of anxiety/depression If so can you expand on this?
8. Concern about future health – less prone to worrying?

Do you have any other comments you’d like to make about the treatment or your involvement in this trial?
TCM Health Consultation Group

Experience of treatment
1. Can I start by asking you about the health consultation itself?
2. What was involved?
3. Any surprises, or was it pretty much what you expected?
4. What was it like for you coming along twice a week for the four weeks?
5. Any other comments about what it was actually like having the treatment?
6. If practical advice was given, did you find it useful in managing your pain?

Expectation and belief in Chinese medicine health consultation
3. Did you believe that Chinese medicine health consultation will help with your pain
4. Did you expect that Chinese medicine health consultation will help with your pain

Did the Health Consult make any difference in
1. How you feel in you day to day life?
   If so, could you expand on your feeling?
2. The quality of life in general?
   If so, can you explain how it has affected your quality of life?
3. In your pain level?
   If so, could you expand on that?
4. Sleep quality – get to sleep more easily? wake early less often? more likely to feel you’ve had a good night’s sleep
5. Energy levels – able to get more done? for example?
6. Sexual function – more likely to feel like it? less painful? more enjoyable?
7. Degree of anxiety/depression
   If so can you expand on this?
8. Concern about future health – less prone to worrying?

Do you have any other comments you’d like to make about the treatment or your involvement in this trial?

Appendix 3 Focus Groups Forms
NHS Standard Care Group

Experience of treatment
1. Can I start by asking you about being randomised into the regular NHS standard care?
2. Did you think that being in this study, help with your pain level?
3. Any surprises, or was it pretty much what you expected?
4. What was it like for you not receiving any treatment from the study?
5. Any other comments about what it was actually like being in the standard care group?
6. Did you find completing the questionnaire help with your pain level?

Expectation and belief in being part of this study
1. Did you believe that taking part in this study will help with your pain?
2. Did you expect that taking part in this study will help with your pain?

Does taking part in this study make any difference in
1. How you feel in your day to day life?
2. If so, could you expand on your feeling?
3. The quality of life in general?
4. If so, can you explain how it has affected your quality of life?
5. In your pain level?
6. If so, could you expand on that?
7. Sleep quality – get to sleep more easily? wake early less often? more likely to feel you’ve had a good night’s sleep
8. Energy levels – able to get more done? for example?
9. Sexual function – more likely to feel like it? less painful? more enjoyable?
10. Degree of anxiety/depression
11. If so can you expand on this?
12. Concern about future health – less prone to worrying?

Do you have any other comments you’d like to make about the treatment or your involvement in this trial?

Appendix 3 Focus Groups Forms
This is OT…oh, there we go, I think that’s it going now. It’s OT’s phone, so I’ve not used that before, but it look as though…there’s a wee thing going round, so I’m assuming it’s working. [laughs] I’ll put this on, on there, as well. Right. Okay, think we’re in business. So, thanks a lot for coming today, um, to…to tell us about your experiences of the…the treatment. As I said, my name’s GH, and I’m a researcher with the palliative care team here, so OT asked if I would run…oh…

R: I have one late…one lady.

F: Oh right, one more, okay, come in, hi.

R: Thanks, sorry I’m late.

F: That’s alright, we’re only…well, we haven’t quite started yet so, um, if I could maybe just ask you to sign your name. There you go. Oh, another one, great.

R: Just literally finished.

F: Yeah, smashing.

R: I’m J.

F: Hi, hi, I’m G. We can do all the introductions just in a minute once we get this bit done. Thanks. There you go, one for you. Please help yourself to any drinks or fruit or anything up there that you fancy.

R: Lovely. Sorry, I was giving you my phone.

F: And…um…there you go. So that’s S… over there and J… Right, um, I was just introducing myself to the others. Um…my name’s GH, I’m a researcher with the palliative care team here in the Royal Infirmary, um, so I get involved in all sorts of research, really, um, and OT asked if I would run this focus group for her, so that’s why I’m here, um, tonight. Could I maybe just go round and ask you all to say who you are, and then we…we’ll get started. Can I start with yourself?

R: Yeah, I’m TM.

F: Okay, thanks TM.

R: I’m J, G, J.

R: I’m C

R: S

R: L

R: And S

F: And S, right. Um…you haven’t met one another, I take it?

R: No.

F: No, no, right, right. Okay. Um…well, as you know, it’s the…the group tonight is to find out about your experiences of the treatment that you’ve received, um, from OT, so can I maybe just start by asking you, um, what the actual treatment was like itself, what…what was involved in your treatment?

R: Getting pins stuck in you.

F: Pins stuck in you, right, okay. Uh-huh.

R: Attached to electrodes.

R: Electrodes, aye, yeah.

F: Right.

R: [inaudible 02:59] with acupuncture.

F: Right, uh-huh, uh-huh. So, um, did you go to a number of different sessions, or how did…how did that work?

R: It was twice a week.

F: Twice a week, uh-huh, and for…for how many weeks?

R: I think it was four?

R: It was seven or eight...

R: Seven.

R: Weeks.

F: Mmm-hmm, mm-hmm, right. And can you maybe just talk me through, you know, the session, what actually happened when you went in and stuff and…

R: Um, you’d go in and she’d look at your tongue…
Right, uh-huh.
…which was really weird.
Yes.

Um…and then she just asked you a couple of questions about why you were there, where your pain was, had to go on your…like a scale, you know, to ten…
Uh-huh.
…um…how you’d been in the past week, and then you would get up on the bed and she would start sticking pins in you.
Right, right.
Electrocuting you with the… [laughs]
Right, oh gosh. It doesn’t sound very comfortable.
It was actually alright, it was…
I found it quite relaxing.
Uh-huh.
Yeah, yeah.
I got used to it…
Uh-huh?
…but at times I thought…
Yes.
…my muscles were going to jump out my fingers…
Aye.
…it was like painful, but then once that you’re relaxed, it was okay…
Yes, yes.
…once you got into it, sort of thing.
Right, uh-huh.
So the twitches could be quite uncomfortable, like…
The twitches, yeah, they were quite strong, yeah.
…like there’s a spasm kind of thing, so they were quite uncomfortable, but I think it’s kind of…you just ride it out because you know it’s going to help you…
Yeah, right, yes.
I ended up with cramp in my ankle for three days.
Really? Uh-huh.
Yeah, whenever she did like my leg…
Uh-huh.
…and my leg would just start dancing on its own…
Oh goodness.
…then it would just be cramp for three days.
Yes, yeah.
Other than that, it was okay. [laughs]
Uh-huh, uh-huh, uh-huh. So was the treatment, was it pretty much what you expected, or were there any surprises about it?
I thought it was what I expected. I didn’t know it was going to be the…the…the electrodes.
No, that’s the same…same as me…
Uh-huh.
…I wasn’t quite sure what that was…I was quite scared, really…
Right.
…I was apprehensive.
Right, right, so…did OT explain that to you, what…what it was all about, so…
Mm-hmm, yeah, mm-hmm.
Did that…did it feel a bit better once you kind of knew what…what it was for?
Kind of, it was after the first time, then you know what…what you’re expecting.
Uh-huh.
But each time was kind of different for me.
Uh-huh.
I was different…not different sensations, but just different places, I suppose and…
Mm-hmm.
…different pulses, but I don’t think I ever had it on really strong, ’cos I couldn’t stand the…
Mm-hmm.
…the…whatever spasm was in my hands and stuff, yeah
Right, right.
I had to get…normally get that turned down a bit so that I didn’t…

Appendix 3 Focus Groups Forms
F: Right.
R: ...have to go through that, 'cos it was quite bad.
F: Uh-huh, uh-huh. What about the others, how did you find it?
R: I've had acupuncture before, but I didn’t know about the actual acupuncture part until she like she explained it.
F: Mm-hmm.
R: And I think I was a bit nervous, but kind of curious and excited about it as well, so I didn’t really…
F: Mm-hmm.
R: I kind of overloaded the scared part, if that makes sense. [laughs]
F: Mm-hmm, mm-hmm.
R: I’ve had acupuncture before as well.
F: Right.
R: And the thought of the electrodes was quite like having TENS, it was quite similar.
F: Right, uh-huh, uh-huh.
R: Fine. [laughs]
F: Yeah.
R: My first time.
F: Right.
R: I’ve been authorised that I can get it again…
F: Uh-huh.
R: ...through the pain clinic.
F: Oh right, okay.
R: Yeah, so was I, I’ve got an appointment.
R: Yeah, aye.
R: I have to be referred as well, so…
F: Right, right.
R: I’ve…
R: 'Cos one thing it done for me was help me sleep at night.
F: Mm-hmm, mm-hmm.
R: It helped me…
R: I went through…I went through about four years, eh, either pacing the floor at night time…
F: Yes.
R: ...or having broken sleep.
F: Oh gosh.
R: When I started on my acupuncture, I could sleep through the night.
F: Uh-huh.
R: Even just getting four solid hours…
F: Mm-hmm, mm-hhm.
R: ...was just like a full night’s sleep for me.
F: Mm-hmm, mm-hmm.
R: That was the best bit.
R: I never noticed anything much after the day of the treatment, but on the day of the treatment, I always felt better after it…
F: Mm-hmm.
R: ...and then relaxed going home, and yeah, it helped me sleep, but it never sort of continued. I think unless you were getting it every single day, then…
F: Mm-hmm, mm-hmm.
R: Um…
F: For me, I was kind of excited about it because I have had a full knee reconstruction.
F: Right.
R: So it’s the same side, and so one isn’t helping each other…
F: Uh-huh.
R: ...so like it was through a martial art, and, um, so I’ve had acupuncture and stuff before…
F: Uh-huh.
R: ...and yeah, I absolutely loved it, stronger the better, to be honest [laughs]…
F: Right, right.
R: ...and you could just see it all twitching.
F: Uh-huh.
R: Okay, [inaudible 07:10] it wasn’t the greatest thing, but like I…like you say, once you relax…

Appendix 3 Focus Groups Forms
R: Yeah, yeah.
F: Uh-huh.
R: …because when they get the oil out and then I would try and breathe…
R: Yeah.
R: …but when the needle would first go in, it was…
R: Sore.
R: Oh jeez, but apparently that’s my body remembering all the surgery. It was just [inaudible 07:25]…
F: Yes, yes.
R: …I was like, oh, okay…I did find as well, slept like a baby.
R: Yeah, yeah.
F: Uh-huh, uh-huh.
R: But I also tied this up with going to an osteopath as well…
F: Mm-hmm.
R: …so, yeah, both definitely helping.
F: Mm-hmm, mm-hmm, mm-hmm, yes, yeah. You were saying, um, she was…you were quite surprised that she looked at your tongue, yeah.
R: Yeah, didn’t know that had anything…
R: Your tongue tells you how healthy you are.
R: Is that right?  
F: Uh-huh, uh-huh.
R: Is that to do with Chinese medicine?
R: It’s quite…it’s Chinese medicine that she went into.
F: Right.
R: Um…I have my boobs and everything pierced, and she just happened to ask me one day, she says, have you got anything else pierced apart from your nose…
R: [laughs]…I went, [inaudible 08:05]. She says, can you take them out, because apparently it interferes in your central…
R: Oh right.
F: Oh really?
R: Your stomach meridian, I think it is.
F: Right, uh-huh, uh-huh.
R: Yes, yes.
R: But, um, it’s no’ really made much difference for the pain.
F: Uh-huh, uh-huh, yeah.
R: To be honest, but…
F: Right.
R: …I thought, I’ll try it and see…
F: Mm-hmm.
R: …just thinking, you know, just in case.
F: Mm-hmm, mm-hmm.
R: I think I would just go…I’ve had pain for over 30 years and I’ll never get rid of it now, but, um, because it relaxes me on the day, at least…
R: Yeah.
R: …then I suppose that’s why I’m getting referred back just to give it a bash.
F: Mm-hmm.
R: My daughter, she’s going next week, actually, she’s just had an appointment to see OT.
F: Right.
R: So she’s…her whole family’s falling to bits, but, um, yeah, she’s now going as well, so I’ll see how she gets on with it, but [inaudible 08:51].
R: It was just the…getting the…the…like the night’s sleep.
F: Uh-huh.
R: Because nobody can run on no sleeping, constantly.
F: No, no, mm-hmm, mm-hmm.
R: It just wears you out, it makes your pain worse, it just makes everything worse.
R: Oh absolutely.
R: Yeah, it does.
R: So getting that sleep…
F: Mm-hmm, mm-hmm, yes.
R: …even for the solid four hours or that…
F: Yes, yeah.
R: That's a cracky.
R: Yes.
R: Happy mummy.
R: Uh-huh.
F: What about yourselves with the sleep thing, did that…
R: I've always slept like…
F: Right.
R: I oversleep with that, 'cos my fatigue's like super bad, so I'd like…it didn’t really affect my sleep because I always sleep like twelve, fourteen hours a night, so…
F: Mm-hmm, mm-hmm.
R: …it’s kind of the opposite. [laughs]
F: Yeah, right, right.
R: That’s weird for me, ‘cos I suffer from extreme fatigue, and yet I can’t sleep at night.
R: I have to nap like most days.
F: Yes.
R: …then I dose for a couple of hours and I mean, I’m…’cos of the illness I’ve got, I…I suffer from extreme fatigue, and yet I’m still…
F: Mm-hmm.
R: …I’m always tired, I’m always…
R: Are you not taking [inaudible 09:47]
R: Yeah, it doesn’t help.
R: No.
R: No, um, the last one was Amitriptyline and unless I take five a day, then it’ll dose me off for a couple of hours.
F: Mm-hmm.
R: Or sooner, but then half an hour I’ve taken them, but if I’m only on one or two, then it doesn’t make any difference.
F: Mm-hmm.
R: But I actually take some more.
R: So you don’t sleep though, after a couple of hours, that’s when you start getting the junkie itches.
R: Yeah.
F: Mn.
R: See, I’m on Duloxetine as well and Amitriptyline, and I’m just clawing.
R: I can’t take that.
R: Duloxetine makes me ill.
R: I’ve had HRT, I’ve had load of different things…
R: Aye, so have I.
R: …so getting on [inaudible 10:15]
F: Uh-huh, uh-huh.
R: Duloxetine just…I take one and the whole room swims, so…
R: Oh no, no.
R: Give it. [laughs]
R: Aye, Patsy. [laughs]
F: Everybody’s different.
R: I know, it’s funny, yeah.
F: Yeah, yeah, uh-huh, uh-huh. And what was it like going along for it, it was twice for…a week for four weeks?
R: Yeah, and then…
F: Sorry, seven, yeah, so how…what was that commitment-wise, like, you know?
R: Fine for me.
R: Fine, just…
R: I’m really very tired, so I’m…I don’t work, so…
F: Right, right.
R: And I don’t work either, I can’t work.
R: I work like an hour and a half week, so it’s about as much as I can manage just now.
F: Right.
R: My work’s quite accommodating, they just…
F: Yeah.
R: …we’ll let them go, so…
F: Oh, that’s…that’s good, uh-huh, and yourself, S?
R: I thought it was quite a commitment, actually…
F: Mm-hmm, mm-hmm.
R: …but worth it, need something to look forward to.
F: Yes, yes.
R: So it kind of takes up the whole day.
R: Yeah.
R: Yeah, by the time you get your stuff...and yeah, you don’t actually want to do anything when you go home and I feel quite relaxed.
R: That’s it, yeah.
R: [inaudible 11:10] and after that I’m like…no.
F: Yes, yes.
R: Just sitting in the van. [laughs]
F: Yeah, yeah, uh-huh, uh-huh, uh-huh. Yeah. Any other comments about what it was actually like having the treatment?
R: I thought it was quite relaxing.
R: I was just about to say, I found it quite relaxing.
F: Uh-huh, uh-huh.
R: Yeah, once you...as I said, once I got over the initial few type things…
F: Uh-huh.
R: ...she’s use the oil, and I always found that better…
R: Loved the oil.
F: Yes, yeah.
R: ...that would help me relax.
F: Mm-hmm, mm-hmm.
R: ...and then she would keep talking to me, and then once she put the light and that out and everything was sort of not jumping about again, I was fine…
F: Mm-hmm, mm-hmm, mm-hmm.
R: ...I could relax after that, so yeah, it was quite good that way.
F: Mm-hmm, yes, yeah. So did everyone find that, that it was pretty relaxing?
R: I would find after a couple of...like a couple of minutes of having the electric…I wouldn’t feel it anymore, so…
F: Uh-huh.
R: ...I had to keep asking her for to keep putting it up.
F: Right.
R: And then I wouldn’t feel it again and I was like, well, I can only feel one needle…
F: Uh-huh.
R: ...I can’t feel the other one, and she was just like...just keep putting it up and then…
F: Mm-hmm, mm-hmm.
R: ...oh, I can feel it now, um…
F: Mm-hmm.
R: ...but I found it a godsend.
F: Mm-hmm.
R: It took my pain away for a day, two days after the treatment…
F: Mm-hmm, mm-hmm.
R: ...which I hadn’t had in over six years, so…
F: Yeah.
R: ...it made a big difference, I felt I had energy…
F: Uh-huh.
R: ...the following day, and I was…
F: Uh-huh, uh-huh.
R: ...kept having the back of my…don’t go and do everything that can get done because…
F: [inaudible 12:30, voices overlapping]
R: You just knocked yourself back about four weeks.
F: Yes, yeah, uh-huh.
R: So it was...it was something different.
F: Mm-hmm, mm-hmm, mm-hmm.
R: It was…
F: Yes.
R: It was a godsend.
F: Yes.
R: I think it was…
R: It was couple of days a week.
R: ...allowing you to pace yourself as well.
F: Uh-huh.

Appendix 3 Focus Groups Forms
Because you…well, for me, it was helping me, anyway, so I had more energy…
Mm-hmm.
…so I just thought I was just like Wonder Woman.
Mm-hmm, mm-hmm.
You know, first couple of times I was coming home and everything was getting done in the same
day.
Right.
Um, and then after that I was like that, no, just…just stop. [laughs]
Uh-huh, uh-huh, yes, yes.
I thought it was quite weird being pain free.
Yeah.
Like it was quite weird getting used to…
Yeah.
…having, ’cos for me, like say my appointment was at like three in the afternoon or something, I
wouldn’t have any pain, like zero pain until about half ten, 11 at night…
Mm-hmm.
…and even then it was just like…like what a normal person would find like a niggling headache.
Mm-hmm, mm-hmm.
Just…it was almost nothing, like…
Mm-hmm.
…you barely notice it and…the next day my pain would come back, but it wasn’t quite as bad,
and then the next day it was back…
It builds itself back up, eh?
Yeah, but it’s kind of…I likened it to like if you have like a 60 hour a week job and you hate your
job…
Mm.
…and you go away for a week’s holiday, that’s kind of the equivalent of it, like you’re in constant
pain…
Mm-hmm.
…and it’s quite debilitating and you’re exhausted, but then for a few hours…
Mm-hmm.
…or twice a week, you were having this lovely holiday where you were just pain free.
Yes.
I think it was just nice not to think about it.
Yeah.
Sort of constant [inaudible 13:58]
I wasn’t pain free.
No, I wasn’t.
[coughing]
Uh-huh, so there’s breaks in there.
Yeah, but and…and it was…it affected me a different way. I felt like in my head, I felt like I had
more energy, I felt more bubbly type thing…
Mm-hmm.
…although the pain was still there, I felt more relaxed going home, and more cheerful sort of
thing…
Mm-hmm, mm-hmm.
…but you know, it didn’t really take my pain away, so…
Mm-hmm, mm-hmm, mm-hmm.
It took some of mine away.
The shooting legs and the stabbing…
Right.
…but I’ve got a niggle permanently…
Yeah.
…getting stabbed in the side, and that’s never went, that’s where it all is.
Uh-huh, uh-huh, uh-huh. Yeah. And you were saying as well…
Mine’s was the same, but like you were saying with the electrodes and that, where I was getting
my needles put in, I have got no sensation…
Yeah.
…because of the surgeries that I’ve had, so I never felt the needles going in.
Oh, I did. [laughs]
Mm-hmm, mm-hmm.
I never felt anything going in, at all.
Appendix 3 Focus Groups Forms
Depending where they were for me, like some of them I didn’t feel at all, and some of them were like...

Yes, a couple I didn’t really

Well, she did start moving after maybe about two weeks, like moving the area where they were going to be...

Mm-hmm.

…just to see how it affected.

Mm-mm, mm-hmm.

I remember when she put one needle in or something, and she must have took that needle out when I wasn’t aware of it, and I suddenly jumped and I felt this pain, and I said, oh, have you touched the needle? She says, it’s not there.

Mm, mm-hmm.

And it was like after she’d taken it out...

Mm-hmm.

…but I didn’t realise that she’d done it, ‘cos I thought it was still in and she’d twanged it like she does.

Yes, yes. Uh-huh, uh-huh. Did OT give you any practical advice about…about managing your pain, and if she did, did that help at all?

Yeah, it was just…learning to pace yourself.

Mm-hmm, mm-hmm.

As she said, like I was going home and doing wonders, but not doing everything all in one go.

Mm-hmm, mm-hmm.

Pace yourself on what you can do, and just see if you can try and build it up a wee bit...

Mm-hmm, mm-hmm.

…to something else. Um…and obviously try and relax at some point.

Mm-hmm.

Was easier.

Yes.

Try and relax your body at some point.

Uh-huh.

In between.

[coughing]

Well, I try most nights, I’ll try and just relax my body before I go to bed.

Mm-hmm.

Um…’cos that’s me, I mean, I’m back to getting up through the night and everything now.

Mm-hmm.

Because all my pain’s on my right side...

Right.

So as soon as I turn onto my right side, that’s me up.

Mm-hmm.

It’s just trying to keep everything flowing.

I went to the other…I think it was part of this appointment, I can’t remember it’s how I…but I was sent up to the Astley Ainslie, and part of it was about…like it was a shrink, basically…

Mm-hmm.

…and it was all about like cause of pain can bring depression and stuff.

Mm-hmm, mm-hmm.

Um, but I’ve never been depressed, but dinnae get me wrong...

Mm-hmm.

…gets me down.

Mm

But I…I’m not disssing it at all.

Uh-huh.

But it wasn’t for me.

Yes.

Because I was…she says to me that I have to imagine my pain as like clouds on a windy day, and then...

Yes.

…then OT says to me as well, imagine it’s a colour...

Uh-huh.

…and to me, that’s just nuts...

Uh-huh, uh-huh.

…I can’t, but I get the thinking...

Yeah, yeah, yeah.
R: …I totally get the thinking, but what I do for myself, I do…if I’m busy, like you’ve probably figured out I do dog grooming. See when my mind’s not on it…
F: Uh-huh.
R: …so when my mind’s off it…
F: Yes, yes.
R: …sorry, it’s things like that I notice it the most when I’m driving, sitting still.
[inaudible 17:32, voices overlapping]
R: …or you’re trying to relax to get to your bed and you’re like…
F: Uh-huh, yes.
R: …you’re just like, no, go away.
F: Uh-huh.
R: But yeah, I don’t think that I can imagine it being clouds [laughs], somehow, or a colour.
R: Yeah, [inaudible 17:45] about that.
F: Some people are better at kind of [inaudible 17:48] than others, aren’t they?
[laughter]
R: Sorry.
R: It’s alright.
R: Oh.
F: And the pain side for yourself, S, what was that like?
R: Similar to yours. I feel almost pain free when I got up from the bed…
F: Uh-huh.
R: …but just gradually it would come back.
F: Yes.
R: I wouldn’t say it lasted a…a few days or anything.
F: Uh-huh, uh-huh.
R: Just as the day went on…
F: Right.
R: …but like you say, just even standing up and being aware that you’re not in pain is…
F: Mm-hmm.
R: …really foreign.
F: Gosh.
R: Yeah, it’s weird.
F: Yeah, yeah.
R: Yeah, see, I went to that pain management course as well, and I’d literally just come off the course just before the acupuncture started…
F: Mm-hmm
R: …and that worked really well for me because a lot of the stuff Ooi Thye was saying sort of tied in with some…some…sorry…some of the stuff that they were saying…
F: Mm-hmm.
R: …in the pain management, and I, like…I know it’s not for everybody, that pain management course, some people…I know a lot of people left, but I…it really helped me…
F: Mm-hmm.
R: …especially for things like pacing…
F: Mm-hmm.
R: …and the physio side of things as well.
F: Right.
R: So a lot of the stuff Ooi Thye was saying tied in with that…
F: Uh-huh.
R: …and sometimes she’d bring something up and I was like, oh yeah, we just did that…
F: Yeah.
R: …so that can help.
F: Mm-hmm.
R: And, um, she actually suggested a lot of like, um, emotional stuff for me, because…
F: Mm-hmm.
R: …obviously your emotions and your pain link in really…
F: Mm-hmm.
R: …like a lot, so, um, there were some days I came in and there was actually one session I just burst into tears…
F: Mm-hmm, mm-hmm.
R: …which was really embarrassing…
F: Yeah.
R: …but she was so lovely about it, but she just suggested like just starting to write a journal again.
F: Right.

Appendix 3 Focus Groups Forms
R: And that was quite cathartic…
F: Uh-huh.
R: It’s kind of like letting everything out a bit…
F: Mm-hmm.
R: …and just writing a lot and then…so that helped a lot. I used to write a journal, but I…I never keep up with it, but she was really encouraging that side of things…
F: Uh-huh, uh-huh.
R: …and that helped a lot as well.
F: Right, right, yes.
R: It was kind of like that for me, it was a lot of emotions…
F: Mm.
R: …because I’ve got four different illnesses, and…that I don’t know what pain’s what…
F: Mm-hmm, mm-hmm.
R: …so I don’t remember since the age of 11, I’ve never really been without pain, so I don’t remember what it’s like.
F: Mm.
R: So she was…she was doing the sort of same for me, you know, try to be kinder to myself, try to accept, you know, be more accepting of things and try to think of the sensations I was getting as not painful
F: Yeah.
R: Because one of them’s neuropathic pain, so…
F: Mm-hmm.
R: …immediately she was going to put the needle in, I was obviously getting tense.
F: [inaudible 20:01, voices overlapping]
R: Will it hurt…
F: Mm.
R: …you know, ‘cos it’s like someone could just poke me, and that would hurt me for hours.
F: Mm-hmm, mm-hmm.
R: It’s almost a placebo effect, but the opposite.
F: Yeah.
R: Right, right, yes.
R: So that’s why I was panicky with the needles…
F: Uh-huh, uh-huh.
R: …but she was good that way, I had to take in photos of what I was like before, you know…
F: Mm-hmm, mm-hmm.
R: …when I was younger and stuff, and she sort of helped me that way as well, yeah.
F: Right.
R: In a more emotional type way.
F: Yes. Uh-huh, uh-huh. What…in terms of actually believing that the acupuncture would help with your pain, I mean, did you have…do you have that belief or did you have that belief that it would help?
R: I was…well, I was at the stage where I would try anything. I have tried everything…
F: Uh-huh.
R: …so I thought, well, one more thing probably won’t do much damage, you know.
F: Yeah, but it was kind of not so much will this…I think this is going to work, I might as well try.
R: I went into it with an open mind…
F: Uh-huh.
R: …I didnae go in with…wi’ any illusions or anything, just…
F: Yes.
R: …went in with an open mind and thought, well, if this does anything, so be it.
F: Uh-huh, uh-huh. Right.
R: For me, it was just like a different way to attack it…
F: Mm-hmm.
R: …like so you were taking the drugs…
F: Mm-hmm, mm-hmm.
R: …you’re doing exercises for your…
F: Mm-hmm.
R: …sciatic nerve and all that…
F: Mm-hmm.
R: …but I just dinna like pain patches and don’t know if anybody else is waiting to get a pain patch…
F: Yeah.
R: …but they can burn your nerves…

Appendix 3 Focus Groups Forms
F:  Mm-hmm.
R:  …um, but yeah, I’ve got Lidocaine patches on, but…so just for me, the acupuncture, it was like let’s try and attack it somewhere else.
F:  Right, right.
R:  Sick of popping pills, if I’m dead honest.
F:  Uh-huh, uh-huh.
R:  I feel like I rattle.
R:  Yeah, yeah, yeah.
R:  Like it’s the constipation, it’s the…
F:  Uh-huh.
R:  …bowel, it’s just everything, it’s just an absolute royal pain the ass. [laughs]
F:  Mm-hmm.
[inaudible 21:36, voices overlapping]
F:  Yes.
R:  And you know, I…I don’t know about you girls, but I feel like I…because I’m back living with my mum, because I was on crutches for three years, right…
F:  Uh-huh.
R:  …so I’m like, I just feel like I moan…
F:  Mm.
R:  …and I get sick of myself moaning.
F:  Yes, yeah.
R:  Do you know what I mean? I’m hearing myself, I’m going oh god, my side, my side, oh, I’ve got shooting pains, I’m like…
F:  Mm-hmm, mm-hmm.
R:  …change the bloody record.
F:  Mm-hmm.
R:  Aye, aye, aye.
R:  Annoying yourself, yeah? I do.
F:  Yes.
R:  I try…I tried with OT because I’ve never…none of the medications have ever worked for me now…
F:  Uh-huh.
R:  …so I’ve now just weaned myself off everything. They were…they weren’t working when I was on them, so…
R:  [inaudible 22:14]
R:  …there’s no point in being on…
R:  [inaudible 22:16]
R:  …so I’m not off everything and this was just another option, because I actually met OT in an endometriosis meeting.
F:  Right.
R:  ‘Cos that’s my main illness, and then I’ve had other things come from that like fibromyalgia and stuff…
F:  Mm-hmm, mm-hmm.
R:  …but the main one’s endometriosis, that’s how I met her, it was a conference…
F:  Mm-hmm.
R:  …and, um, it was to see if pain would…if, you know, they would ease that kind of pain.
F:  Mm-hmm.
R:  How many times have you had surgery?
R:  12.
R:  Have you really? Jesus.
R:  Put you up to four.
R:  My daughter’s up to eight already, she’s only just turned 19.
R:  What…what’s happening, is yours [inaudible 22:45]
R:  Joining together, your organs and stuff?
R:  That…that did years and years ago, I mean…
R:  You had a hysterectomy?
R:  Yeah, I was 35, I’m now 51, so…
R:  And did that help the endometriosis?
R:  No, I had pain free for a year…
R:  Aye.
R:  …and then it came back with a vengeance [inaudible 23:00]
R:  It just travels, doesn’t it? [coughs]
R:  Yeah, massage and…

Appendix 3 Focus Groups Forms
R: The last time my daughter had treatment... no, sorry, the second time she had treatment, they took it away from the... the bottom of your stomach.
F: Mm, mm-mm, mm-hmm.
R: I think that’s the thing as well, like yous... selfishly, you know, I’m sure every single person in this room has got like a friend or a family member who’s had cancer...
F: Mm.
R: ...but, you know, this is like... you feel like you’re moaning, but it’s incurable, that’s the thing.
F: Yes, yes.
R: And it’s just like knowing that you... you don’t know the outcome...
F: Yes, uh-huh.
R: ...but then, that’s why I’m asking, it’s...
F: Yes, yes.
R: So like how...how I found out I had it was, um, through this [inaudible 23:31]... emotionally speaking I was like checked out completely...
F: Uh-huh, uh-huh.
R: ...I got that, so I’d went to my doctor for about, oh, two years.
F: Mm-hmm.
R: Um, no, and then I eventually got tested for endometriosis and that was it, and it was a total relief to know that I wasn’t making this up.
F: Mm, mm-hmm, mm-hmm.
R: And, um... but then to find out that... because she actually had a hysterectomy as well...
F: Mm-hmm.
R: ...and God bless her, since... she’s since died of bowel cancer...
F: Mm.
R: ...and these are all the questions that I’ve got because it keeps attaching my bowel, my bowel is getting, like, fused
R: Yeah.
R: ...and all the rest of it.
F: Uh-huh, uh-huh.
R: So it’s kind of like I know what you’re saying, a hysterectomy...
R: My bladder was up in my ribcage at one point, so...
F: Oh yes, yes.
R: ...they had to stick a catheter in for a fortnight. Sorry.
F: Uh-huh.
R: ...but it’s the reality though.
R: I mean, I’ve had completely... I don’t have anything anymore, anywhere, but I still have the pain.
R: Sorry, can I just you a wee laugh? My mum’s had loads of surgery in the last three years, like had a twisted bowel, she had three prolapses, hysterectomy, now got gallstones, so I was like that to her, like, you’re going to just walk about like that.
[laughter]
R: [inaudible 24:30] And that reminds me, it just makes it rare, for some reason, they take it all out, and you still get bigger
R: Yeah, yeah.
R: That’s all the surgery.
R: Well, [inaudible 24:37] had a hysterectomy because everything’s all stuck together.
R: My bowel, my bladder and my womb, everything’s just... aye.
R: They should really... well, I don’t know... I was all stuck together, it was like when I had my daughter, I had to have a transfusion with her because I was on the table for over three years, because they didn’t realise how badly messed I was inside, so...
R: Yeah, well...
R: ...she was fine, but I wasn’t, but, um...
R: Goodness.
R: They said that about my insides, and my insides are wrecked.
R: Jings.
R: Sort of chance, and the first thing they said...
R: Have they tried a laser on it to laser the [inaudible 25:06]
R: No. Um... because I’ve got bother with one of my kidneys as well through a surgery that went wrong, shall we say, um, that’s all affected as well...
F: Mm.
R: ...so they’ve said no.
F: Mm-hmm.
R: I suppose it depends who you see. It’s like my daughter, she... I... I don’t know how I didn’t know she had it, they said it’s not hereditary.
F: Mm-hmm.
R: But right from the age of 13 she became unwell, and she was in and out of hospital every two to three weeks, it was so stressful, and then I kept thinking that the symptoms were there…
F: Mm.
R: …but I didn’t know really what it was. She wouldn’t go to school, I’m thinking, you know, she was just lazy, didn’t want to go…
F: Mm, mm-hmm.
R: …but I… I didn’t remember what I was like, when I was her age.
F: Yes, yeah, yeah.
R: It didn’t dawn on me that was what was going on…
F: Mm-hmm, mm-hmm.
R: …and it was when I had to be referred back to Dr D. who’s my surgeon at [inaudible 25:53], he’s lovely.
F: Yeah.
R: I’d seen him in 2007 and then I ended up back with him…
F: Mm-hmm, mm-hmm.
R: …after going through everything…
R: Somebody cocked up the surgery.
R: Yeah, and he asked me about my daughter, and I told him and he looked at the records, he saw every time she was in and out, and he said, refer her to me.
F: Mm-hmm.
R: And as soon as I referred her to him, he diagnosed it, um, she was 17, and she’s 19 now.
R: My daughter was diagnosed when she was 15.
R: She’s getting another surgery again in… they have to keep taking her in every year.
F: Uh-huh.
R: Yeah, I’m about yearly as well.
F: Gosh, gosh. So can I come back again to asking you just how you feel in your day to day life?

R: Exhausted.
F: Exhausted, yeah.
R: What’s life?
R: There’s crap days and crapper days.
R: Yeah.
R: Do you know, you were talking about just get up and get on with it.
R: The last two days – and this isn’t a word of a lie…
F: Mm-hmm, mm-hmm.
R: …the last two days I’ve said to like my friend, I was like, I actually feel like I’ve turned a corner.
F: Mm-hmm.
R: I dinnae feel so knackered…
F: Mm-hmm, mm-hmm.
R: I started working for [inaudible 26:45]…
F: Mm-hmm.
R: …and it’s a physical job. Sometimes with just coming in…
F: Yes, yeah.
R: …I just feel like… felt like I’ve done ten rounds with Tyson.
F: Uh-huh.
R: But the last two days I’ve felt so…
R: That’s a different kind of… that’s a different kind of tired though.
R: Oh, I know that, but like…I know what it’s like to feel tired with this…
R: Yeah, yeah, yeah.
R: …it’s just when you’re wiped out…
R: Yeah.
R: …it’s like the thought of doing anything, you’re just like, oh no… [laughs]
F: Yes, yeah.
R: It makes you miserable, though.
[inaudible 27:06, voices overlapping]
R: I’ve cried trying to hoover…
F: Yes.
R: …you know, because I… it can take me all day to do something…
F: Yes
R: …and I don’t work, and…
F: Mm.
R: …but at the same time it’s like it all overwhelms me…
...and I’m just about in tears thinking, I’ve not done this, I’ve not done that…

Mm, mm-hmm, mm-hmm.

...oh my God, it’s ten o’clock at night, and I’ve still not done the dishes.

I find myself cancelling a lot.

Yeah.

I do it a lot, and it’s…

Mm-hmm, mm-hmm.

...that’s a bit rubbish, that’s…

Yeah, yeah.

The endometriosis is one of the…

This is the thing, it’s like…you go and do a day’s work, you dinnae want to go and do something else at night time…

Yes, yesh.

...because you’re completely…well, for me, completely wiped out.

Yeah.

I worked right up until 2009, so…and then I became medically retired, but I was one of the first people to be, for endometriosis.

Mm-hmm.

That’s just...there’s hardly anybody’s aware of what it is, half the time.

Yeah, I know.

Especially companies and stuff.

Yeah.

But I…

So in terms of quality of life, what would you say your quality of life is like?

Limited.

Limited?

Yeah.

Very limited.

Yeah, restricted.

Uh-huh.

I mean, I’m currently trying to figure out a way to work from home, because I can’t imagine myself not doing something not doing something…

Mm-hmm, mm-hmm.

...with music…

Mm-hmm, mm-hmm.

...at the very least, so like, I’ve been trying to redecorate one of my rooms, and it’s a tiny room, it’s like two point one metres by three point six metres or something, it’s tiny, and it’s taken me over a year just to paint it.

Mm, mm-hmm.

And I mean, okay, that sounds worse than it is, because I’ve actually been doing like some intricate stuff round the border, but even still, like, I have had months where I just couldn’t face going up a ladder.

Yeah, uh-huh, uh-huh.

‘Cos just the idea of standing upright is just insane, and so like I keep pushing off stuff, everything in life’s just been…

Uh-huh.

...postponed, so like…

Uh-huh.

...um, like I keep cancelling my friends, friends are dropping like flies…

Mm.

...and like postponing life, like, goals and…

Mm.

...like...and it’s just...I am a hermit at the moment…

Mm-hmm, mm-hmm.

...like I leave the house maybe once, twice a week…

Mm.

...if that, and even then it’s just to go round the corner, because I live just behind the Kirkgate in Leith…
F: Mm-hmm.
R: ...so I’m two minutes away from the shops...
F: Mm
R: ...and even then I have to build myself up...
F: Mm-hmm.
R: ...to just leave the house...
F: Yes.
R: ...just to go to one shop to buy one thing.
F: Yes, ye
R: So that’s basically it in a nutshell. [laughs]
F: So has the electroacupuncture hit...had any impact on your quality of life, and if so, what...what has it done for you?
R: Helps my shooting pains
F: Right.
R: The hot shooting pains which...that’s for me the most annoying thing.
F: Uh-huh, uh-huh.
R: It did help with that
F: Mm-hmm.
R: Me, it was worth getting a sleep.
F: Yeah, getting a sleep, uh-huh, uh-huh.
R: Yeah, me it was just the...even if it was just for the one night, just feeling...
F: Yeah.
R: ...better within myself.
F: Just a wee bit of relief.
R: Wee bit of relief, and that the pain would be there, but I would be feeling other things as well, I’d be feeling relaxed...
F: Mm-hmm, mm-hhm.
R: ...and stuff, so it kind of took it away from...
F: Yes.
R: ...for at least a night or so.
F: Yeah, yeah, and what about yourselves in terms of how it’s helped your quality of life?
R: It helps when you’re getting...when I was getting treatment.
F: Right, right.
R: For that period it was...
F: Right.
R: ...okay, it was good.
F: Uh-huh, uh-huh.
R: I feel the same, it was great at the time...
F: Yeah.
R: ...but I didn’t feel any lasting benefit.
F: Right, okay, uh-huh, uh-huh.
R: So like if...if like...if I could get it like once a week or something...
F: Mm-hmm.
R: ...I think that would...if it definitely impact my, like, my quality of life, but as I said now, it’s not...
F: Mm-hmm.
R: ...it’s...I mean, I was back in February or something...
F: Right, right.
R: I’ve been over a year since I’ve had any acupuncture.
F: Uh-huh.
R: And I’ve been waiting for this meeting because I’ve already been approved that I can get it...you know, again.
F: Right.
R: Through the pain clinic.
F: Mm-hmm, mm-hhm.
R: Yeah, I’ve just to contact Dr [inaudible 30:38]...
F: Yeah.
R: ...just give her a phone call and she passes me on to OT.
F: Mm-hmm.
[coughing]
F: So is it the same for all of you, really, then, that it’s helped for your [inaudible 30:50], but...
R: Yeah, definitely.
R: I’m kind of the...because of my knee, like I’ve had cruciate done twice...
F: Uh-huh.
R: ...and all that, right, so, OT was like, Jools, we need to get you to stop training.
F: Mm-hmm.
R: Now, since I’ve stopped training, um, ‘cos Dr D actually thinks that I did the damage when I was
like in my early teens...
F: Mm-hmm.
R: ...with just like hip flexers and all of that, um, but then... [inaudible 31:11] I’m losing the
plot... see this is another thing, meds, they just go boom...
F: Right.
R: ...forgot what I was saying.
R: Yeah, yeah.
R: Do you get that? Like...
R: I get that with some of mine.
R: Like what was I just saying? [laughs]
F: Yes, yes.
R: That’s just the fibromyalgia with me, I dinnae... I’m not on meds now, but my mind’s well away.
[laughs]
R: But... aye, the quality of life, um... like you’ve got to just get on with it.
R: Mm, that’s it.
R: That’s the thing, you’ve got to get on with it.
R: People’ll stop you in the street and go, ‘how’re you doing’ [inaudible 31:37] different day.
F: Yes, yeah, mm-hmm.
R: I try the best not to let the... the pain stop...
F: Uh-huh.
R: ...my life. I mean, I’ve got the full time job...
F: Uh-huh.
R: ...and I’ve got a two year old daughter...
F: Yes.
R: ...and that’s... that is my life.
F: Mm-hmm, mm-hmm, mm-hmm.
R: Um... but when my daughter came along, I wasn’t... I didn’t have pain when I was pregnant.
F: Mm-hmm.
R: Which was amazing though, because I don’t know what’s wrong with me, I still haven’t had a
diagnosis...
F: Uh-huh, uh-huh.
R: ... and then... but I’m adamant it’s womb-related...
F: Uh-huh.
R: ... because then why would I not be in pain when I was pregnant?
F: Yes, yes.
R: But two weeks after she came along, I was in... I was hospitalised for two weeks near enough.
F: Mm-hmm
R: Um... on morphine, because the pain... I thought I was having another kid.
F: Mm-hmm, mm-hmm, mm-hmm.
R: Jeez.
R: It was... I thought my womb was trying to escape me again.
F: Yes, yeah.
R: Um... and ever since then...
F: Mm-hmm.
R: ... the pain’s never went away again.
F: Mm-hmm.
R: But you know, finding you come home from your work and your daughter just wants your
attention...
F: Yes.
R: ... and...
R: It takes your mind to it, yeah.
R: See... see just trying even... get a conversation in, sometimes you can do it, sometimes you
can’t...
F: Uh-huh.
R: ... and I find myself lying on the couch, ‘cos I can’t lift myself up...
F: Yeah.
R: ... because I’m knackered from working.
F: Mm-hmm, mm-hmm.
R: But you just... just want to be there for the wean...
F: Mm-hmm.
R: …but when you got the acupuncture…
F: Yes.
R: …you were going home, it was…it was so different…
F: Yes.
R: …it was…go home for three, four hours before she went to be, and…and had a conversation with her…
F: Yes.
R: …I painted with her…
F: Uh-huh.
R: …I did things with her that I hadn’t done before.
F: Yes.
R: I couldn’t think…
F: Uh-huh.
R: …time for that at all, it was…
R: It did give you a wee bit of a [inaudible 33:06] of energy, and make you feel more normal.
R: Yeah.
R: It just…
R: Yeah, yeah.
R: Because I mean, I…sometimes I don’t even want to talk to people…
F: Mm-hmm.
R: …and like my…I’ll sit on the bus and all I can hear’s my mum talking away to me, and I’m thinking…and nothing comes out of my mouth.
R: Nothing’s going in, is it? [laughs]
R: Because I just…I just don’t even have the energy to want to speak.
F: Mm-hmm.
R: You know, so it’s like she’s constantly…like my daughter as well, just keep talking and talking and talking at times…
F: Mm-hmm.
R: …and I just don’t want to speak to anybody [laughs]…
F: Mm-hmm, mm-hmm.
R: …so I suppose it’s…it’s one of the ways that like affects your life, you just can’t be bothered.
F: Yes.
R: One…one thing that, um, OT suggested, and I haven’t started is, is yoga.
F: Mm-hmm.
R: But I’ve remembered what I was saying is, the…like the quality of life…
F: Uh-huh.
R: …like stopping doing my training, very similarly the stretches that you do for your sciatic nerve…
F: Uh-huh.
R: …and that’s…I do a lot of it in training, I’ve actually found that I’ve…it’s been worse, because I’ve had a hamstring transplant, it’s ’cos it’s all connected…
F: Mm-hmm.
R: …it’s…I have to train to maintain this and keep this strong.
F: Mm-hmm.
R: And then it’s…if not, it’s the tendon overwrite…
F: Mm-hmm, mm-hmm.
R: …it’s just all…
F: Mm-hmm, mm-hmm, mm-hmm.
R: …so see getting the acupuncture and then going and getting a massage, perfect…
F: Mm-hmm, mm-hmm.
R: …absolutely perfect, and like you’re saying, even just a [inaudible 34:13]…
R: Yeah.
R: …to feel like I’m getting…
R: Yeah.
R: Go and walk my dog, you know, and just like something.
F: Yes, yes.
R: Go and see my friend, go for dinner…
F: Uh-huh, uh-huh.
R: …go to the cinema mid-week, when would that ever happen?
F: Yes.
R: You know, ’cos like…
R: I just do it but…
R: Meds…meds at eight o’clock…
F: Uh-huh, uh-huh.
R: And that’s you done for the day.
F: Yes.
R: And if I don’t do them then, I cannot get up.
F: Yes.
R: I used to have arguments when my daughter was younger, it was quite stressful, because she
would wonder why I was just too tired to do anythin
F: Uh-huh, uh-huh.
R: You know, even uptown…
F: Mm.
R: …I say, look, I can’t…can’t go any further, Emily…
F: Mm-hmm, mm-hmm.
R: …you know, she wants to go in the shop, in every single shop that’s there.
F: Mm-hmm, mm-hmm.
R: Um, and spend hours and hours in…but now she realises.
[inaudible 34:48, voice overlapping]
R: Because she’s got the same thing, so…
F: Yes, yeah.
R: …but it’s taken all these years.
R: And I also think as well, like when, um, you know, like before I’ve worked in loads of clubs and
stuff, and it’s like…they don’t like…say if it’s like a guy, they’ll be like endometriosis, what’s
that? Women’s troubles, and it’s like, oh, I don’t want to hear.
F: Mm.
R: But you actually try and live with pain…
F: Mm.
R: …every single day.
F: Mm-hmm.
R: Now, it depends on the scale of it, but…
F: Mm-hmm.
R: …for me right now, it’s sitting at about a five to six…
F: Yes.
R: …just sitting stabbing.
R: Yeah, yeah, but it’s no’ that, because of the way your endometriosis [inaudible 35:17], because
my pain’s here…
F: Uh-huh.
R: …that’s like the core of your body…
F: Yes.
R: …so practically every movement you make, you know yourself, working in a bar, you’re standing
up, you’re…
F: Yes, yes.
R: I mean, I have to pack in a bar job that I…and I loved my bar job…
F: Uh-huh.
R: …’cos I had two jobs. I had my own job and a bar job…
F: Mm-hmm, mm-hmm.
R: …and I had to pack in my bar job first, and that broke my heart.
F: Mm-hmm, mm-hmm.
R: Because I loved it, absolutely loved it.
F: Mm-hmm, mm-hmm.
R: That’s…
R: And then I had to stop…
F: Yes.
R: …because I was getting to the stage where…like you would be talking to somebody. I worked in
a nursery…
F: Uh-huh.
R: …and I’d look at a kid and go…poof, what was I thinking? What’s your name?
F: Uh-huh.
R: Completely gone.
F: Yes, yeah.
R: On the meds you were just like…I mean, sometimes I just stagger about the place…
F: Mm.
R: …and people go like that, on the drink again, C. Aye, nae bother.

Appendix 3 Focus Groups Forms
F: Mm-hmm, mm-hmm.
R: Twat, not had a drink for five year.
F: Mm-hmm, yes.
R: I remember being up on stage singing and trying to introduce the band and forgetting their names, and I’d playing with them for years.
F: Yes, yes.
R: This is awful. I was in the middle...
R: It’s still good to know [inaudible 36:21]
[inaudible 36:22, voices overlapping]
R: Do you like just forget things?
R: Yeah.
R: Yeah, yeah.
R: I think it’s just the pain, I think it just...
[inaudible 36:30, voices overlapping]
R: Because it’s there all the time, it overrides everything.
F: Yeah, and if you’ve lived with it for such a long time...
F: Yes.
R: …even the meds, and they don’t work, it just takes over.
R: The other thing…the…no saliva either. Like you’re talking…
R: Yeah you’re dry.
R: You’re like, no…
R: Want a sip of water, aye.
R: Honest to God, I need to go home and take my meds. [laughs]
F: What a shame, yes. Look, if you’re…if you’re really uncomfortable…
R: I am having to cope…
F: Yeah, yeah.
R: I am…I am due for them….meant to be home ages ago. [laughs]
F: No, absolutely.
R: What is the time?
F: It’s, um…
R: Twenty to seven.
F: Twenty…twenty to seven.
R: Another five minutes.
F: Yeah, well just if you need to go, that’s fine, yes.
R: ‘Cos I think like, I’ve just had an MRI just the other week…
F: Uh-huh, uh-huh.
R: …and Dr D’s maybe thinking it’s going and spreading further…
F: Yes, yeah.
R: …and I think since I’ve seen OT it’s definitely on my sciatic nerve.
F: Uh-huh, uh-huh.
R: This is why I’m thinking, just go back and do exercise…
F: Yes.
R: …because…
F: Mm-hmm.
R: …that…because that’s a new thing.
F: Mm-hmm, mm-hmm.
R: Since I’ve stopped doing the exercise or…
F: Mm-hmm, mm-hmm.
R: …the physio, let’s say, that is…the pain is definitely…
F: Mm.
R: …oh, without a shadow of a doubt…
F: Mm-hmm.
R: …really bouncing at my kneecap and all of that, eh
F: Yes, yes, yeah.
R: It can’t help having the endometriosis as well ‘cos that…
R: Well, the two are right in against…
F: Yes, yeah, uh-huh.
R: Because it’s nerves, innit? Hey ho. And this is the thing, ‘cos it’s not physical, like people would see you on the crutches and think…
F: Uh-huh, uh-huh.
R: Yeah.
R: …they’d be like, take a seat, but if you’re there sheet white and you’re like…

Appendix 3 Focus Groups Forms
F: Yes, yeah.
R: ...well, what’s wrong with you now?
F: [inaudible 37:45, voice overlapping]
R: You’re letting the side down again.
F: Yes, yes.
R: You know, especially if you’re working with a team.
F: Uh-huh, uh-huh.
R: Well, I’ve just been classed as disabled now, and I’ve been fighting since 2009…
F: Mm.
R: ...but I’ve now been…and I’ve now got the…you know, the free bus pass, but I still feel…I feel that everybody’s looking at me when…
F: Mm.
R: …I’m putting my disabled bus pass on it, and…and I think the bus driver’s maybe thinking…what’s wrong with her, do you know what I mean…
F: Mm-hmm.
R: …there’s nothing there, you know…
F: Mm-hmm.
R: Yeah.
F: Mm.
R: …you’re not walking with sticks…
F: Mm-hmm, mm-hmm.
R: …you’re not in a wheelchair, sort of thing.
F: Yes.
R: I sometimes use a stick, though, and like I’ve got a wee…
R: Oh aye, aye.
R: …got a wee like foldy uppy one, and see sometimes I do find like I’m stuck in the middle of a supermarket and think, oh my God, I can’t walk any further.
F: Yeah.
R: And it just helps, because my pain’s on the left, and I just have it on my right like sort of…
F: Yeah.
R: …like…
R: To compensate. [inaudible 38:30, voices overlapping]
R: And then if you’re on the bus with a stick…
F: Mm-hmm.
R: …then people’s attitudes change.
F: Mm.
R: I was…I was walking in town…
F: Mm-hmm.
R: …and people…you like it relaxes… [inaudible 38:41, voices overlapping]
R: Subconsciously as well, like your…my pain’s [coughing] on the left side, but because it’s all in my left side…
F: Yes.
R: …I stand, like all my weight is on the right.
F: Yeah, I do, yeah.
R: So then you go home and you’re like, oh, wait a minute, your back’s all sore…
F: Uh-huh, uh-huh.
R: …and it’s just…just having to be aware of it.
F: Yes.
R: And what…and what I was going to say, OT, she did suggest yoga, and I haven’t had time, I really haven’t…
F: Uh-huh, uh-huh, uh-huh.
R: …um, but I’d be quite keen to try that.
F: Yeah, yeah.
R: [inaudible 39:06] yoga, actually, when she…she suggested it, and I just haven’t got round to doing it yet. [laughs]
F: Mm, mm.
R: I keep forgetting.
F: Yes, yes.
R: I was told years ago to do that in Pilates and I just…it’s like the years, I have no concept of time anymore.
F: Mm.

Appendix 3 Focus Groups Forms
R: Just days and…and months and that just fly right past me.
F: Uh-huh, uh-huh.
R: Before I know, it’s been about two years since someone mentioned anything like that to me.
F: Yes, yeah.
R: So I’ve not done it either.
F: Mm-hmm, mm-hmm. And the sex side of things, did the acupuncture help…
R: Single.
F: What’s that? [laughter]
R: Did the acupuncture help with that at all?
F: Not for me, no.
R: I would say it did for me.
F: Uh-huh, uh-huh, uh-huh.
R: I…I have really bad pain with it…
F: Right, right.
R: …sometimes. Um…it…getting my Mirena taken out helped, actually, but, um, other than, no, it didn’t help.
F: Uh-huh, uh-huh.
R: I don’t bother, I…I…
F: Yeah.
R: You know, because with the endometriosis being so bad…
F: Mm-hmm.
R: …I’ve never…
F: Mm-hmm.
R: …wanted a sex life…
F: Mm-hmm.
R: …so, um, that’s caused a lot of problems for me in relationships…
F: Right.
R: …so now it’s a case of I just live on my own…
F: Uh-huh.
R: …and don’t…don’t bother, so…
F: Yeah. Mm-hmm, mm-hmm.
R: I mean, I don’t…I just can’t be bothered.
F: Yeah.
[laughter]
R: Or if for two minutes, no, you’re alright, pal.
[laughter]
R: Just you go to the bathroom.
F: Yeah.
R: I’m just thankful ‘cos I got married the two days after…
F: Yes.
R: …my session ended with the acupuncture.
F: Oh right, right.
R: That was good timing then.
[laughter]
R: I managed to get through most of the day…
F: Yeah.
R: …not going above three or four out of ten…
F: Right, right.
R: …which was just [inaudible 40:31]
R: But that just feels normal.
[inaudible 40:34, voices overlapping]
R: Three, four’s a good day.
F: Yeah, yeah.
R: Peak up to about eight nine, that’s…
F: Uh-huh, uh-huh.
R: …it’s just…cannae even think straight. [laughs]
F: Uh-huh, uh-huh, uh-huh.
R: See now, I’m just sitting here, just…it’s…
F: Mm.
R: …it’s stabbing and…
R: Yes, yeah. Jeez.
F: Yeah, and I guess that must have an impact on your mood as well.
R: Especially if I’m hungry.
R: Yeah.
laughter
R: I know.
F: Yes, yeah.
R: Can be cranky, yeah.
F: Yes, yes, uh-huh.
R: Um, and then there’s only been recently, I’ve been suffering like from the fatigue…
F: Uh-huh.
R: ...so I was studying, like I was doing six day weeks last year for ten months, I just didn’t have time.
F: Mm-hmm.
R: Like literally didn’t have time to even think, and, um, it wasn’t ‘til I started slowing down I was like wait a minute…
F: Mm-hmm.
R: …I’m knackered.
F: Mm, mm-hmm.
R: And it’s…yes, so like working for myself, I’m a slow starter, so…
F: Yes, yeah.
R: …I’ve got so, so busy recently, and that’s what I’m saying, I actually feel like I’ve turned a bit of a corner that I’m not so tired.
F: Uh-huh.
R: Like completely wiped out.
F: It’s a distraction as well, though…
R: Well, yeah.
F: …not thinking about your pain because you’re doing something else.
R: Yeah, yeah.
R: But pets tend to relax you.
R: Yeah.
R: Kind of…you know, anyway, because we’re…
R: Yeah.
R: …my daughter decided last year she wanted a dog.
F: Uh-huh.
R: He’s my dog.
[inaudible 41:46, voices overlapping]

R: He’s with me all the time [coughing] and if I have to get a…got a wee Jack Russell…
F: Uh-huh.
R: I says to her, don’t get a big dog, I can’t take a big dog out.
F: Mm, mm-hmm, mm-hmm.
R: I find he’s certainly…
R: Gets you up.
R: He…he, um…
R: Gets you up and moving.
R: …senses…senses when I’m sore…
F: Mm-hmm, mm-hmm.
R: …because he literally comes and lies across my knees…
F: Mm-hmm.
R: …so I can’t get up.
R: They’re no’ daft.
F: Yes.
R: So that I cannot get up.
F: Uh-huh.
R: And he’ll just lie there, and if I try to move him, he digs his claws in.
F: Uh-huh, uh-huh.
R: So I can’t move, and he’ll stay there for maybe about half an hour, um…think, oh well, that’s you, you’ve had enough time, you can get up now.
F: Uh-huh, uh-huh.
R: Yeah.
R: Mine’s is a Rhodesian ridgeback, it’s a big dog.
R: Oh, is he good?
R: He’s actually my ex-partner’s, but I’ve had him since he was two months…
F: Uh-huh, uh-huh.
R: …so even though we’re split up now for the last three years, I have him during the week and he has him at weekends and…
F: Mm-hmm, mm-hmm.
R: …it’s not even so much the walking…
R: [inaudible 42:36]
R: …what did you say?
R: Poop bags. [laughs]
F: Yes, yeah.
R: It’s not even so much the walking, um, I mean, he’s okay with me walking now, but it’s…it’s more a case of he just does this silly face at times…
F: Right.
R: …and he just makes me laugh.
R: Yeah, oh aye, they just enhance your life.
R: Exactly, so if I didn’t have him…
F: Mm-hmm, mm-hmm.
R: …I think I’d be worse, because…
R: That’s what I’m saying…
R: Yeah, yeah, but being on your own though, I don’t know if your daughter lives with you, but…
R: She does, but it doesnae matter, she lives in her room.
[inaudible 43:00, voices overlapping]
R: Mine’s the same, yes.
R: That’s the thing, it…it’ll get you up, it’ll get you out.
R: Yeah.
R: If I didn’t have him, I think it would be worse…
F: Yes, uh-huh, uh-huh.
R: …because that’s what…
R: More so in the house.
R: …have to kind of get up in the mornings.
R: Everybody get a dog.
[laughter]
R: I’m living with three cats now.
R: Sorry, I’ve got four cats, a lizard and two fish and a dog.
R: I’m actually going to have to go to the toilet.
F: Right, I thought…there’s one just outside on the right hand…if you just turn right when you out the door…
R: Yeah. It might take me a while.
F: I’ll not keep you long, I mean, we’re almost…we’re almost through now, um, so we’ve covered…well, we’ve spoken about sleep, for some of you, your sleep has improved. Has that been, um, the quality of your sleep or how long you’re aiming to sleep for or long…
R: Longer.
R: It’s the long…it’s the length of time I was sleeping, because I was sleeping, I wasn’t kind of…I don’t move as much…
F: Mm, mm-hmm.
R: …[inaudible 43:54] I dinnae move as much through the night, but as soon as I go onto my right side, depending on how bad my pain is…
F: Mm-hmm.
R: …that’s me, I’m up…
F: Mm.
R: …regardless of whether I’ve slept for an hour or…
F: Mm-hmm, mm-hmm.
R: …four hours.
R: In terms of like the…Amitriptyline, that kept…that helped me stay sleeping.
F: Mm.
R: See I’ve got…the Duloxetine…
F: Mm.
R: …the [inaudible 44:12] and every other tablet…
F: Mm-hmm, mm-hmm.
R: I had Pregabalin in that as well, but I’ve had to come off of that.
R: I’ve come off of that.
F: Yes, yeah, yeah.
R: That’s just knocked me nuts.
F: Uh-huh, uh-huh.
R: Have you ever tried using a body pillow, ‘cos that really helped me…
R: Yes.
R: …like a lot, um, just having something between my legs helps…

Appendix 3 Focus Groups Forms

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R: Yeah, yeah.
F: Uh-huh, uh-huh.
R: …to like…it was like…stop the pain [inaudible 44:32]
F: Yes. Uh-huh, uh-huh.
R: I find that actually…’cos I was saying that obviously…like I did find that it was much easier to get up in the morning.
F: Mm-hmm.
R: ‘Cos that’s my problem, is waking up, I think.
F: Mm-hmm, mm-hmm.
R: I can…I can sleep…I can fall asleep anywhere and my boyfriend jokes about me like…we were on a plane together once, and he was like, I bet you’ll fall asleep before we take off…
F: Mm-hmm, mm-hmm.
R: …like hahaha, and then he went to turn round to me and we hadn’t even started moving, and I’d fallen asleep…
F: Yes, yeah.
R: …so I can fall asleep anywhere.
F: Uh-huh, uh-huh. Yes.
R: And like…but waking up, I find really hard to do.
F: Mm-hmm, mm-hmm.
R: Like it’s…it’s like swimming through sludge.
R: Do you take drugs at night?
R: Um…not too late, no, usually like leave off, like I’ll take them maybe ten or 11. It depends on how bad my pain is.
F: Mm, mm.
R: See I started taking them earlier…
F: Mm.
R: …and I just feel the difference in the morning, massively…
F: Mm-hmm.
R: …um, because I’m just like naturally waking up, maybe…
F: Uh-huh.
R: …about a couple of hours to go for my alarm.
F: Right.
R: And then that two hours I’m like, oh, I feel refreshed…
F: Uh-huh.
R: …but if I take them late…
F: Mm.
R: …half ten, 11…
R: Cannae get up.
R: …[inaudible 45:31]
F: Mm-hmm, mm.
R: That…that means quite early, ’cos my boyfriend works in a pub, so…
[inaudible 45:36, voices overlapping]
R: So I’m usually in bed at like two in the morning.
F: Yeah, uh-huh, uh-huh. Um…in terms of worrying about your future health, has the…having the acupuncture helped at all with that? Do you feel that you’re less prone to worry about, you know…
R: If I could get it again, I would be less worried.
F: Uh-huh, uh-huh.
R: But actually having it, not so much, but yeah, I mean, if I had like…if I was able to get referred by the NHS to get it again…
F: Mm-hmm, mm-hmm.
R: …I would be much less worried about everything, really.
F: Yes, yes, uh-huh.
R: I’m worried about the future, but it’s because of what I do.
F: Uh-huh.
R: If I’m to go and get a like hysterectomy or whatever, further down the line…
F: Mm-hmm.
R: …it’s like, oh well.
F: Mm-hmm, mm-hmm.
R: You know, that’s the bit that’s scary, maybe.
F: Mm-hmm, mm-hmm.
R: Need to call in hands on deck. [laughs]
R: But yeah, um, and just knowing that there’s no cure.
F: Uh-huh.
R: That’s the most annoying thing.
F: Mm-hmm.
R: That’s just ‘cos it’s one of these things.
F: And I know everybody’s different.
R: Mm-hmm, mm-hmm.
F: Like you know there was a girl whose dog I groomed, she’s like, oh, I was diagnosed when I was 22…
R: …and she’s only had one surgery, only had one surgery, like no bother since, nothing.
F: Mm-hmm, mm-hmm.
R: Absolutely nothing, and then when I get told it’s stage one, I’m like stage one? And Dr D’s like, no, no, it’s just where it in your tissue…
F: Yes.
R: …I was like, oh right…
F: Yes.
R: …sometimes I’m a total wuss.
F: Uh-huh, uh-huh.
R: Stage one. [laughs] Like what’s stage two going to be like?
R: It only goes up to four, so you’re alright.
F: You could be stage…you could be stage four and have no pain.
R: Yeah, well that…
R: Yeah, exactly, aye, that’s right, yeah.
F: So what about the others in terms of worrying about the future, your future health?
R: Actually helped not worrying having it.
F: Uh-huh.
R: Basically not having it just feel as bad as I did before…
F: Mm-hmm.
R: …but it was quite good to have…to see how much improvement I felt from having something that was quite natural…
F: Good, right.
R: …as opposed to all the medication.
F: Uh-huh, uh-huh, uh-huh.
R: And I did try the yoga. I never thought I could do that, I’d go to…it’s almost like disabled yoga, but…
F: Really?
R: …I still feel good for doing it, and doing something, it feels like really positive.
F: Yeah.
R: Where do you go for that?
R: I do it at Meadowlark, um, in the Meadows.
R: Oh right, okay.
R: Mm-hmm.
R: So was it…was it just yoga, it’s that what it was called?
R: Yeah, it’s called gentle yoga.
R: Gentle yoga, okay.
R: See I just keep thinking that I can’t relax enough…
F: Mm-hmm.
R: …to actually do something like that, you know, it’s like…
R: I think you get better at it, like I find that you can switch off.
R: Yeah, but I’m always agitated and my mind’s always elsewhere…
F: Mm, mm-hmm.
R: …and I just can’t…
F: Try.
R: …imagine myself being relaxed enough to actually do it.
F: Mm-hmm, mm-hmm, mm-hmm.
R: That’s why I’ve never really tried it.
F: Mm.
R: I just don’t worry about anything.
F: Right.
R: I dinnae…
R: I’m a worrier constantly.
R: [coughs] Like see, I…I don’t…I don’t worry about things, I don’t, um…I’ve seen myself taking like wee dips…
F: Mm-hmm.
R: …you know, like my lass’ll say to me, I think you’re depressed, and I’m like that, eh no, here’s a mental kick up the arse to yourself, C, just get back on it.
F: Mm-hmm, mm-hmm.
R: You know, um…and then she was diagnosed with the endometriosis and then a couple of years ago, she’s got a personality disorder as well…
F: Mm-hmm.
R: …so I thought, well, I need to be there for you…
F: Uh-huh.
R: …rather than you being there for me.
F: Yes, yes.
R: …you know, so I just dinnae let things…
F: Get to you.
R: Yeah.
F: Uh-huh, uh-huh.
R: I think when you’ve got someone else to look after as well, like my daughter being diagnosed now…
F: Mm-hmm, mm-hmm.
R: …it’s good that we’re both under the same consultant, it’s great, but it’s like I’ve not been…although I…I’ve just coped with at home…I mean, I’ve had really severe bad attacks…
F: Mm-hmm, mm-hmm.
R: …and vomiting and everything. I…I don’t go to the hospital now because I have to be there for her
F: Mm.
R: …and then I’ve got the dog as well, so…
F: Yeah, yeah.
R: …it’s been nearly three years now and I haven’t been to the hospital…
F: Mm-hmm.
R: …which is unusual.
F: Mm-hmm.
R: Sometimes I’m there eight times a year.
F: Mm-hmm.
R: But since I’ve had Emily, and she’s got…she’s the one that’s in and out of hospital now.
F: Mm-hmm, mm-hmm.
R: So…yes, yeah.
F: Well, I think we’ll…
R: I find this helps sometimes.
[laughter]
F: Yeah, yeah, uh-huh, just sitting like that.
R: I think it’s where I sit at my work practically the whole day.
F: Yes, yeah.
R: Well, when my endometriosis…[inaudible 49:38] endometriosis came back it came back in my back.
R: Oh, excellent.
R: It came back with a vengeance in my back.
R: It just gets better. [laughs]
R: So, it’s because when you have surgery it can sneak into your spine then.
R: Yeah, yeah.
R: That’s how it came back.
R: My daughter’s…
R: We might be fine. [laughs]
R: Well, it’s doing my head in.
R: This is it, she’s got…she’s got to get into the roots of everything, right.
F: Mm-hmm.
R: So she’s like…I’m coming down these stairs, she’s like that…see that endometriosis? I went, aye. Do you ken it can travel to your brain? I was like that, L, settle yourself, doll, you’ve just been diagnosed. [laughs] Do you know what I mean?
F: Yes, yeah.
R: Well, what if it goes to my brain? I says, well, I’ll just have to push you about the streets in your wheelchair.
F: Uh-huh, yes.
R: They do say that, right enough, but I don’t know if that’s part of the reason that you go a bit…like your mind goes, I don’t know.
R: Yeah.
R: I think it’s in like one per cent of the case…
R: It’s very rare.
R: Yeah.
R: Very rare.
R: Very rare.
R: But I was…I was like…well, I worked all my life up until I was 45…
R: Aye.
R: …and whatnot, then [inaudible 50:40] 2009, and my mind started to go really badly just before then, so I…but then they said it’s kind of the endometriosis, but then they also said it’s because I now have fibromyalgia.
R: Yeah.
R: And you get brain fog, so…
F: Mm-hmm.
R: …I was doing things I wasn’t aware of for like six weeks in a row at work and I had no choice, I either got sacked or I got medically retired…
F: Mm, right.
R: …because I was working in a bank, so…
R: Right.
R: …transferring millions of pounds to…[inaudible 51:01]
[laughter]
[inaudible 51:05, voices overlapping]
R: But I don’t know, it was a bit of both for me…
R: Yeah.
R: …’cos I’d had fibromyalgia as well which I got from the endometriosis, it’s like my other illnesses have come from that…
R: Yeah.
R: …that was the main one…
F: Mm-hmm, mm-hmm, mm-hmm.
R: …and then all of a sudden I now have four.
R: What else have you got? [inaudible 51:25]
R: IBS, neuropathic pain and fibromyalgia.
R: And IBS is awfully similar symptoms, eh?
R: It’s…yeah. You get that kind of automatically…
F: Mm-hmm.
R: …with the endo, so…
F: Mm-hmm, mm-hmm.
R: Aye, sometimes all of a sudden I’m just like…like I…like jean…I can’t even pull my jeans up sometimes
F: Yes, yeah.
R: Like my God, where does this come from?
R: It’ll be there for a while, sorry.
[laughter]
R: Then when you get to a certain age, you just willnae go.
R: It’s partly called endo belly.
R: [inaudible 51:49] endo belly. [laughs]
R: Well, I’ve…this endo belly’s doing my head in, like I…
F: Yes, yeah.
R: …it took me ten years to actually get rid of some weight after having my daughter, ‘cos they’ll say are you still pregnant.
R: Oh really?
R: Did it…did it help once you had stretched out with your pregnancy? They say that [inaudible 52:02].
R: [inaudible 52:02] asking me, I dinnae even remember five minutes, how am I going to remember 19 years ago, sorry. [laughs]
R: I remember that.
F: Well, look, it’s been really helpful. Can I maybe just finish off by asking each of you just to try and sum up what difference it’s made to you having the treatment?
R: I think it just…
R: I was a lot more happier.
R: Yeah, bit more positive.
R: Yeah
R: Better outlook on life, knowing that there’s…I think for me, it was more knowing that there’s
something there that’s not medicated
F: Uh-huh.
R: That you know it’s just…it’s just a needle…
F: Mm-hmm, mm-hmm.
R: …and it’s not putting anything into my body, I’m not…
F: Yes.
R: …having to take loads of drugs. I think it was just something…knowing there’s something out
there that you can take or do…
F: Uh-huh, uh-huh.
R: …that can…gives you a couple of hours a day…
F: Yeah.
R: …twice a week…
F: Mm-hmm.
R: …then it’s something that I’d grasp onto than have nothing…
F: Mm-hmm.
R: …and be in pain forever, so…
F: Yeah, yeah. L, what would you say?
R: Yeah, I…I was a lot more positive and a lot more pain free, and it was just…it was a lot easier to
get through the week knowing that even if it was just a few hours of less pain…
F: Uh-huh.
R: …it was just so much easier to cope with everything.
F: Mm, mm-hmm.
R: And I think, like I had quite a big crash, pain wise and depression wise, like not…it wasn’t like
soon afterwards…
F: Mm-hmm.
R: …but it was like…and so I’ve…I had mine in February, so about May, June, I had a bad sort of
crash for maybe a couple of months…
F: Mm-hmm.
R: …and at that point, like the pain was so bad I couldn’t even do…sweeping in the hallwa
F: Mm-hmm.
R: …like or change a cat litter tray…
F: Mm-hmm.
R: My boyfriend was total…working full time and…
F: Yeah.
R: …he was doing everything in the house…
F: Mm-hmm.
R: …and he nearly left me because of it all.
F: Mm-hmm.
R: And I kind of feel like…like I don’t know if that would have been quite as bad if I’d have had
something like…I don’t know what I mean?
F: Mm-hmm, mm-hmm.
R: And I didn’t crash because I wasn’t getting it, but I…I think if I had been still getting it, maybe
that wouldn’t have happened so much.
F: Mm-hmm, mm-hmm.
R: Um…it just…it…during the time of getting it, everything was just…well, much better, basically.
F: Yes, good, good.
R: Yeah, I feel the same. I felt much more able to cope when I was having it…
F: Uh-huh.
R: …just looking at my emotional wellbeing and…
F: Mm-hmm.
R: …stuff that I never considered. I’m so focused on trying to deal with the pain all the time…
F: Right.
R: …I always put everything else to the side.
F: Uh-huh, uh-huh.
R: Being able to sleep and things like that…
F: Yes.
R: …were massively helpful to me.
F: Uh-huh, uh-huh, good, good.
R: And like you, I felt a bit fed up after…
F: Mm, mm-hmm, mm-hmm.
R: …I had it, ‘cos it had been a month of really, really positive…
F: Yes, yeah.
R: …great, and back to just feeling as bad.
F: Uh-huh, yeah, yeah. Mm-hmm. S, what would you…how would you sum it up?
R: Me, I’m C.
F: Oh, C, sorry, C.
R: We’re the medicated ones. [laughs]
F: Yeah, well, it’s age with me.
R: It’s…yeah, I found it…because I could get a sleep, I was much better…
F: Uh-huh.
R: …‘cos I could sleep all night.
F: Yeah.
R: Or most of the night…
F: Mm-hmm, mm-hmm, mm-hmm.
R: …getting that solid few hours’ sleep…
F: Mm-hmm, mm-hmm.
R: …really helped me immensely.
F: Good, good.
R: And then like a bit more, um, energy.
F: Uh-huh. And J?
R: Um, yeah, for me, the exact same.
F: Mm.
R: Didn’t completely get me pain free, but it did help.
F: Mm-hmm.
R: Um, and like yourself, I sleep like a log anyway, so…
F: Mm-hmm, mm-hmm.
R: …like I certainly felt more relaxed, and it’s just another angle.
F: Yes, good, good. Tracey, have you got any final…
R: Um, well, just basically the same. It’s more my wellbeing OT helped…
F: Mm-hmm, mm-hmm.
R: …because…
R: And she’s lovely.
R: …it helped take the pain.
R: Oh, she is.
F: She is, she’s lovely.
R: Yeah, she is lovely, she…she was…yeah, she’s kind of made me try and be better…nicer to myself…
F: Mm-hmm.
R: …sometimes, and more accepting and…
F: Mm.
R: ….because I feel it’s too late for me now ‘cos nothing’s really worked…
F: Mm-hmm, mm-hmm.
R: …so it’s more emotional…
F: Right.
R: ….with me now, and that’s how she was trying to help me.
F: Uh-huh.
R: And so I would have no problem going back to her, because even for that few hours afterwards…
F: Mm-hmm.
R: …I still felt better within myself, so…
F: Mm-hmm, mm-hmm.
R: …yeah, I’d still carry on with it.
F: Good, good. Well, many thanks for coming and talking to me, it’s been a pleasure meeting you and just hearing about your, you know, your stories, so many thanks again, and do…
R: Thanks for listening.
F: …help yourself to, um, any food, just take it…take some away with you.
R: Yeah.
R: [inaudible 56:09]
R: Can I say something to you guys before we’re away?
R: Yeah.
R: Um…I don’t know if you guys know about it, there’s an endometriosis support group in Edinburgh.
R: Yeah. I just found out about it, um, before I seen OT, ‘cos that was the first…
R: The last one was supposed to be September, but they had to cancel, but I think the next one will probably be December-ish, but I think if you go into the endometriosis UK website, there’s a link there. Either that or on Facebook, I think it’s Endometriosis Edinburgh, and there’s an Endometriosis Scotland. If you go to that and then speak to, um, there’s…if you just post and ask about it, then somebody’ll…

R: There’s two women…I can’t remember…

R: LH and SH and it’s amazing, it’s…like it’s really helpful, so just if anyone’s interested in…

R: Yeah, that’s how I…I found out about OT, because she was…

R: Yeah [inaudible 56:54]

R: …were you at that conference as well?

R: Um, no, but the…the girls have spoken about it…

R: Right, yeah, yeah.

R: …in the…in the support group, so…

R: Well, I actually wasn’t going to go to the conference, I wasn’t going to go there, I was going to go for my daughter, but she just got out of hospital the night before and she wasn’t able to go, and I thought, well, I’ll just go along, and that’s how I met OT when I was there. L…

End of transcript
POSTER PRESENTATION

14th World Congress of the European Association for Palliative Care (EAPC)
8-10 May 2015, Copenhagen, Denmark

Title
Acupuncture For Pain Management

Background
Patients with cancer seek complementary and alternative medicine, including acupuncture. We hypothesize that the meridian balance method (BM) electro-acupuncture (EA) alleviates pain, improves physical and emotional functioning in women with chronic pelvic pain (CPP). A review of the literature was undertaken to inform a clinical study.

Methods & Results
Comprehensive literature searches on EA and pain yielded studies that demonstrated that endogenous opioid peptides in the central nervous system mediate its analgesic effect. Several large-scale studies and an individual patient meta-analysis on certain painful conditions have shown that verum acupuncture is only slightly more effective than sham acupuncture; both were more superior to standard care controls. Such studies and those before 2008 typically focused on the needling effects and ignored the context effects. It is now acknowledged that acupuncture is a complex intervention, which consists of a Traditional Chinese Medicine (TCM) Health Consultation plus acupuncture needling (acupuncture treatment). Clinical evidence supports the importance of context in health outcomes for example, Kaptchuk demonstrated that a supportive patient-practitioner relationship provided symptoms relief and enhanced quality of life in patients with irritable bowel syndrome. Taken together, these studies would suggest that the physiological effect of acupuncture needling and, a supportive patient/healthcare provider relationship (the context effect) play a role in control of painful symptoms.

Conclusions
The above studies led to the reformulation of our hypothesis and study design: the meridian BMEA treatment alleviates pain, improves physical and emotional functioning, in women with CPP. A pilot study that is underway will examine the impact of TCM Health Consultation + BMEA, (context effect + electro-acupuncture needling) comparing it with TCM Health Consultation (context effect) and usual care only.
Title
Electro-acupuncture treatment for women with chronic pelvic pain: a three-arm randomised controlled pilot study using a mixed methods approach.

Introduction
Chronic pelvic pain (CPP) affects over 1 million women in the United Kingdom with an estimated annual healthcare cost of over £150 million. Standard treatments are associated with unacceptable side effects. Large-scale studies on acupuncture treatment for other chronic pain conditions suggest that besides acupuncture needling, patient-healthcare provider interaction might play a role in pain reduction. We hypothesize that electro-acupuncture (EA) treatment consisting of acupuncture needling + traditional Chinese Medicine Health Consult (TCM HC) maybe effective for managing CPP symptoms. We wish to explore the role of EA treatment in CPP in a future large randomised controlled trial (RCT). The primary objective of this pilot study is to determine recruitment and retention rate and the secondary objective is to evaluate the effectiveness of EA treatment.

Materials and Methods
Thirty women with CPP were randomised into: EA treatment (Group 1), TCM HC (Group 2) or standard care (SC, Group 3). The interventions’ effects were assessed by validated pain, physical and emotional functioning questionnaires at weeks 0, 4, 8 and 12 of the study. Focus group discussions to explore participants’ experience of the study were conducted.

Results
Recruitment was completed three months ahead of schedule. Of the 59 referrals, 30 (51%) were randomised (95% CI 38% - 63%). Retention as defined by return of questionnaires was 90% in Group 3, 80% in Group 1, and 53% in Group 2, with 95% CI 74-96, 63-90, 36-70 respectively. There was a significant difference (Mann-Whitney test, P=0.023) in attendance between the intervention groups: 85% (Group 1) vs 56% (Group 2). Questionnaire analyses showed a trend towards improvements in painful symptoms (Visual Analog Score) in Groups 1 and 2. (P<0.05) compared to Group 3. Thematic analysis of focus groups data suggested that there was an improvement in pain and sleep in Groups 1 and 2.

Conclusions
This study supports the feasibility of a future large RCT to determine the effectiveness of EA treatment in CPP and provides preliminary evidence that EA treatment could be effective.
Scottish Pain Research Community (SPaRC), Sixth Annual Scientific Meeting
18th March 2016 Dundee Scotland.

Title: The impact of electro-acupuncture (EA) on women with chronic pelvic pain: a three-arm randomised controlled pilot study.

Background: Chronic pelvic pain (CPP) affects 3-4% of women worldwide. Proven treatments for CPP are limited and unsatisfactory. We hypothesize that electro-acupuncture treatment consisting of acupuncture needling and traditional Chinese medicine Health Consult (TCM HC) may be effective for CPP. Large-scale studies on acupuncture treatment for other chronic pain conditions suggest that besides acupuncture needling, patient-healthcare provider interaction might play a role in pain reduction.

Primary Objectives: To determine recruitment and retention rates in NHS Lothian within the inclusion/exclusion criteria.

Secondary Objectives: To determine the effectiveness and acceptability of proposed methods of recruitment, randomisation, intervention and assessment tools.

Methods: Participants with chronic pelvic pain were recruited and randomised to: EA treatment (Group 1), TCM HC (Group 2) or standard care (Group 3). Validated pain, physical and emotional functioning questionnaires were administered to all participants at weeks 0, 4, 8 and 12. Focus group discussions exploring participants’ experience of the study were conducted.

Results: Thirty participants were recruited out of 59 eligible (52%). There is a significant difference in attendance between the 2 intervention groups with attendance being poorer in group 2. Questionnaire responses analysis showed a trend towards improvements (VAS score) on pain levels in Groups 1 and 2 compared to the control. However, these findings should be treated as provisional in a pilot study with low power. Qualitative data will shed light on the quantitative results.

Conclusion: The study showed that recruitment and retention rates in a comparable centre are achievable. There are some signals pointing to an improvement in the pain level in Groups 1 and 2, but not in the control.

Relevance for patient care: The results, although preliminary may provide a viable choice for pain management.
The BMEA study: the impact of meridien balanced method electroacupuncture on women with chronic pelvic pain—a three-arm randomised controlled pilot study using a mixed-methods approach

Ooi Thyco Chong,1 Hilary O D Critchley,1 Andrew W Horne,1 Robert Elton,2 Erna Haraldrsdottir,3 Marie Fallon4

ABSTRACT

INTRODUCTION Chronic pelvic pain (CPP) affects 2–4% of women worldwide. Proven treatments for CPP are limited and unsatisfactory. The meridien balance method (BMEA) electroacupuncture (EA) treatment (BMEA + Traditional Chinese Medicine Health Consultations (TCM-HC)) may be effective for CPP. Previous EA studies have demonstrated an analgesic effect. Large scale studies on acupuncture for other chronic pain conditions suggest that patient healthcare provider interaction might play a role in pain reduction. We propose a pilot study to explore the effectiveness of the meridien BMEA treatment in managing women with CPP to inform a future large randomised controlled trial.

Methods and analysis: A 3-armed randomised controlled pilot study is proposed with an aim to recruit 30 women with CPP in National Health Service (NHS) Lothian. Randomisation will be to BMEA treatment, TCM-HC or standard care (SC). Validated pain, physical and emotional functioning questionnaires will be administered to all participants at weeks 0, 4, 8 and 12. Focus group discussions will be conducted within week 12 questionnaires are completed. The primary objective is to determine recruitment and retention rates. The secondary objectives aim to assess the effectiveness and acceptability of the proposed methods of recruitment, randomisation, interventions and assessment tools.

Ethics and dissemination: Ethical approval has been obtained from the Scotland Research Ethics Committee (REC 14/SS/0252). Data will be published in peer-reviewed journals and presented at international conferences.

Trial registration number: NCT02295111.

INTRODUCTION

Over one million women in the UK suffer from chronic pelvic pain (CPP). Annual healthcare expenditures are estimated at over £150 million.2,3 CPP impacts negatively on quality of life and work productivity;5 CPP is associated with conditions such as endometriosis, painful bladder syndrome and irritable bowel syndrome. Up to 49% of women with CPP referred for diagnostic laparoscopy, have no apparent underlying cause identified for their painful symptoms.6 The management of CPP is complex and treatment is often unsatisfactory.7 We believe that acupuncture may be a helpful adjunct in the management of CPP. Our hypothesis is that the meridien BMEA treatment alleviates pain, and improves physical and emotional functioning, in women with CPP.

Meridian balance method acupuncture

For this study, we have chosen the meridien balance method (BMEA) acupuncture8 which is a novel approach for the management of painful conditions. With this style of acupuncture, pain relief is expected once the needle is inserted in the appropriately chosen acupuncture points.

The meridien BM acupuncture offers an interactive and systematic strategy to formulate a treatment plan through the diagnosis of the sick meridian and selection of a healthy meridian and acupuncture points. Meridian balancing has been well described in the Huang Di Nei Jing, a seminal classical Chinese medicine (CCM) text9 as well as in modern text.5,6,9 Modern traditional Chinese medicine (TCM) emerges out of the standardisation of CCM, and is one of the most popular approaches used by professional acupuncturists in the UK. In comparison, the meridien BM acupuncture is
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| Table 1  Five systems of meridian balance method |
|----------|----------|----------|----------|----------|
| System 1 | System 2 | System 3 | System 4 | System 5 |
| Sick meridian | Name Sharing | Branching | Interior/exterior | Clock Opposite | Clock Neighbour |
| LU/hand Taiyang | SP | UB | LI | UB | LR |
| Li/hand Yangming | ST | LR | LI | UB | LR |
| ST/foot Yangming | LI | PC | SI | GB | SP |
| SP/foot Taiyin | LU | SI | ST | TH | HT |
| HT/foot Shaoyin | KL | GB | SI | GB | SP |
| SI/hand Taiyang | UB | SP | HT | LR | UB |
| UB/foot Taiyang | SI | LU | KL | LU | SI |
| HT/foot Shaoyin | HT | TH | UB | LI | PC |
| PC/hand Jueyin | LR | ST | TH | ST | KL |
| TH/hand Shaoyang | GB | KL | PC | SP | GB |
| GB/foot Shaoyang | TH | HT | LR | HT | TH |
| LR/foot Jueyin | PC | LI | GB | SI | LU |

Meridian Names: GB, gallbladder; HT, heart; KL, kidney; LI, large intestine; LR, liver; LU, lung; PC, pericardium; SI, small intestine; SP, spleen; ST, stomach; TH, triple heater; UB, urinary bladder.

The five systems of meridian BM

The meridian BM acupuncture has several key features: the five systems of meridian balancing (table 1), mirror and image methods.6

Image and mirror methods

Once the healthy meridian for treating the sick meridian is identified, the image or mirror method is employed to locate more precisely the areas of the body to be treated. The acupuncturist palpates the meridian of the identified area for the best acupuncture point(s) that will relieve the pain. Thus, point selections are individualised.

The image method maps the relationship between the limb and the whole body (table 2). For example, the hand images the genitals, coccyx and sacrum, and the forearm images the lower abdomen and lower back.5

Electrostimulation

To maximise the specific effects of acupuncture needling, the needles may be stimulated manually (manual acupuncture; MA) or with micro electric current (electroacupuncture, EA). Although there have been no studies to show that EA enhances the analgesic effect of the meridian BM acupuncture, it is, however, the method of choice for several reasons. Evidence from animal and human studies showed that both MA and EA produce analgesic effect.17 EA appears to be more effective than MA in some painful conditions. To obtain
an analgesic effect in EA, the optimum time for the needle stimulation is 20–30 min with the frequencies set at 2 and 100 Hz. Based on these parameters, it is impractical to be manipulating the acupuncture needles manually for 20–30 min and also be consistent. With EA one can set both parameters precisely at every treatment. EA may be measured objectively and is easier to control and standardise than MA.

The context and content effects
There is mounting evidence that acupuncture treatments for chronic pain, such as low back pain, headache, shoulder and neck pain, are effective. However, a recent individual patient data meta-analysis on the use of acupuncture for chronic pain conditions found a small, statistically significant effect size when compared with sham acupuncture. The effect size was larger and statistically significant when compared with usual care controls. This would suggest that as well as the specific needling effects, other factors within the context of the acupuncture treatment play a role in reducing pain, such as the characteristics of the healthcare providers and patients, for example, their beliefs and expectations; the provider-patient interactions as well as how the treatment is administered. The effects that result from the complex interactions of such characteristics are known as the context effect. This effect was demonstrated in a study of pain management in patients with irritable bowel syndrome, showing that an enhanced provider-patient relationship could help alleviate pain. Patients were randomised on a waiting list (no placebo or interaction with healthcare provider), therapeutic ritual (placebo sham acupuncture with limited interaction) or a supportive relationship (placebo sham acupuncture with enhanced relationship). The supportive relationship produced the most adequate relief of symptoms and enhanced quality of life.

The proposed pilot study will compare the specific effects of the meridian balanced method (BM) EA needling + the context effects of a Traditional Chinese Medicine Health Consultation (BMEA/TCM HC), with context effects of a TCM HC (patient–healthcare provider interaction) and standard care (SC). This study will enable us to tease out the different components of acupuncture treatment that contribute to its analgesic effect and to collect important information to inform a future definitive RCT.

Objectives
Primary objective
The primary objective is to determine recruitment and retention rates in National Health Service (NHS) Lothian within defined inclusion/exclusion criteria.

Secondary objectives
To determine the effectiveness and acceptability to participants of the proposed methods of recruitment, randomisation, interventions and assessment tools.

End points
Primary end points
1. The proportion of eligible patients randomised into the study;
2. The proportion of randomised patients who complete all treatment interventions and questionnaires at the final follow-up.

Secondary end points
Data on the effectiveness and acceptability of proposed methods of recruitment, randomisation, interventions and assessment tools.

METHODS AND ANALYSIS
Study design
This is a single-centre, open, three-armed parallel randomised controlled pilot study comparing a meridian BMEA + TCM HC (group 1), with TCM HC (group 2) and SC (group 3, figure 1), using a mixed-methods approach. It includes quantitative method using validated questionnaires and qualitative method using focus groups post-week 12 questionnaire completion, as well as field notes and a reflexive diary.

Delivery of intervention in groups 1 and 2
The following descriptions of our study interventions adhered to guidelines in the ‘Revised Standards for Reporting Interventions in Clinical Trial of Acupuncture (STRICTA): Extending the CONSORT Statement.’

The principal investigator (PI: OTC) will deliver all eight BMEA + TCM HC interventions for group 1 and TCM HC for group 2 within the same setting in NHS Lothian. The first intervention for both groups will last approximately 60 min. Subsequent seven interventions for both groups will last no longer than 40 min. All participants will receive twice weekly interventions for 4 weeks. Participants in group 2 will not receive the meridian BMEA. With permission from the participants, all interventions in groups 1 and 2 will be audio-taped to ensure standardisation of procedures and techniques.

All participants in groups 1, 2 and 3 will complete the questionnaires at weeks 0, 4, 8 and 12, and will be invited to the focus group discussions. Similarly, group 1 participants will complete the questionnaires at weeks 0, 4, 8 and 12, and will be invited to the focus group discussions.

TCM HC (groups 1 and 2)
Individualised TCM HC
For groups 1 and 2 will share the same approach to the TCM HC. The initial TCM HC will be based on Chinese medicine theory that typically includes history taking: inspecting, listening and inspection of the tongue. Each participant will receive individualised advice based on the specific needs and presenting symptoms. Dietary advice based on Chinese medicine nutrition and other appropriate self-care skills, such as breathing techniques and physical activities recommended and...
modified to accommodate the participant’s changing pattern of pain, sleep, level of anxiety or other health needs. Breathing techniques involve getting the partici- pant to focus her attention on each breath in and out. No herbal medicine therapy will be prescribed.

**Individualised and systematic acupuncture point selections**

**Step 1: Diagnose the affected/sick meridian(s)**

This first fundamental and very important step requires the acupuncturist to instruct the patient to indicate where the pain is located, so that the affected meridian (s) can be diagnosed accurately.

**Step 2: Identify the balancing meridian(s) based on the five systems**

Once the affected meridian(s) is/are identified, one of the following meridians can be chosen to balance the affected meridian(s):

- System 1: Foot Taiyin (name sharing meridian);
- System 2: Foot Taiyang (branching meridian);
- System 3: Hand Yangming (interior/exterior);

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System 4: Foot Taiyang (clock opposite);
System 5: Foot jueyin (clock neighbour).

Step 3: Acupuncture point(s) selection for treatment
Once the balancing meridian has been selected, step 3 involves locating the therapeutic points along the balancing meridian by using the mirror or the image method. The acupuncturist will palpate for the most tender and tight point(s) (ashii points) along the balancing meridian. The ashii point(s) is/are the therapeutic point(s) if on pressing the point(s), the patient reports that the pain has been reduced. Thus, point selections are based on the steps outlined and not on TCM pattern diagnosis.

Step 4: Connecting the battery operated AS SUPER 4 digital stimulator to the acupuncture needles
The negatively charged, black lead (to stimulate) will be connected to the acupuncture needle inserted in the point that gave the most pain relief, while the positively charged lead (red) will be connected to another needle inserted in the same area. We will use the ‘AS SUPER 4’ electro-stimulator (Manufacturer: Schwa-medico, Germany) with four outputs. The electro-stimulator emits a square wave of low frequency (2 Hz) for 3 s alternating with high frequency (100 Hz). Programme 2 will be selected and the duration of treatment will be no shorter than 20 min and no longer than 90 min. These parameters are based on the work of Han et al. The intensity of the electrical stimulation will be adjusted based on the participant’s feedback, to produce a strong sensation without pain or discomfort.

Depth of needle insertion
The depth of the needle insertion will be adapted to the thickness of the muscles and subcutaneous fatty tissue. For example, for the gluteal muscle, typically a 0.9 mm x 55 mm (3 inches) long the needle will be inserted to a depth of between 1.0 and 2.0 inches. For the forearm, typically a 0.18 mm x 30 mm (1.20 inches) will be inserted to a depth of about 0.25-0.75 inch. The number of needles inserted will be individualised. We will use Dong Bang (Korea) and Acoline needles (China).

Group 3—SC
Participants will follow their SC as given by their clinician. SC is defined here as care and treatment that patients would normally receive at The Pelvic Pain Service, NHS Lothian: oral analgesics, neuromodulators such as anti-inflammatories and antidepressants, hormonal approaches, counselling/behavioural therapy or surgical interventions when indicated. The Pelvic Pain Service consists of consultant gynaecologist, anaesthetist specialising in pain, a psychologist and a specialist nurse. The participants will not receive the meridian BMEA treatment or the TCM HC.

Participants
Thirty (30) women (aged greater than or equal to 18 years) with a history of CPP will be recruited.

Sample size
We believe that a sample size of 30 patients is appropriate for a pilot study and will allow estimation of percentage rates of recruitment and retention to within a SE of at most 10%.

Inclusion criteria
- CPP longer than 6 months duration;
- Average numerical pain score of at least 4 out of 10 in the previous week;
- Able and willing to comply with intervention;
- Women aged 18 and above.

Exclusion criteria
- Pregnancy;
- Malignancy;
- Severe bleeding disorders (eg, type 2, 3 Von Willebrand disease);
- Regular anticoagulant administration;
- Severe needle phobia;
- A history of seizures;
- A pace maker in situ;
- Moderate to severe psychiatric illness (currently under the care of a psychiatrist);
- Treatment with EA and meridian BM within the past 6 months.

Randomisation procedure
We will use an envelope randomisation system created by our statistician. There will be 30 sealed envelopes: 10 meridian BMEA + TCM HC (group 1), 10 TCM HC (group 2) and 10 SC (group 3). The envelopes are randomly assigned a number from 1 to 30. At the start of the study, the first participant who passes the screening will receive envelope number 1; and the second will receive the envelope number 2 and so on. The envelope will be opened in front of the participant by a member of the research team who screens the participant. If randomised into either groups 1 or 2, the participant will receive the appropriate treatment on the same day. If randomised into group 3, the participant will be instructed to continue the NHS SC. There will be no stratification.

Intervention
Eligible women will be randomised into meridian BMEA + TCM HC (group 1), TCM HC (group 2) or SC (group 3). Participants in group 1 will receive eight interventions twice a week for 4 weeks. Participants in group 2 will receive eight TCM HC twice a week for 4 weeks. Participants in group 3 will receive optimal SC (table 4). With permission from the participants, all interventions in groups 1 and 2 will be audiotaped to ensure standardisation of procedures and techniques.
Acupuncturist information
The PI (OTC) completed 2196 h of acupuncture training and obtained a Masters of Science Degree in Acupuncture at an accredited school in New York City, USA. She is trained in four styles of acupuncture: TCM, Kiko Matsamuto Japanese style, Five Element and the meridian balanced method. She studied EA as part of her acupuncture training and at the British Medical Acupuncture Society (BMAS). She has over 10 years of experience using Five Element acupuncture to address psychoemotional issues and the meridian balanced method acupuncture for pain management in hospital settings such as the New York University Cancer Institute and Royal Infirmary of Edinburgh, UK. She is a Professional Registered Nurse, a National Board Certified Acupuncturist and Chinese medicine herbalist in New York State, USA. She is also Professional Registered Nurse in the UK.

Data collection
Screening
Eligible women will be consented and screened by a member of the research team. They will be randomized when they have passed screening. All data will be recorded on a case record form and transferred to a secure database.

Assessment tools
Before randomization, a questionnaire (baseline week 0) will be given to all participants. This will include the following validated tools:
1. Visual analogue scale;
2. Brief Pain Inventory (BPI);
3. Hospital Anxiety and Depression Scale (HADS);
4. Quality Of Life SF-12;
5. Sexual Activity Questionnaire (SAQ);
6. Pain Catastrophising Questionnaire (PCQ);
7. Work Productivity and Activity Impairment Questionnaire (WPAIQ).
The set of questionnaires at baseline (week 0) will include participants’ demographic and relevant clinical information. The same questionnaire will be posted to all participants at weeks 4, 8 and 12 with an addressed envelope enclosed.

Focus groups
Three focus group discussions will be conducted after questionnaires in week 12 are completed. All participants from the groups 1, 2 and 3 will be sent a letter of invitation to the focus group discussions. To ensure a high turnout, a week before the designated date of the respective focus group discussions, a member of the research team will contact each participant to encourage them to attend. In order not to bias the group discussions, the PI (OTC) who provides the interventions will not be conducting the focus groups. A separate member of the research team will conduct the three focus group discussions lasting approximately 60 min each. A content guide will be used in each group to focus the discussions, which will provide additional data relevant to the study. The topic guide will focus on questions that will explore the participants’ perceived benefits or otherwise of the BMEA treatment (group 1), TCM HC (group 2) and NHSC (group 3). The focus groups will provide in-depth exploration of how and if the perceived benefits affect the quality of their lives, such as sleep quality, energy levels and sexual activities. The discussions will be audiotaped, transcribed and thematically analysed.

Field notes and a reflective diary
The PI will keep field notes and a reflective diary during the course of the study. After each intervention, the PI will write notes related to her own observation of salient events, discussions, remarks or behaviours that provide more information about the participant and her experience of pain, as well as the possible impact or otherwise of the intervention. For example, the PI might notice changes in facial colour or expression when a participant describes how the CPP impacted her life; or a participant who started a treatment intervention apparently agitated but who is looking calmer at the close of the session. Such data can add scope and depth as well as illuminate the different aspects of the interventions and the patient–healthcare provider interactions that might not be captured otherwise. In her reflective diary, the PI will make a note of her thoughts, feelings and insights of such observations. This reflective practice involves the PI to be introspective, conscious of her role, reactions and assumptions she brings to the intervention and the research process.
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Adverse events
When administered by an appropriately trained and qualified acupuncturist, EA is safe and serious adverse events (SAEs) are not anticipated. However, any SAEs that occur during the study will be reported in the participant’s medical record and followed up until resolution of the event. We will also report it to the ACCORD Research Governance (http://www.accord.ed.ac.uk) and Quality Assurance Office based at the University of Edinburgh within 24 h. After randomisation, participants in groups 1 and 2 will be instructed to contact a member of the clinical research team if they have an event that necessitates hospitalisation, or results in significant disability or incapacity. In addition, they will be asked about the occurrence of adverse effects at every of the eight visits during the study. Open-ended and non-leading verbal questioning of the participant will be used to enquire about adverse events, or if they have been admitted to hospital. If there is any doubt as to whether a clinical observation is an AE, the event will be recorded.

End of study
The end of study is defined as the last participant’s last visit.

Proposed analyses
Determine recruitment and retention rates
The recruitment rate will be calculated from the number of eligible patients in the participant log. An acceptable recruitment rate is about 50%. We aim to retain 90% of these recruited to the study. If retention rates are low, we will explore the reasons why at the post-study focus group discussions. Information obtained in the discussions will be used to improve compliance in any future study.

CIs will be calculated for the estimates of rates of recruitment, retention and unanswered questions. The study is not powered to allow comparisons between the randomised groups, and outcomes in each group will just be summarised rather than being compared by formal statistical tests.

Data from the focus groups will be analysed thematically. Thematic analysis aims to highlight and record patterns or themes within a set of data. Such themes capture a certain phenomenon and could be related to the specific research questions or shed light on a specific salient event. Thematic analysis is commonly used in analysis in qualitative research.

Effectiveness and acceptability of proposed methods of recruitment, randomisation, BMEA treatments, TCM HC and assessment tools
Effectiveness will be measured by reductions in pain and associated symptoms such as sleep disturbances, anxiety or depression that are covered in the questionnaires. Additional information on effectiveness, not covered in the questionnaires, will be captured in the focus groups.

The appropriateness of assessment tools used can be assessed through examination of data completion and patterns of missing data. The focus groups will be complementary to understanding if the tools chosen are appropriate and will also provide information on acceptability of recruitment, randomisation and the treatments themselves.

Ethics and dissemination
Data will be presented at international conferences and published in peer-reviewed journals. We will make the information obtained from the study available to the public through national bodies and charities. Participants will be informed of the result of the trial via the Pelvic Pain Clinic, NHS Lothian.

DISCUSSION
We believe that a definitive evaluation of the effectiveness of the meridian BMEA treatment in the management of CPP requires a multicentre randomised controlled trial (RCT). We anticipate potential difficulties in a large RCT in acupuncture for chronic pain, and therefore we have designed this pilot study to evaluate its feasibility.

Both MA90 and EA91,92 are safe when performed by appropriately trained acupuncturists. However, because of some theoretical safety concerns, we have erred on the side of caution to exclude, for example, patients who have a history of seizures or have an implanted pace maker.

According to Chinese medicine theory, pain results from blocked meridians leading to an imbalance in the system. On the surface of the body is a network of 12 meridians (6 yin and 6 yang) that connect acupuncture points together.93 Theoretically, these meridians act as a conduit between the surface of the body and the internal organs. The meridian BM acupuncture treats pain by balancing these meridians, for example, using a ‘healthy’ yin meridian to balance a ‘blocked’ yang meridian.94 However, there are considerable skepticism and controversies surrounding these theories and the existence as physical entities of acupuncture points and the meridian system. Despite efforts to understand these systems, there are continued disagreements as to what they constitute.95,96 Indeed, the PI (OTC) argues that it is more useful to view these systems as a conceptual framework that guides the clinical practice of acupuncture, rather than to argue if they exist. Tangentially related to this view is work undertaken by Langevin at al25 whereby it is hypothesised that acupuncture points and meridians have correspondence to the connective tissue and not as illustrated in Chinese medicine text.

A survey of the literature indicates that this is the first study to investigate the effectiveness of the meridian BMEA treatment for CPP in women using a mixed-methods approach. The mixed-methods approach utilises validated questionnaires and focus group
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Discussions, field notes and a reflexive diary. Undertaking a mixed-methods approach is one of the strengths of the study because we are examining the feasibility of studying a complex intervention, which involves a number of phenomena, which include: TCM health consult, EA and the context effect. Alongside an understanding of participants’ perceived benefits or otherwise of the interventions, this methodology will also help us to understand the role of the researcher in the study intervention. The focus group discussions will capture participants’ subjective experiences of the study intervention.

It is generally considered that the gold standard in effectiveness of RCB is the use of a placebo control for the study intervention. However, our pilot study does not employ a placebo (sham acupuncture treatment) for several reasons. A considerable body of evidence from large-scale effectiveness studies has demonstrated that sham acupuncture treatments as controls are problematic. For some chronic pain conditions, the observed effects of acupuncture treatments are larger in usual care controls when compared with sham controls. This might suggest that sham acupuncture treatments have physiological effects, and are thus not inert. Past sham controlled studies have employed techniques such as shallow needling, and needling with a retractable needle or toothpick.15,16 Such techniques create a sensation not dissimilar to light touch which has some data to show that it has physiological effects.17 It is also conceivable and probable that shallow needling and needling with a retractable needle elicit similar physiological effects as deep needling. These sham acupuncture techniques are therefore inappropriate. We feel that until better sham techniques are available, it is prudent to design a study that does not employ a placebo control.

Context effects such as expectancy18 treatment rituals19 or patient-provider interactions20 have been shown to have an impact on the experience of pain. These may have confounded past studies and might explain the small effect sizes when sham acupuncture treatments were compared with true acupuncture treatments. Attempting to separate the context effects of acupuncture treatment from the specific effects of acupuncture needling presents a major challenge in this area of research. In response, we have designed a three arm RCT to address these challenges. The first arm includes acupuncture needling, electro-stimulation (specific effects of needling) and the patient-healthcare provider interactions (context effects). Participants in group 3 (SC) will receive the standard NHS care for CPP. Having these two control groups is likely to yield the true effect size of the specific effect of EA needling and the non-specific (context effect) of the patient-healthcare provider interactions. We acknowledge that this pilot study is investigating only one aspect of the several context effects of acupuncture treatment. However, we believe that understanding the clinical outcome of the patient–healthcare provider relationships will create a critical mass of literature to influence the education of future generations of healthcare professionals. The UK SIGN 196 guideline for the management of chronic pain acknowledged that while preliminary data showed that the nature of such a relationship could influence clinical outcome, there are not enough high-quality studies to recommend widespread training.21 (Management of chronic pain. Edinburgh: SIGN; December 2013. Available from URL: http://www.sign.ac.uk/ accessed March 2013.)

In assessing the outcome of the interventions, we have chosen validated assessment tools rather than using TCM outcome measures. This is because there are no standardized or validated TCM outcome measures. Arguably, better known validated questionnaires might be more meaningful within a biomedical setting than TCM outcome measures.

In conclusion, our pilot study protocol will enable us to determine the retention and recruitment rate as well as the patients’ experience of the study intervention. It will help us gain better insight into the impact of meridian BMEA needling and the patient-practitioner relationship on CPP in women.

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Contributors OTW, HODC, AWN and MF were involved in research, contribution of original material, editing and approval of final manuscript. RE and IH were involved in editing and approval of this manuscript.

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Competing interests None declared.

Ethics approval South East Scotland Research Ethics Committee 02 (REC 14/ SS/1022).

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES


22 August 2014

Miss Ooi Thye Chong
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Dear Miss Chong

Study title: The BMEA Study: The impact of meridian balanced method (BM) electro-acupuncture (EA) treatment on women with chronic pelvic pain (CPP): A three-arm randomized controlled pilot study.

REC reference: 14/SS/1022
Protocol number: n/a
IRAS project ID: 154800

The Research Ethics Committee reviewed the above application at the meeting held on 20 August 2014. Thank you and other co researchers for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Ms Joyce Clearie, joyce.clearie@nhslothian.scot.nhs.uk.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

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Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. As doing a pregnancy test this needs to be explained in the information sheet
2. Storage and destruction of audio tapes needs to be explained in information sheets
3. Invitation letter needs to come from a member of the clinical team
4. Remove any use of term health consult as this still appears in places in study documentation. Please amend where appropriate.
5. If withdraw from study data withdrawn too? Please confirm
6. First word of the Do I have to take part section of information sheet should be No
7. Inconsistent information is given at present on data storage will it be held for 5 years or 10 years. Please be consistent and amend appropriately.
8. Do final typographical and grammatical check of all supporting documentation
9. PIS page 2 Last paragraph inconsistent reference to the Electro-acupuncture + TCM Health Consultation in title there it is referred to other way round. As TCM Health Consultation + Electro-acupuncture (EA) Please amend appropriately.

[Where additional conditions are specified by the REC 1-9 above.]
You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at [http://www.rdforum.nhs.uk](http://www.rdforum.nhs.uk).

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials
All clinical trials (defined as the first four categories on question 2 of the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g., when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Summary of discussion at the meeting

Ethical issues raised, noted and resolved in preliminary discussion
Suitability of the applicant and supporting staff
No particular issues were raised as applicant and supporting staff appeared very suitable.

Independent review
The Committee considered this was acceptable.
Suitability of supporting information
Now overall acceptable with only minor adjustments needed e.g., mention of pregnancy testing and final typographical and grammatical check carried out.
Other general comments
None
Suitability of the summary of the research
The Committee considered this was acceptable.

Ethical issues raised by the Committee in private discussion, together with responses given by the researcher when invited into the meeting

The Chair welcomed the Chief Investigator Miss Ooi Thye Chong to the meeting and co-researcher Ann Doust and Professor Fallon and Prof Hilary Critchley to the meeting and thanked them for making herself available to discuss the study.

Social or scientific value: scientific design and conduct of the study, including patient and public involvement
The Committee considered this overall to now be a generally well presented study with good public involvement and commented that it was greatly improved from the previous submission.
Following query the researcher confirmed that she worked with the pelvic pain team and they would identify patients who were potential participants and information would be given at that time on the study. The researcher was asked if TCM usually includes Acupuncture. She explained what TCH Health Consultation consisted of and advised that were 5 arms to TCM one of involved acupuncture. In this study TCM HC no acupuncture given at that point.

In response to query from the Committee explained that previous study was more of a feasibility study rather than a pilot study. **Recruitment arrangements and access to health information and fair participant selection**

Now overall acceptable

**Favourable risk benefit ratio: anticipated benefit/risks for research participants present and future**

Now overall acceptable

**Care and protection of research participants: respect for potential and enrolled participants’ welfare and dignity**

Now overall acceptable

**Informed consent process and the adequacy and completeness of participant information**

Now overall acceptable with only minor adjustments needed and final typographical and grammatical checks.

It was felt that the researchers had justified why not provided a flow chart of interventions as instead noted that have now adequately described patient journey and this was felt acceptable.

**Approved documents**

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tr>
<td>Covering letter on headed paper [Cover letter responding to UNFO letter]</td>
<td></td>
<td>06 August 2014</td>
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<td>Covering letter on headed paper [BMEA_cover letter]</td>
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<td>GP/consultant information sheets or letters [BMEA_GP letter]</td>
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<td>Research protocol or project proposal [BMEA_protocol]</td>
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<td>Summary CV for Chief Investigator (CI) [Ooi Thye Chong CV]</td>
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<td>Summary CV for supervisor (student research) [Marie Fallon CV]</td>
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Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/SS/1022 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely

[Signature]

Appendix 7 Ethics Letter
Ms Joanne Mair  
Chair  
E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Enclosures:  
List of names and professions of members who were present at the meeting and those who submitted written comments  
“After ethical review – guidance for researchers” [SL-AR2 for other studies]

Copy to:  
Ms Marise Bucukoglu  
Mrs Karen Haggart, Research & Development Department
South East Scotland 02

Attendance at Committee meeting on 20 August 2014

Committee Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
<th>Notes</th>
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<tr>
<td>Dr Balkishan Agrawal</td>
<td>General Practitioner</td>
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<tr>
<td>Mr William Farquhar</td>
<td>Retired</td>
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<tr>
<td>Mrs Alanah Kirby</td>
<td>Senior Lecturer</td>
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<td></td>
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<tr>
<td>Dr Yann Maidment</td>
<td>General Dental Practitioner</td>
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<tr>
<td>Ms Joanne Mair</td>
<td>Portfolio Manager</td>
<td>Yes</td>
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<tr>
<td>Mr Lindsay Murray</td>
<td>Health &amp; Safety Manager</td>
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<tr>
<td>Mr Hugh Olson</td>
<td>Lawyer</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Dr Lynne Philip</td>
<td>General Practitioner</td>
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<tr>
<td>Mr Alec Richard</td>
<td>Researcher</td>
<td>Yes</td>
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<tr>
<td>Professor Lindsay Sawyer</td>
<td>Retired University Lecturer</td>
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<tr>
<td>Mrs Anne Tod</td>
<td>Retired</td>
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<tr>
<td>Dr Hester Ward</td>
<td>Public Health Consultant</td>
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<tr>
<td>Mrs Louisa Wilson</td>
<td>Senior Research Monitor</td>
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<tr>
<td>Mrs Helen Wright</td>
<td>Pharmacy Assessor</td>
<td>Yes</td>
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Also in attendance:

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<th>Name</th>
<th>Position (or reason for attending)</th>
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<tr>
<td>Dr Alex Bailey</td>
<td>Scientific Officer</td>
</tr>
<tr>
<td>Ms Joyce Clearie</td>
<td>REC Manager</td>
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</table>
References:


FREYD, M. 1923. The graphic rating scale. *Journal of Educational Psychology*, 14, 83.


References


GRACE, V. & ZONDERVAN, K. 2006. Chronic pelvic pain in women in New Zealand: comparative well-being, comorbidity, and impact on work and other activities. Health care for women international, 27, 585-599.


HARRIS, K., LI, K., FLYNN, C. & CHOW, E. 2007. Worst, average or current pain in the Brief Pain Inventory: which should be used to calculate the response to palliative radiotherapy in patients with bone metastases? *Clinical Oncology*, 19, 523-527.


KAPTCHUK, T. J. 2002. The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance? Annals Of Internal Medicine, 136, 817-825.


PEETS, J. & POMERANZ, B. 1978. CXBK mice deficient in opiate receptors show poor electroacupuncture analgesia.


**References**


SMARR, K. L. & KEEFER, A. L. 2011. Measures of depression and depressive symptoms: Beck Depression Inventory-II (BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D), Geriatric Depression Scale (GDS), Hospital Anxiety and Depression Scale (HADS), and Patient Health Questionnaire-9 (PHQ-9). Arthritis care & research, 63, S454-S466.


TAN, R. 2003. Dr. Tan's Strategy of Twelve Magical Points, San Diego, California.

TAN, R., RUSH S. 1996. Twelve and Twelve in Acupuncture, San Diego, California, USA.


References


