An Investigation into the Effectiveness of Osteopathic Treatment for Reducing Perimenopausal Symptoms

Katharine Bone

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UNITEC Institute of Technology

Declaration

Name of candidate: Katharine Bone

This Thesis/Dissertation/Research Project entitled **"An Investigation into the Effectiveness of Osteopathic Treatment for Reducing Perimenopausal Symptoms"** is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy

Candidate's declaration

I confirm that:

- This Thesis/Dissertation/Research Project represents my own work;
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.
  Research Ethics Committee Approval Number: **2011-1173**

Candidate Signature: ……Date: 19/03/2012

Student number: **1295474**

Abstract

Background: The onset of perimenopause is a significant life event for a woman, carrying with it physical, medical, psychosocial and cultural significance. An estimated 85% of women report recurring symptoms that occur in the transition to menopause.

Objective: To determine if Osteopathic Manual Therapy delivered over four weeks is an effective modality for treating symptoms associated with perimenopause.

Methods: Six participants experiencing perimenopausal symptoms each received four osteopathic treatments. Baseline and follow-up measures included the Menopause Quality of Life Questionnaire, the Greene Climacteric Scale and a Hot Flush Dairy in which participants recorded the frequency and intensity of any flushes. A follow up interview was also undertaken to gather information regarding their thoughts and experiences throughout the course of the treatments.

Results: The frequency and severity of perimenopausal complaints exhibited substantial and rapid reductions. Changes in the physical ($p < 0.005$) and psychological ($p = 0.007$) domains of the Menopause Quality of Life Questionnaire, along with the somatic ($p < 0.006$), anxiety ($p = 0.013$) and vasomotor ($p < 0.025$) domains of the Greene Climacteric Scale attained statistical significance. Communication, Overall Wellbeing and Lack of Knowledge arose as the key themes following qualitative analyses of the follow up interviews.

Conclusions: The results of this study indicate that Osteopathic Manual Therapy may be an effective modality for the reduction of perimenopausal symptoms. Further to this study, randomised controlled trials with greater participant numbers will help to provide more conclusive data about the possible benefit of this therapy for women experiencing perimenopausal symptoms.

Key words: Complementary and alternative medicine, menopause, osteopathy, hot flushes, menopause symptoms.

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Abbreviations

CAM	–	Complementary and Alternative Medicine
HRT	–	Hormone Replacement Therapy
OMT	–	Osteopathic Manual Therapy
GnRH	–	Gonadotrophin Releasing Hormone
FMP	–	Final Menstrual Period
LH	–	Luteinising Hormone
FSH	–	Follicle Stimulating Hormone
STRAW	–	Stages of Reproductive Aging Workshop
WHI	–	Women's Health Initiative
MENoQL	–	Menopause Quality of Life Questionnaire
GCS	–	Greene Climacteric Scale

Appendix

Introduction to Thesis

As women transition through the menopausal process, an estimated 85% report at least one symptom, most notably hot flushes (Bruce & Rymer, 2009; Dennerstein et al., 1993; McKinlay, 1996; Woods & Mitchell, 2005). The often severe and debilitating symptoms associated with menopause are reported to effect attendance, mental concentration and output at work, as well as influencing social life, psychological health and sense of well being (Ogurlu, Küçük, & Aksu, 2010). The results of the Women's Health Initiative and the Million Women Study have forced health practitioners and patients alike to rethink the use of Hormone Replacement Therapy for perimenopausal symptoms (Northrup, 2006; Rossouw, Anderson, & Prentice, 2002; Sievert, 2006).

A significant proportion of women are beginning to use Complementary or Alternative Medicines (CAMs) for alleviation of their menopausal related symptoms, believing them to be safer and more natural (Kessel & Kronenberg, 2004; Rees, 2006). This trend has been occurring despite a lack of definitive research that would suggest CAMs are an effective form of treatment for perimenopausal symptoms. Given the holistic principals that underpin osteopathy, it is arguable that the complementary nature of modality therapy may be an effective treatment for the often broad and variable symptoms of menopause. There has been only one menopausal related study completed in osteopathic medicine (Cleary & Fox, 1994), however significant methodological downfalls render this research unreliable and ungeneralisable to the wider population. Thus, the purpose of the study described in this thesis is to determine to what extent Osteopathic Manual Therapy can reduce the common symptoms of perimenopause.

This thesis is arranged in three main sections:
Section 1 is a literature review that outlines the physiology of menstruation and menopause, the stages of menopause, the risk of early or late menopause including factors that may influence age at onset, symptoms, and both conventional and alternative treatments. Section 2 of this thesis contains a manuscript formatted for submission to the *International Journal of Osteopathic Medicine*. Section 3 (appendices) contains all other

relevant material supplementary to the thesis. The aim of the study reported in the manuscript was to determine whether Osteopathic Manual Therapy delivered over a four week period is an effective therapy for the treatment and management of perimenopausal symptoms.

Section One

Literature Review

Literature Review

Introduction

For some women the transition from one phase of life to another, via menopause, is an uneventful affair. For others, the constant daily symptoms begin to affect the quality of their lives and they are driven to search for some means of relief (Cleary & Fox, 1994; Rahman, Zainudin, & Mun, 2010). The World Health Organisation defines menopause as "the permanent cessation of menstruation for 12 months or more" (World Health Organisation Scientific Group, 1996, p. 12). Following this, women are termed postmenopausal. The time prior to menopause is termed perimenopause. It is during this time that women notice changes in the characteristics of their menstrual cycles and the onset of symptoms often associated with perimenopause. Globally, women begin perimenopause between 45 and 47 years of age and menopause between 47 and 55 years of age (Bruce & Rymer, 2009; Do et al., 1998), however several factors are theorised to influence age at onset. In this review, these will be addressed with respect to the consequent health problems that can arise when menopause is reached outside its normal range. The symptoms associated with perimenopause vary considerably from woman to woman and will be discussed in relation to conventional treatment options available to menopausal women, particularly looking at the risks and benefits of Hormone Replacement Therapy (HRT). The final section of the review examines the limited literature surrounding treatment of perimenopausal complaints with Complementary and Alternative Medicines (CAMs), looking specifically at acupuncture, exercise therapy, bioidentical hormones and Osteopathic Manual Therapy (OMT).

Physiology of the Menstrual Cycle and Menopause

A baby girl is born with approximately 100,000,000 primordial follicles, the cellular progenitor of the female reproductive gamete. During childhood, half of these follicles are absorbed by the body and by the time menstruation begins the remaining number of follicles is in the order of 400,000. Throughout a woman's reproductive life, approximately 400 antral follicles grow into mature follicles and ovulate. The remaining follicles undergo atresia and are reabsorbed by the body. From around 45 years of age only a small number

of follicles remain to be stimulated, and the production of the female sex hormones decreases as the number of follicles approach zero. This loss in follicular activity results in the phenomenon known as menopause, a normal physiological and physical change experienced by middle-aged women. Using age 50 as a proxy age for menopause it is projected that by 2030 the world population of menopausal and postmenopausal women will reach 1.2 billion, with 47 million new entrants each year (Hill, 1996).

The normal reproductive years of the female are characterised by monthly rhythmical changes in the rates of hormone secretion and corresponding physical changes in the ovaries and other sexual organs. The ovarian changes that occur throughout the menstrual cycle depend completely upon the hypothalamus – pituitary – gonadal axis and the hormones it controls (Bray, Cragg, Macknight, & Mills, 2005; Guyton & Hall, 2006). Gonadotrophin Releasing Hormone (GnRH) is secreted from the hypothalamus and acts on the anterior pituitary gland which in turn releases Follicle Stimulating Hormone (FSH) and Luteinising Hormone (LH). FSH is responsible for follicle development while LH stimulates development of the corpus luteum. In the initial stages of the new menstrual cycle 8 – 12 antral follicles are stimulated by FSH in the ovaries. As the follicles proliferate they develop the ability to release oestrogen, one of two ovarian sex hormones; the second, progesterone, is secreted from the corpus luteum that forms from the ruptured follicle in the luteal phase of menstruation (Bray et al., 2005). Alongside the secretion of oestrogen and progesterone, inhibin A and B are also secreted from within the ovaries. Inhibin A is derived from the pre-ovulatory follicle, whereas inhibin B is the product of the pool of growing follicles (Guyton & Hall, 2006; Lund, 2008; Sievert, 2006; Woods & Mitchell, 2004). Together their primary function is to down regulate the synthesis of FSH and inhibit subsequent secretion. The cyclic nature of menstruation relies upon the complex feedback loops of the ovarian hormones to ensure the female body is conditioned for reproduction.

The follicular phase incorporates everything from menses, referred to as Day One, to ovulation, which generally occurs around Day Fourteen of the cycle. During menstruation the low levels of oestrogen and progesterone allow the production of FSH to peak during the first few days of the new cycle. During this increase, the pool of antral follicles compete against each other until the follicle releasing the highest concentration of inhibin A, thereby

inhibiting further development of the remaining follicles, becomes the pre-ovulatory follicle. As this follicle continues to develop, increasing amounts of oestrogen and inhibin A are produced (Bray et al., 2005; Burger, Dudley, Robertson, & Dennerstein, 2002; Sievert, 2006). The increasing concentration of oestrogen acts on the uterus, stimulating regeneration and growth of endometrial remnants left after the previous menstrual cycle (Bray et al., 2005; Guyton & Hall, 2006). The rise in oestrogen also induces a mid cycle LH surge which triggers ovulation (Burger et al., 2007). The luteal phase follows ovulation and encompasses everything from this point to menses. Oestrogen continues to promote proliferative activity in the endometrium, while under the action of progesterone, the endometrial glands become primed for implantation. If implantation does not occur, the corpus luteum regresses, there is a rapid fall in the secretion of oestrogen and progesterone and the endometrium enters a state of ischemia, precipitating the onset of menses (Guyton & Hall, 2006; Huether & McCance, 2008).

The hormonal alterations that occur in response to the depleting antral follicle pool can be seen as early as the fourth decade (Lund, 2008; MacNaughton, Banah, McCloud, Hee, & Burger, 1992; Santoro, Brown, Adel, & Skurnick, 1996; Woods & Mitchell, 2004). It has been theorised that both inhibin A and B plays a significant role in the initial endocrine changes that occur prior to menopause (Burger et al., 2002; Lund, 2008). As the number of follicles diminishes, the concentrations of inhibin's decrease, weakening the complex negative feed-back loop that forms part of the mechanism controlling the concentration of FSH (Guyton & Hall, 2006; Lund, 2008; MacNaughton et al., 1992; Santoro et al., 1996). This results in a higher than usual FSH concentration, thereby stimulation of the pre-ovulatory follicle continues, preserving normal levels of serum oestrogen through the early stages of menopause (Lund, 2008). As ovulation ceases, the levels of inhibin A fall, reflecting the lack of a pre-ovulatory follicle available for stimulation. It is at this point that the concentration of oestrogen falls, thus even higher levels of FSH result. Further to this, progesterone levels remain low throughout the cycle since there is no corpus luteum in an anovulatory cycle. These physiological mechanisms underpin the natural shift from regular cycles of ovulation and menstruation towards permanent infertility.

Stages of Menopause

In 2001 the Stages of Reproductive Aging Workshop (STRAW) was held by the North American Menopause Society to develop a staging system for late reproductive function. Perimenopause was split into two phases: early and late. A woman was deemed to be in the early phase when the length of her menstrual cycle changed by seven days or more but menses were still occurring regularly (McKinlay, 1996; Soules et al., 2001). The late phase was characterised by two skipped menstrual cycles and at least one intermenstrual interval of 60 days or more. (Soules et al., 2001). The mean age of onset for perimenopause is reported to be between 45.5 and 47.5 years (Burger et al., 2002; McKinlay, 1996) with an average duration of 4 years (Burger et al., 2002). However, these parameters vary considerably between women. Many women find it difficult to pinpoint their final menstrual period (FMP) as a result of the indefinite time period over which perimenopause can occur and the possibility of long-term irregularity and amenorrhoea (Burger et al., 2007; McKinlay, 1996).

Risks associated with early or late menopause

As life expectancy increases, the factors that influence the average age at which women begin menopause have become important. This is mainly due to the number of postmenopausal health problems that can arise when menopause is reached outside of the normal range. Early onset of menopause results in premature exposure to low oestrogen levels leading to a greater incidence of cardiovascular disease and osteoporosis (Gallagher, 2007; Rossouw et al., 2002). Hu et al. (1999) reported that women who begin menopause before the age of 50 years incur a risk of cardiovascular disease that is 38% higher than women who begin menopause after this age. Further to this, each year that menopause is postponed, it has been estimated that there is a 2% fall in the mortality due to cardiovascular disease (Hu et al., 1999; Parente, Faerstein, Celeste, & Werneck, 2008; van der Schouw, van der Graaf, Steyerberg, Eijkemans, & Banga, 1996). Similarly, premature exposure to decreased oestrogen can lower bone density therefore resulting in higher fracture rates and an increase in the prevalence of osteoporosis (Gallagher, 2007). Although there are clear adverse health consequences associated with early menopause, later menopause is also linked with negative health ramifications. McPherson, Steel and Dixon

(2000) suggest that mammary cells proliferate in response to prolonged exposure to oestrogen, possibly leading to hyperplastic changes and the increased risk of developing breast cancer (Clemons & Goss, 2001). Ovarian and uterine cells are thought to be affected by the same mechanism, however there is little more than anecdotal evidence based on clinical observation to support this theory. The relationship between cardiovascular disease and early menopause is strongly evident (Hu et al., 1999), more so than that of the relationship between breast cancer and late menopause. However, as yet there is insufficient evidence to evaluate the relative risk associated with the occurrence of menopause onset.

Factors Influencing the Onset of Menopause

Several factors have been implicated in influencing the age of menopause, including smoking, obesity, alcohol consumption, socio-economic status, later menarche, long menstrual cycles, multiparity and the use of oral contraceptive (Chang et al., 2007; Dvornyk et al., 2006; Kato et al., 1998; Lawlor, Ebrahim, & Smith, 2003; Wise, Krieger, Zierler, & Harlow, 2002). Smoking, alcohol consumption and obesity are the most heavily researched of these and investigations into the remaining factors are sparse and variable.

Smoking

One of the strongest and most clearly demonstrated factors influencing age at menopause is cigarette smoking. Evidence consistently suggests women who smoke during the transitional period reach menopause 1-2 years earlier than non-smokers (Harlow & Signorello, 2000; Kinney, Kline, & Levin, 2006; Mikkelsen, Graff-Iversen, Sundby, & Bjertness, 2007; Parente et al., 2008; van Asselt et al., 2004). Despite this, there is uncertainty in the literature about the relative effects of past smoking, smoking doses and duration of smoking.

It is postulated that tobacco smoke contains polycylic hydrocarbons that may be toxic to ovarian germ cells. Subsequently this may lead to oestrogen deficiency related to follicular exhaustion and the consequent increase in FSH due to diminishing inhibin levels (Harlow & Signorello, 2000; Parente et al., 2008; van Asselt et al., 2004). Moreover, alkaloid

components of tobacco smoke, including nicotine and anabasine, may have a metabolic effect, lowering oestrogen levels by interfering with the pathways involved in synthesis (Harlow & Signorello, 2000). Cigarette smoke constituents are thought to inhibit granulosa cell aromatase and other key enzymes in oestrogen synthesis, with the result of reducing oestrogen production in-situ. The effect of ovarian destruction would still be present even if a woman had stopped smoking before she transitioned to menopause, whereas an effect resulting from altered oestrogen synthesis would occur only if she was currently smoking.

The literature identifies no clear relationship between a history of smoking and the age at which menopause occurs. Kinney et al. (2006) proposed that age of menopause among former smokers is comparable to that among women who never smoked. Mikkelsen et al. (2007) furthered this idea suggesting that cigarette smoking has to have ceased 10 years prior to menopause to considerably reduce the risk of early onset. In contrast to these hypotheses, it could be assumed that a history of smoking would have a substantial effect on age of menopause if there was a permanent loss of ovarian follicles, as has been theorised to result from cigarette use (Harlow & Signorello, 2000; Parente et al., 2008). It is possible that follicles of younger women are more resistant to the effects of smoking and that early cessation of smoking prevents substantial loss of ovarian germ cells. There is, however, no evidence to substantiate this claim. Alternatively, it might be that the more temporary metabolic effect of cigarettes in current smokers has a much greater effect on the levels of oestrogen compared to the influence of past ovarian germ cell destruction. Van Asselt et al. (2004) apparently favour this latter explanation and have stated that smoking at the time of perimenopause is much more important than smoking history in explaining an earlier onset of menopause. There is insufficient knowledge surrounding the interaction between the constituents of tobacco and the female reproduction organs to determine which of these mechanisms is the dominant factor. It is likely that a combination of permanent ovarian germ cell destruction, and the continued alteration in oestrogen synthesis occurring in current smokers is the reason for the proposed effect of age in perimenopausal women.

There is a significant amount of literature that supports the relationship between current smoking and early menopause, however there is little known about the effect of dose and

duration. Kinney et al. (2006) reported that women who were classified as heavy smokers, defined as smoking 14 or more cigarettes per day at the time of their final menstrual period, were likely to experience menopause 2.8 [95% Confidence Interval -4.8 – -0.8] years earlier than non smoking women**.** Further to this, Mikkelsen (2007) conducted a population based, cross-sectional study that included a sub sample of 2,123 postmenopausal women born between 1940 and 1941. The results showed that total exposure to smoking (calculated as the product of the number of cigarettes per day and the length of time as a smoker) was positively related to early menopause and, at the highest doses, nearly doubled the odds of early onset. In a subsequent systematic review of the relationship between smoking and age at menopause, Parente (2008) concluded that there was insubstantial evidence to draw a conclusion on the relationship between the two variables and age at menopause. It is unknown why the studies conducted by Mikkelesen et al. and Kinney et al. were not included in the review; however the conflicting evidence illustrates the requirement for further research to be undertaken to provide definitive results.

Alcohol Consumption

Compared with the interest in smoking, few studies have examined the consumption of alcohol in relation to age at menopause. Alcohol consumption increases levels of plasma oestrogen in pre- and postmenopausal women (Gill, 2000). With respect to postmenopausal women, Katsouyanni, Boyle and Trichopoulous (1991), Hankinson et al. (1995) and Nagata Kabuto, Takatsuka and Shimizu (1997) have all reported a positive association between alcohol and oestrogen levels. The largest of these studies, Katsouyanni et al. noted that urinary oestrogen levels increased by 20% in response to a daily intake of one standard drink. Kinney et al. (2006) collected extensive data pertaining to the amount and frequency of alcohol consumption. The estimated age at natural menopause was 2.2 [95% CI 0.5 – 3.9] years later for women who drank alcohol 5 – 7 days per week when compared to women who drank no alcohol (Kinney et al., 2006). When results were analysed in terms of standard drinks per week, women who fell into the higher consumption bracket on average reached natural menopause 2.9 [95% CI 0.2 – 5.5] years later than women who drank no alcohol (Kinney et al., 2006). The findings from the latter study are consistent with the smaller studies (Mikkelsen et al., 2007; Torgerson, Thomas, Campbell, & Reid, 1997) without the

absence of key methodological and statistical information. Despite this, further research needs to be undertaken to reproduce and corroborate the research reported by Kinney et al.

Obesity

Obesity is considered to be an independent factor not only affecting general mortality and morbidity, but also inducing early onset menopause and aggravating related symptoms (Mastorakos & Paltoglou, 2009). Menopause is associated with the redistribution of adipose tissue, leading to increased abdominal fat stores and increased risk of chronic illness (Teede, Lombard, & Deeks, 2010). It is commonly accepted that obese women have increased peripheral conversion of androstenedione to oestrogen and that this, combined with a reduction in the circulating sex hormone-binding globulin, leads to an overall increase in the bioavailable oestrogen (Harlow & Signorello, 2000; Kato et al., 1998; Morris & Currie, 2010). Body size and fat distribution have been analysed in relation to age at menopause, as it is hypothesised that the hormonal and metabolic changes associated with obesity may contribute to a delay in the onset of menopause (Hardy, Mishra, & Kuh, 2008). Results from general population studies however have been inconsistent, showing either no association (Do et al., 1998) nor that heavier women have a later menopause (Kato et al., 1998).

In a large longitudinal study analysing 5,961 Australian female twins aged 17 – 88 years for potential predictors of age at natural menopause, Do et. al (1998) reported no relationship between level of obesity and onset of menopause when analysing the entire cohort. Despite reporting this finding there was insufficient numerical information included in the report to determine the size of this effect. In a prospective study, Kato et. al. (1998) analysed data from the New York University Women's Study, in which 4,694 premenopausal women aged between 34 – 61 years were followed for an average of 5.4 years. Compared with women in the lowest quintile of body mass index, the relative risks for the third, fourth and fifth quintiles were 0.99, 0.88 and 0.87 respectively. Conclusions were drawn that the more estrogenic environment associated with female obesity delayed the onset of menopause by several years (Kato et al., 1998). Furthermore, it is claimed that extreme leanness resulting from serious illness or excessive exercise combined with relative dietary

restriction, can suppress ovarian function resulting in the early onset of menopause (Kato et al., 1998). In addition, due to the limited numerical reporting, there was a lack of advanced statistical correction that would have been required to account for confounders such as other medical problems or current medications. It is conceivable that the effect of obesity on age at menopause is not direct, but comes about through a range of factors not always accounted for in statistical analysis. Additional research into the effect of obesity on age at menopause is required, especially given the health problems that can stem from later menopausal onset. Determining the importance of the relationship could be imperative to managing the onset and symptoms of menopause (Rachoń & Teede, 2010), particularly in light of the global obesity epidemic.

Symptoms

Perimenopausal women experience a variety of symptoms which can be broadly grouped into vasomotor, sexual, physical or psychological complaints (Rahman et al., 2010). Common symptoms include, but are not limited to: hot flushes, night sweats, joint pain, muscle tension, panic attacks, headaches/migraines, fatigue and depression (Cleary & Fox, 1994; McKinlay, 1996; Rahman et al., 2010). Symptoms associated with menopause are thought to escalate in the lead up to a women's FMP. Irrespective of their severity, they can be disabling, affecting a women's social life, psychological health, sense of well-being and ability to work (Bruce & Rymer, 2009).

Vasomotor Symptoms

Hot flushes, sweating and night sweats are cumulatively termed vasomotor symptoms and are commonly discussed between patient and physician. They are a major cause of reduced quality of life in a large percentage of perimenopausal women, but, as they are not fatal and generally subside of their own accord, there has been little research or clinical interest (Sturdee, 2008). The impact of hot flushes, in particular, on quality of life is considerable and often underestimated. Flushing may regularly interfere with work and daily activities, as well as sleep, causing insomnia, fatigue, loss of concentration, decrease in output, and depression, all of which can interfere with family and personal relationships (Andrikoula & Prelevic, 2009; Freedman, 1998; Sturdee, 2008). There are considerable differences in the

severity of vasomotor symptoms reported in different countries and among different races. In Europe and North America, the hot flush is reported as the most common symptom of menopause, affecting around 70% of women and persisting on average for 2 – 5 years, although some 20% continue to flush into their seventies and eighties (Andrikoula & Prelevic, 2009). By comparison, they are a relatively unreported symptom in Japanese populations, affecting between 5-18% women (Andrikoula & Prelevic, 2009; Freeman & Sherif, 2007). Given the large disparity between European and Asian cultures it is difficult to determine whether the lower rates of reporting in Asian countries is because they do not suffer from them or they do not consider it culturally acceptable to discuss it.

The physiology of the menopausal hot flush is poorly understood. Given their systemic nature, they are likely to arise from an alteration in the central nervous system thermoregulatory set-point located in the anterior portion of the hypothalamus. Changes in core body temperature are recognised in the thermoregulatory centre, which controls physiological reponses that either conserve or dissipate heat (Stearns et al., 2002). In non-symptomatic women core temperature is maintained by balancing heat production from metabolism and heat loss via sweating and cutaneous vasodilation, or heat conservation by cutaneous vasoconstriction (Freedman, 1998). In premenopausal women the threshold between shivering and sweating is wide, however, as women begin to go through menopause this threshold narrows (Stearns et al., 2002). As a result of an external trigger, such as a change in ambient temperature, immediate changes in hormones lead to the sensation of a hot flush (Stearns et al., 2002). The trigger initiates a series of heat loss mechanisms, including cutaneous vasodilation, flushing and sweating, which cause a slight drop in core temperature and relief from symptoms (Stearns et al., 2002). It is not known what causes the alteration in the thermoregulatory set-point, although it is thought to be mediated by the change in plasma oestrogen concentrations as women progress through menopause (Andrikoula & Prelevic, 2009; Sturdee, 2008). Oestrogen levels are known to decline throughout menopause and women with low circulating concentrations of oestrogen are more likely to be subjected to hot flushes (Stearns et al., 2002). However, oestrogen levels remain low throughout menopause and the frequency of hot flushes generally subsides throughout this transition. Moreover, according to Sturdee (2008), young women with ovarian dysgenesis, a congenital condition resulting in the malfunction of the

ovaries, never have hot flushes despite very low levels of oestrogen. Thus, it may be that the initial drop in oestrogen is responsible for the narrowed thermoregulatory set-point, which through other biochemical changes such as the altered concentrations of gonadotropins and neurotransitters, remains reduced for the duration of the transition (Stearns et al., 2002). The limited understanding surrounding the aetiology of vasomotor symptoms renders them difficult to alleviate in perimenopausal women.

Sexual Symptoms

Sexual function is a complex, integrated phenomenon that reflects the health and coordination not only of the ovaries and hormones, but also of the cardiovascular system, the brain, the spinal cord and the peripheral nerves (Alan, 2004; Levin & Riley, 2007). The stability of a women's relationship with sexual partners, attitudes toward sex and aging, vaginal dryness, and cultural background have a much greater impact on sexual functioning than menopause itself (Northrup, 2006). Women often report change in sexual desire, a loss of libido or vaginal dryness during menopause; however, given the multitude of interlinking factors that contribute to healthy sexual function, it is a difficult area to assess. Vaginal dryness is thought to be the most common sexual symptom that occurs as a direct result of lower oestrogen levels (Bruce & Rymer, 2009; Ogurlu et al., 2010). The vagina is rich in oestrogen receptors, and a decline in oestrogen levels through the menopause transition can lead to a loss of elasticity, vascularity and adiposity in this region (Sievert, 2006). As a result, midlife women report painful sexual intercourse more often than younger women (Northrup, 2006; Sievert, 2006). Women who are not having sexual relations may not necessarily notice a change however, dryness can also lead to irritation, burning sensations and more urinary tract infections (Sievert, 2006). Given the highly personal and multi-factorial nature of sexual related symptoms they are often only reported to health practitioners once they reach an unmanageable level.

Musculoskeletal Symptoms

Women experience symptoms such as joint aches and pains, headaches and general stiffness at many times during their lives, not only during menopause. Wood and Mitchell (2005) suggest that the prevalence of these symptoms increases from 41% in late

reproductive stage, to 47% throughout the early menopause transition and to 53% at in late menopause (Woods & Mitchell, 2005). This increase could be attributed solely to the aging process, but with the physiological changes occurring at this time it is likely that both menopause and increasing age contribute to the increase in symptoms. Osteoarthritis (OA), described as internal degeneration of the joint surfaces as a result of lifetime wear and tear, is a significant determinant of joint and muscle pain in the aging population, especially women (Gallagher, 2007). It is postulated that oestrogen deficiency plays a role in initiating or accelerating the degenerative process, however its specific effect is not known (Magliano, 2010). Treatment of OA with HRT has produced conflicting results on cartilage degradation and repair, which may stem from the various definitions of OA and the varied prescriptions of HRT utilised (Birchfield, 2001; Magliano, 2010). As a result women taking HRT have shown both lower (Soules et al., 2001) and higher (von Mühlen, Morton, von Mühlen, & Barrett-Connor, 2002) incidences of OA and osteoporotic fractures, particularly of the hip. Apart from the potential role of declining oestrogen, another possibility to explain the marked prevalence of musculoskeletal complaints through perimenopause is that these symptoms are manageable until they are combined with other perimenopausal factors and symptoms.

Psychological Symptoms

Bruce and Rymer (2009) suggest that there is a higher incidence of depressive illnesses in women than in men, and these are exacerbated during midlife. It is well known that physiologically unstable endocrine periods in life such as puberty, pregnancy, the postnatal period, the premenstrual phase and menopause, are associated with an increased likelihood of developing depressive tendencies (Birkhäuser, 2002). Common symptoms include but are not limited to feeling “blue”, loss of memory, irritability, poor concentration, tiredness and loss of self-confidence (Bruce & Rymer, 2009). A bio-cultural perspective suggests that although there a number of oestrogen, progesterone and testosterone receptors in the brain (Bruce & Rymer, 2009; Guyton & Hall, 2006), cultural context provides unique pressure and concerns that contributes to the risk of depression among women undergoing the menopausal transition. Many women throughout the Western world are dealing simultaneously with persistent hot flushes, concerns about adolescent children, responsibility for aging parents, daily stresses and financial pressures (Birkhäuser, 2002;

Northrup, 2006; Sievert, 2006). The onset of depressive illness during midlife cannot be clearly attributed to menopause alone, however the combination of hormonal changes and non-endocrine risk factors common during this phase are likely to be the cause of exacerbated symptoms (Judd, Hickey, & Bryant, 2012). Given the diversity of symptoms, and the complex, multi-factorial aetiology, effective treatment has yet to be determined.

Conventional Treatment

Hormone Replacement Therapy (HRT)

Oestrogen products to ameliorate or eliminate symptoms of menopause such hot flushes and night sweats, vaginal dryness and atrophy were first approved by the Food and Drug Administration in 1941. Several studies have shown that oestrogen and combined oestrogen-progesterone therapies reduced vasomotor symptoms and vaginal complaints by up to 77% [95% CI 58 – 88] relative to a placebo (MacLennan, Lester, & Moore, 2001). However, there is limited research to suggest that HRT has the same degree of benefit on musculoskeletal and depressive symptoms associated with menopause. Positive effects of HRT on musculoskeletal symptoms were found in an Australian study of 2,130 postmenopausal women, of whom 63% complained of joint ache and muscle pain at study entry. After one year of treatment the proportion of women experiencing joint pain decreased to 57% in women allocated to combined HRT, but stayed the same in the placebo group (Welton et al., 2008). These results followed an intervention period of 12 months and medication was only given to those women suffering from concurrent severe vasomotor symptoms. Similarly, the effects of HRT on depressive symptoms are contradictory. Randomised controlled trials investigating the effect of HRT on depressive symptoms in perimenopausal women without a current diagnosis of depression, have reported both reduced scores for measures of depressive symptoms (Yaffe, Sawaya, Lieberburg, & Grady, 1998) and no effect on mood (van Duijn, 1996). Further research needs to be conducted to determine the safety and effectiveness of HRT in a cohort of women suffering from musculoskeletal complaints in the absence of vasomotor symptoms. Moreover, the role HRT plays in alleviating depressive symptoms needs to be further investigated.

HRT has generated significant controversy in the 60-plus years since it was FDA approved. In the late 1970's oestrogen given alone was found to increase the risk of uterine cancer due to its proliferative action (Cabot, 2005; Grady, Gebretsadik, Kerlikowske, Ernster, & Petitti, 1995; Rossouw et al., 2002; Smith, Prentice, Thompson, & Herrmann, 1975; Ziel & Finkle, 1975). Synthetic progesterone was thereafter combined with oestrogen to decrease the risk in women with a uterus. Although in avoiding HRT-induced uterine cancer new dangers were uncovered, namely, increased risk of breast and ovarian cancers, cardiovascular disease and blood clots (Rossouw et al., 2002).

Risks of Hormone Replacement Therapy

In 1992 the Women's Health Initiative (WHI), developed a multi-arm study which sought to compare the effectiveness of postmenopausal HRT, diet modification and vitamin supplements on heart disease, hip fractures, breast and colorectal cancers (Rossouw et al., 2002). The hormone trial had two arms; the oestrogen-alone study of women without a uterus and the oestrogen-plus-progesterone study of women with a uterus. In the combined hormone trial 16,608 healthy postmenopausal women were recruited from 40 clinical centres around America and randomised into a treatment (n=8,506) or placebo group (n=8,102). The planned duration of the study was 8.5 years however in 2002, 5.2 years into the study, the trial was stopped following a recommendation from the data and safety monitoring board (Rossouw et al., 2002). This recommendation arose primarily because analysis showed that the incidence of coronary heart disease, invasive breast cancer, stroke and pulmonary embolism were not counter-balanced by the small reductions in hip fractures and colorectal cancers (Rossouw et al., 2002).

The Million Women Study was a national study of more than one million British women aged 50 and over (Beral, Bull, Green, & Reeves, 2007). It was a collaborative project which saw Cancer Research UK and the National Health Service work together to answer many questions about the factors affecting women's health in this age group. One aspect of the study investigated the relationship between specific types of cancer, in particular ovarian and breast, and HRT. Postmenopausal women (n=948,576) with no previous cancer or history of hysterectomy were included in the analyses. Of these women 50% had used HRT

at some stage throughout their transition and 30% were still current users (Beral et al., 2007). The average follow up was 5.3 years per woman for incidence of ovarian cancer and 6.9 years for death. Current users of HRT were 1.20 times [95% CI 1.09 – 1.32] more likely to develop ovarian cancer and 1.23 [95% CI 1.09 – 1.38] times more likely to die from it than non-users of HRT (Beral et al., 2007). In women who were current users of HRT, the risk of ovarian cancer was greater with increasing duration of use, but did not vary according to the hormonal constituents, the mode of administration, or the type of HRT regime (Beral et al., 2007). Women who developed ovarian cancer were diagnosed on an average of 2.4 years after the date that HRT use was last reported (Beral et al., 2007). The results corroborated findings of previous studies (Bosetti et al., 2001; Folsom, Anderson, & Ross, 2004; Risch, 1996) although there is limited scope to draw comparison because past studies included relatively few women within their cohorts who used HRT and subsequently developed ovarian cancer.

As with the risk of ovarian cancer, prior to the Million Women Study little was known about the relationship between HRT use and the incidence of breast cancer. Participants (n=1,084,110) aged between 50 – 64 years, provided information about their HRT use and were followed up for cancer incidence and death. There were 9,364 cases of invasive breast cancers reported after a follow-up period of 2.5 years and 637 deaths reported after a total follow up period of 4.1 years (Million Women Study Collaborators, 2003). Current users of HRT at recruitment were 1.7 times [95% CI 1.6 – 1.8] more likely than those who had never used HRT to develop breast cancer and 1.2 [95% CI 1.0 – 1.5] times more likely to die from it (Million Women Study Collaborators, 2003). Past users of HRT were, however, not at an increased risk of incident or fatal disease compared to those who has never used it (Million Women Study Collaborators, 2003). The Million Women Study Collaborators (2003) reported further data that suggested that the risk of breast cancer was greater in those women that use combined hormone therapy than those who use oestrogen-only formulations. This finding has since been corroborated by large cohort studies completed following the initial results of the Million Women Study (Beral, Reeves, Bull, & Green, 2011; Reeves, Beral, Green, Gathani, & Bull, 2006).

Rossouw et al. (2002) highlighted that the WHI only tested one drug regime in the target population and the results did not necessarily apply to lower dosages of these drugs, other formulations of oral oestrogen and progesterone, or to oestrogens and progesterone administered through the transdermal route. Despite these limitations, the results from the WHI study and those from the Million Women Study provided the first definitive data on the long-term effects of HRT. In the wake of these findings, long term HRT has been supplanted by shorter courses of HRT to control perimenopausal symptoms. The oestrogen-stimulated endometrium still requires protection during the limited duration of HRT, thus the addition of progesterone is considered to be mandatory (Leonetti, Landes, Steinberg, & Anasti, 2005; Leonetti, Longo, & Anasti, 1999). Successful HRT depends upon the safety of the prescribed medication, patient acceptance and adherence. One of the main factors for reduced adherence is the potential for short-term systemic side effects often caused by the progesterone element of the medication. Symptoms commonly attributed to progesterone range from fluid retention, to adverse effects on skin, breast tenderness, bloating, atypical uterine bleeding and perception of weight gain, although it should be noted that these symptoms can and do occur in women who are taking oestrogen-only medications (MacLennan et al., 2001; Panay & Studd, 1997).

Transdermal application of progesterone-based creams for the treatment of perimenopausal complaints and endometrial protection has not been readily studied until recently in light of the systemic side effects caused by oral formulations of HRT. Leonetti et al. (1999) completed a double-blind, placebo-controlled trial that evaluated the effectiveness of transdermal progesterone cream on hot flushes and bone density. While 83% of the treatment group, compared to 19% of the placebo participants, reported improvement or resolution of hot flushes, the number of women showing a gain in bone mineral density exceeding 1.2% did not differ (Leonetti et al., 1999). Many of the women reported the application of vaginal medication uncomfortable and time consuming. Leonetti et al. (2005) subsequently completed a cross-over study that investigated the acceptance and endometrial effects of combined HRT compared to transdermal progesterone cream. Results indicated that there was a negligible difference in post-treatment endometrial biopsies, and 75% of women stated their preference for progesterone cream as opposed to the combined HRT, reporting a marked difference in systemic side effects (Leonetti et al.,

2005). Further research is necessary before the efficacy of progesterone creams in the treatment of menopause-related symptoms can be objectively determined. They are however beneficial when used in conjunction with oestrogen-based treatment to provide endometrial protection as the degree of systemic side effects is reduced (Leonetti et al., 2005). In spite of this, many women are tending to favour intrauterine systems, in which a long-acting, reversible hormonal contraceptive device is placed within the uterus. The local release of progesterone from these appears to further reduce systemic side effects and the system provides a high-level contraception (Leonetti et al., 2005; Leonetti et al., 1999; MacLennan et al., 2001).

Despite the likely efficacy of HRT for the treatment of vasomotor symptoms, the negative connotations now associated with HRT following the WHI and the Million Women study have resulted in women seeking alternative treatments in a bid to alleviate symptoms associated with menopause.

Alternative Treatment

Complementary and Alternative Medicine (CAM) has been defined as "a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine" (Kessel & Kronenberg, 2004, p. 717). Despite this seemingly straightforward definition there is controversy over what is considered a CAM and what is considered conventional medicine. Interest in CAMs for the treatment of perimenopausal symptoms has increased markedly, particularly in the last few years following the results from the WHI and the Million Women Study. Therapies such as bioidentical hormones, acupuncture, exercise therapy, homeopathy, meditation and osteopathy may help to alleviate symptoms; however there is little scientific literature that supports their safety and efficacy for the treatment of menopausal symptoms. The most researched non pharmacological therapies include acupuncture and exercise therapy (Kessel & Kronenberg, 2004; Rees, 2006, 2009); investigations into other therapies such as meditation and homeopathy are limited and unreliable.

Bioidentical Hormones

A hormone is said to be bioidentical if it has exactly the same molecular structure as a hormone produced naturally in the human body (Cabot, 2005). Derived from plants, bioidentical oestrogen cannot be distinguished from its natural counterpart produced in the ovaries. Similarly, standard laboratory tests are unable to distinguish these and reflect the total oestrogen concentration including the bioidentical hormone as well as oestrogen produced in-situ. On the other hand, many HRTs are metabolized into various forms of oestrogen that are not measured by these laboratory tests. Proponents of bioidentical hormones contend that one advantage of bioidentical oestrogen over conventional treatments is that oestrogen levels can be monitored more precisely and treatment individualized accordingly (Northrup, 2006). This is countered with the argument that knowing precise levels hardly matters because it is extremely difficult to know what hormone level to target and symptoms, not levels, should be treated and monitored (Bosarge & Freeman, 2009; Files, Ko, & Pruthi, 2011).

Bioidentical HRT is used in the USA, UK, and New Zealand by alternative health care practitioners for the treatment of symptoms of menopause, with the prevailing assumption that bioidentical HRT provides the benefits of conventional HRT while attenuating the risks (Curcio, Wollner, Schmidt, & Kim, 2006). As these custom preparations are individually created depending on the needs of the patient there is no guarantee of efficacy, safety or consistency (Chervenak, 2009; Curcio et al., 2006). These preparations can vary in their ingredients and dosages from patient to patient. Moreover, the formulations can vary by batch and by pharmacist, and the patient may not get consistent or constant amounts of hormones. Despite these potential downfalls, the promising nature of this treatment approach lacks sufficient data from well-designed comparative trials to support its safety or efficacy (Bosarge & Freeman, 2009). Therefore, promotion of the therapy is based on anecdotal evidence which raises ethical questions about the potential for false and misleading claims relating to bioidentical HRT (Bosarge & Freeman, 2009; Chervenak, 2009).

Acupuncture

Traditional Chinese Medicine acupuncture has long been advocated for the treatment of gynaecological problems (Proctor et al., 2002), including those related to perimenopause (Northrup, 2006). The insertion of fine needles into the skin and underlying tissues has been shown to excite mechanoreceptors which, through interactions with serotonin and endorphins, alter outgoing signalling (Proctor et al., 2002). Several randomised controlled trials have shown consistent results regarding the efficacy for acupuncture on reducing vasomotor symptoms in peri- and postmenopausal women (Borud & White, 2010; Cho & Whang, 2009; Lee, Shin, & Ernst, 2009). In a recent multi-centred randomised controlled trial both peri- and postmenopausal women were allocated into two groups: acupuncture plus usual care (n=116) and usual care alone (n=59) (Kim et al., 2010). The constituents of usual care were not described, but women taking HRT were excluded from the study (Kim et al., 2010). The treatment group received 12 acupuncture sessions and maintained usual care for four weeks, while the control group underwent usual care alone. Kim et al. (2010) reported a 62% reduction in the frequency and severity of hot flushes in the treatment group compared to a 27% reduction in the usual-care group indicating that acupuncture may be an effective alternative treatment for women who wish to avoid pharmaceutical products to control the symptoms. Earlier studies reported similar results but small sample sizes and poor design of placebo control render their results invalid when compared to the Kim et al. study.

Another recent study, the 'Acupuncture on Hot Flushes Among Menopausal Women' study was a multicenter, randomised controlled trial, conducted in 2006 and 2007 (Borud, Alraek, White, & Grimsgaard, 2010). Participants were postmenopausal women (n=267) experiencing, on average, seven or more hot flushes per 24 hours. Of these women 134 were randomised to acupuncture combined with self care and received 10 individualised Traditional Chinese Medicine acupuncture treatment sessions over 12 weeks. The remaining 133 participants were allocated to the control group and received only advice on self-care (Borud et al., 2010). A one-page leaflet contained information about self-care strategies such as stress management and regular sleep patterns, to relieve menopause symptoms, and study participants were free to use any of these. Broud et. al. (2007) reported results that illustrated the short term reduction in the frequency of hot flushes,

from 12.6 per 24 hours to 3.7 in the treatment group and 5.8 in the control group. Hot flush intensity also decreased by 3.2 units per day in the acupuncture group and 1.8 units in the control group (Borud et al., 2010). These results were no longer present at 6- and 12-month follow ups. The authors concluded that acupuncture can contribute to a more rapid reduction in vasomotor symptoms and therefore increase quality of life in postmenopausal women with no likely long-term effects (Borud et al., 2010). Despite these promising results, many women avoid acupuncture because of the perceived pain and fear associated with placing needles into the body (Proctor et al., 2002), thus may not choose this therapy for perimenopausal symptoms.

Exercise Therapy

Exercise has long been known for its positive effects on general health but has only recently been implicated in providing benefit for women suffering from perimenopausal complaints. Regular activity is thought to reduce vasomotor symptoms, mood swings and sleep disturbances and increase cardiovascular and musculoskeletal health (Ağıl, Abıke, Daşkapan, Alaca, & Tüzün, 2010; Lindh-Åstrand, Nedstrand, Wyon, & Hammar, 2004). Lindh-Astrand et al. (2004) used a Single System Design to determine if regular physical exercise or oral oestrogen therapy decreased vasomotor symptoms and increased the quality of life in previously sedentary post menopausal women. Participants were randomised to either the oral oestrogen therapy (15), or exercise (10) groups. The duration of the study was 12 weeks and participants in the latter group completed 3 hours of aerobic exercise per week. In the exercise group the frequency of hot flushes decreased from 5.1 (Standard Deviation 2.8) flushes per 24 hours to 3.8 per 24 hours (SD 3.0), a reduction of approximately one third, while in the oestrogen group flushes reduced from 8.3 (SD 3.1) per 24 hours to 0.8 (SD 1.2) per 24 hours. The most significant limitation of this study is that the exercise intervention was poorly defined, stating that the intensity of exercise had to be of a level that caused the participant to shower following activity. A more well defined definition and adequate control over participants exercise habits would render more valid data. In more recent research Ağıl et al. (2010) also used a Single System Design to investigate whether the presence of menopausal symptoms was influenced by different types of exercise. Participants were randomised into aerobic (15) and resistance groups (15) and exercised 3 days per week for 8 weeks under the supervision of a physiotherapist (Ağıl et al., 2010).

Overall there was a large reduction in the frequency of hot flushes but there was little difference detected when comparing the effect sizes of the aerobic (0.14) and resistance (0.54) exercise programmes. The most notable difference between the aerobic and resistance groups was found in the effect sizes of the physical domain, 0.78 and 0.49 respectively. Despite the promising nature of these preliminary results, further research utilising randomised controlled trials needs to be conducted to determine the true effect of exercise on menopausal related symptoms.

Osteopathic Manual Therapy (OMT)

In 1884 Andrew Taylor Still coined the term Osteopathy. It is derived from two Greek words; 'osteon' meaning 'bone', and 'pathos' meaning 'suffering' (Parsons & Marcer, 2006). Whilst there is no stringent definition for osteopathy, it is widely accepted that the principles that underpin diagnosis and treatment emphasise the structural and functional integrity of the body. Osteopathy is "distinguished by the fact that it recognises that much pain and disability stems from abnormalities in the function of the body structure as well as damage caused to it by disease" (Parsons & Marcer, 2006, p. 5). To date only one study has investigated the efficacy of osteopathy for treatment of symptoms related to menopause.

Cleary and Fox (1994) conducted a study that aimed to investigate the effect of "Fox's low-force" osteopathic technique on 30 subjects with menopausal symptoms. The treatment group (n=15) received "Fox's low-force" technique to joint restrictions in the spine. A finger or thumb was used to deliver a low force to the joint in a direction that would relieve the apparent movement restriction. This technique is proposed by Fox to relax the joint's protective mechanism, via the muscle spindle, by increasing the length of the muscle, thereby improving mobility and neurological function (Cleary & Fox, 1994). The results showed that change in the treatment group between Week 1 and Week 10 was greater than the control group for the average symptoms score ($p = 0.005$). This study is unlikely to be reproduced as "Fox's low-force" techniques are a relatively unknown technique in osteopathy. In this study, the control group received the same technique as the treatment group, the difference being it was applied to an adjacent spinal segment. The assumption that this placebo treatment would have no effect goes against the holistic philosophies that

define osteopathy as delivering the technique, albeit to a non-dysfunction segment which may have some underlying effect. A further limitation is that there was no practitioner blinding, particularly relevant in this study because the author was the founder of the techniques used in the study, and may have thus had a greater bias in collection and interpretation of results. Despite the limitation of this study, the results that arose indicate osteopathy as a possible modality for the treatment of perimenopausal symptoms. Further research needs to be conducted in order to determine the effectiveness and safety of osteopathy on the treatment of the often debilitating symptoms of perimenopause.

Conclusions

Apart from insubstantial anecdotal evidence, there is little reliable research surrounding the efficacy of OMT in the treatment of perimenopause. This is true of most research pertaining to the effectiveness and safety of common alternative therapies. HRT remains as the pharmaceutical treatment of choice, however many women are seeking alternative forms of relief following the results and publicity that arose from the WHI and Million Women studies. Therefore, further investigation needs to be undertaken to determine the effect of these alternative treatments, specifically osteopathy, so they can be safely used and promoted within this cohort of women.

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Section Two

Manuscript

Note:

This manuscript has been prepared in accordance with the instructions for authors from the *International Journal of Osteopathic Medicine (IJOM)* [see Appendix O]. For the purposes of completion of this thesis some guidelines of *IJOM* have not been followed. In order to maintain readability and consistency of format throughout this thesis graphs, figures and tables have been included in the text. Line spacing has been set at 1.5 rather than 2.0, and APA Referencing has been used throughout to maintain consistency with Unitec presentation guidelines. The word limit has been exceeded to demonstrate the scope of work undertaken in this Mixed-Methods research and to allow a full and evaluative discussion of the results of this study.

Abstract

Background: The onset of perimenopause is a significant life event for a woman, carrying with it physical, medical, psychosocial and cultural significance. An estimated 85% of women report recurring symptoms that occur in the transition to menopause.

Objective: To determine if Osteopathic Manual Therapy delivered over four weeks is an effective modality for treating symptoms associated with perimenopause.

Methods: Six participants experiencing perimenopausal symptoms received four osteopathic treatments. Baseline and follow-up measures included the Menopause Quality of Life Questionnaire, the Greene Climacteric Scale and a Hot Flush Dairy in which participants recorded the frequency and intensity of any flushes. A follow up interview was also undertaken to gather information regarding their thoughts and experiences throughout the course of the treatments.

Results: The frequency and severity of perimenopausal complaints exhibited substantial and rapid reductions. Changes in the physical ($p < 0.005$) and psychological ($p = 0.007$) domains of the Menopause Quality of Life Questionnaire, along with the somatic ($p < 0.006$), anxiety ($p = 0.013$) and vasomotor ($p < 0.025$) domains of the Greene Climacteric Scale attained statistical significance. Communication, Overall Wellbeing and Lack of Knowledge arose as the key themes following qualitative analyses of the follow up interviews.

Conclusions: The results of this study indicate that Osteopathic Manual Therapy may be an effective modality for the reduction of perimenopausal symptoms. Further to this study, randomised controlled trials with greater participant numbers will help to provide more conclusive data about the possible benefit of this therapy for women experiencing perimenopausal symptoms.

Key words: Complementary and alternative medicine, menopause, osteopathy, hot flushes, menopause symptoms.

Introduction

Menopause is a normal physiological process that is experienced by women passing into midlife. The World Health Organisation defines menopause as "the permanent cessation of menstruation for 12 months or more" (World Health Organisation Scientific Group, 1996, p. 12). The physiological process of menopause, although not entirely understood, is well documented. From around 45 years of age only a small number of ovarian follicles remain to be stimulated and the production of female sex hormones decreases as the number of follicles approaches zero. The resulting hypogondal state may cause symptoms and detrimental changes in oestrogen target tissues, including the brain, skeleton, skin and the cardiovascular and genitourinary systems (Collins, 2006). An estimated 85% of women report at least one symptom throughout their transition, most notably hot flushes (Bruce & Rymer, 2009; Dennerstein et al., 1993; McKinlay, 1996; Woods & Mitchell, 2005). The often severe and debilitating nature of these symptoms are reported to effect attendance, concentration and output at work, as well as influencing one's social life, psychological health and sense of well-being (Ogurlu, Küçük, & Aksu, 2010). The inevitable physiological transition necessitates an effective treatment regime, despite the unknown aetiological factors influencing this midlife change.

Hormone Replacement Therapy (HRT) has been used to ameliorate or eliminate symptoms of menopause for over 70 years (Northrup, 2006). Multiple studies have illustrated the beneficial effect HRT has on reducing symptoms arising from oestrogen depletion, namely vasomotor complaints, vaginal dryness and atrophy (Collins, 2006; MacLennan, Lester, & Moore, 2001). The effect of HRT on other common perimenopausal symptoms such as joint pain and depressive tendencies is less clear (Birkhäuser, 2002; Judd, Hickey, & Bryant, 2012; Magliano, 2010). Although HRT provides short-term benefits and improves quality of life, long-term use is associated with increased risk of a number of chronic diseases. The Women's Health Initiative and the Million Women Study were among the first to produce data pertaining to the long term effect of HRT. Preliminary analysis of the WHI data showed that incidence of coronary heart disease, invasive breast cancer, stroke and pulmonary embolism in HRT users was not counter-balanced by the small reductions in hip fractures

and colorectal cancers (Rossouw, Anderson, & Prentice, 2002). Similarly, the Million Women Study found that the incidence of breast and ovarian cancer significantly increased in women who had previously used HRT (Beral, Bull, Green, & Reeves, 2007; Million Women Study Collaborators, 2003).

In the wake of these results there is evidence that practitioners and patients alike are seeking an effective and safe, non-pharmaceutical therapy to combat the symptoms associated with menopause. Complementary and Alternative Medicines (CAMs) such as bioidentical hormones, acupuncture, exercise therapy and osteopathy are being increasingly utilised in order to combat symptoms associated with the transitional period (Kessel & Kronenberg, 2004). This trend has been occurring despite a lack of definitive data supporting the effectiveness of these therapies in the treatment of perimenopausal symptoms. The primary aim of this study was to determine the effectiveness of Osteopathic Manual Therapy as a treatment for perimenopausal symptoms in a clinical setting. To achieve this, the study comprised two parts. The first part quantified changes in symptoms following an 8-week intervention. Following this a second qualitative component was formulated to explore participants' thoughts and experiences during the intervention study.

Methods

Design

This exploratory study employed a mixed-methods design utilising an A-B-C Single System Research Design (SSRD) and *post-hoc* Interpretive Description. SSRD designs are thought to be especially useful for evaluating the effectiveness of interventions when they are novel or when the clinical presentations are widely variable (Riddoch, 1991). Interpretive Description examines a clinical phenomenon with the goal of identifying themes and patterns among subjective perspectives, while also accounting for variation between individuals (Hunt, 2009). Schneider, Whitehead, Elliott, Lobiondo-Wood and Harber (2004) suggest that completing qualitative analyses after quantitative data have been collected is a valid approach to qualitative research and offers a means for making research more meaningful, complete and purposeful than when utilising a single method.

Participants

Participants were initially recruited for the quantitative part of the study via a research advertising website www.getparticipants.com and secondly, as a result of snowball sampling. Women between the ages of 45 – 55 years in early or late perimenopause according to the Stages of Reproductive Aging Workshop (Soules et al., 2001) with perimenopausal symptoms were eligible. Women were excluded from the study if they were currently using HRT or hormone based contraception, or had done so in the preceding six months, had undergone a full hysterectomy, exhibited any contraindications to osteopathic manual therapy (OMT) or if they had received OMT in the previous six months.

Women who registered an interest were then sent an eligibility questionnaire [Appendix A] along with an information sheet [Appendix B] explaining the study. If they were eligible to participate the primary researcher made contact to confirm their willingness and to address any concerns they may have had in relation to the study. They were then asked to sign a consent form [Appendix C]. Ethical approval for this research was granted by the Unitec Research Ethics Committee (UREC 2011-1173) on the 28/6/2011 for data collection until the 28/6/2012 [Appendix D].

Quantitative Study: Investigation Measurements

Measurements of symptoms were recorded during a 2-week pre-intervention phase; a 4-week intervention phase and a 2-week post-intervention phase (see Figure 1).

During the 2-week pre-intervention phase participants completed the self-administered Menopause Quality of Life Questionnaire (MENoQL) and the Greene Climacteric Scale. MENoQl measurements were recorded fortnightly encompassing the previous two weeks and the Greene Climacteric Scale was completed weekly in respect to the previous 24 hours. In addition participants were asked to record each hot flush and rate its intensity as mild, moderate or severe.

The Menopause Quality of Life Questionnaire (MENoQL)

The MENoQL [Appendix E) is a 29-item, self-administered questionnaire developed by Hilditch et al. (1996) to measure the quality of life in menopausal women by assessing the frequency and severity of menopause-related symptoms. The questionnaire has been validated against established research instruments such as the Kupperman Menopausal Index derived from clinical experiences in the 1950s (Kupperman, Blatt, Wiesbader, & Filler, 1953). The symptoms are divided into four domains: vasomotor, psychological, physical, sexual. Each question score ranges from 0-6 (from “not bothered at all” to”extremely bothered”) and the mean score of each domain is used as the overall subscale score.

The Greene Climacteric Scale

The Greene Climacteric Scale [Appendix F] is intended to be a brief measure of core perimenopausal symptoms or complaints (Greene, 1998). The scale yields four main independent symptom domains: vasomotor, somatic, depression and anxiety, but does not consider the effect of the symptoms on quality of life (Greene, 1998). Like the MENoQL, the Greene Climacteric Scale is self-administered; however it has only 21 items and is specific to the symptoms suffered by the participant in the last 24 hours rather than the last fortnight.

Hot Flush Frequency and Intensity

Participants were asked to record, in a provided diary [Appendix G], the occurrence and severity of each hot flush, categorisng it as mild, moderate or severe. A mild hot flush was a warm sensation without sweating which did not disrupt activity; moderate was a warm sensation (with or without sweating) which had a transient and insignificant impact on the participant's activity and severe was a hot sensation with sweating that significantly disrupted the patients activity (Huang, Nir, Chen, Schnyer, & Manber, 2006; Utian, Shoupe, Bachmann, Pinkerton, & Pickar, 2001; Venzke, Calvert, & Gilbertson, 2010). Participants were asked to separate hot flushes that occurred during the day or wakeful period from those that occurred during the nocturnal sleep period (Huang et al., 2006).

Development of the OMT Intervention

As there was little published research on the treatment of perimenopausal symptoms with OMT prior to the intervention, four interviews were held with experienced practitioners (5 years or more in practice). Each practitioner was asked to determine what five structural techniques they would use if a woman with perimenopausal symptoms presented to them. From this information, a semi-standardised treatment protocol [Appendix H] was developed, similar to the one used in Fryer, Alvizator and Lamaro (2005). This allowed the philosophies of osteopathic medicine to be maintained whilst maintaining a degree of consistency in the treatments that each participant received.

Intervention

During the intervention phase, participants attended four, weekly consultations (on the same weekday at the same time each week), in which they received osteopathic treatment relating specifically to their main perimenopausal complaint. Two Osteopathic student practitioners who were currently enrolled in the Master of Osteopathy programme at Unitec New Zealand, and who both signed non-disclosure forms [Appendix I,] performed the treatments. Each student practitioner was supervised by clinic tutors who currently held an annual practicing certificate in New Zealand.

The initial session was 90 minutes and included a comprehensive case history as per standard clinical practice. During this initial session detailed information pertaining to reproductive health was collected using the Female Reproductive History [Appendix J] form. Subsequent osteopathic sessions were up to 45 minutes in duration.

The treatment protocol given to practitioners focused on addressing somatic dysfunctions in the lumbar, thoracic and cervical spine, as well as soft tissues adjacent to these areas. Techniques were explained according to descriptions given in Ward (2003) and Hartman (2001). In order to best address the person's needs the practitioner aimed to discover and assist those locations in the body where the homeostatic, or self-correcting mechanisms, were most impeded.

Figure 1. The procedure during the pre-intervention, intervention and post-intervention phases across the study. The last MENoQL questionnaire was given to participants at the beginning of the ninth week and applied to the two previous weeks. No other outcomes measures were retested at this time.

Data Analysis – Quantitative Data

Data from the MENoQL Questionnaire and the Greene Climacteric Scale were collected using www.surveymonkey.com, an online collection and analysis website, and then downloaded and tabulated into an Excel 2007 spreadsheet. Data pertaining to the frequency and intensity of hot flushes was manually loaded into Excel 2007. Statistical analyses was completed using SPSS version 18 (SPSS, IBM, Armonk, New York). Differences in measurement indices between pre-intervention, intervention and post-intervention phases were analysed using Repeated Measures Analysis of Variance (ANOVA) and Bonferroni *post-hoc* pair-wise comparisons.

Qualitative Study

The qualitative aspect of the study was not included in the initial ethical approval, thus secondary approval was sought. Participants were automatically eligible to take part in this aspect of the study following their participation in the quantitative investigation.

A second information sheet explaining the details of the interview was sent out by email [Appendix K]. UREC decided that written consent in an email would suffice for requirements of informed consent given the participants had finished their treatments. On giving their consent, a suitable time was arranged with participants to conduct the interview. At the beginning of the interview, each participant was reminded that what they were about to say would be recorded. This gave them one final opportunity to withdraw if they were not happy to be recorded.

The interview followed a semi-structured guideline of questions, although care was taken to ensure that questioning was open-ended so as to modulate interviewer bias and, to allow the participant to describe their experience.

The digital audio recordings of the interviews were transferred on to the computer in an MP3 format so they could be transcribed verbatim using Digital Voice Editor, an audio transcription programme. Once all the interviews had been transcribed, each transcript was emailed back to the relevant participant. This allowed participants to ensure what they said was a true and correct representation of their thoughts and experiences. If this was not the case, participants were able to edit the transcript where necessary. This step helped to avoid misinterpretation, adding strength to this aspect of the study (Cresswell, 2007).

Data Analysis – Qualitative Data

Thematic analysis was chosen to analyse the semi-structured interviews in keeping with the exploratory nature of the research (Cresswell, 2007). The transcripts were read repeatedly prior to categorising, coding and creating links (Thorne, Kirkham, & MacDonald-Emes, 1997). Each interview was compared to the others to establish overall themes. The overarching themes were then compared to the results from analysis of outcome measures used in quantitative study.

Results

Six women took part in the quantitative investigation and their characteristics are presented in Table 1. Four of these women (Participants 2, 3, 4, 5) then went on to take part in the qualitative aspect of the research.

Quantitative Results

Overall, the largest effect sizes for change, calculated as (Post-Intervention Score – Pre-Intervention Score) / Pre-Intervention Standard Deviation), were noted for the MENoQL vasomotor domain as well as the psychological, sexual and vasomotor domains in the Greene Climacteric Scale (range = 3.5 – 5.7). Intermediate effects were noted the musculoskeletal domains in both outcome measures (range = 2.5 – 3.0) and smaller effects for Greene Climacteric Scale anxiety and depression domains (range = 0.3 – 1.0; Table 2).

Differences in the MENoQL score between the pre-intervention, intervention and post-intervention stages of the study were found for both the physical (Figure 2; $p < 0.0005$) and the psychological domains (Figure 3; $p = 0.007$), but not for the vasomotor or sexual domains (data not shown). *Post-hoc* pairwise comparisons showed that the pre-intervention physical domain score (Figure 2) was different from both the intervention ($p = 0.004$) and post-intervention phases ($p = 0.007$). Differences between pre-intervention and intervention scores for the psychological domain reached borderline *post-hoc* pairwise significance (Figure 3; $p = 0.05$).

Differences in the Greene Climacteric Scale for the somatic ($p < 0.006$; Figure 4), vasomotor ($p = 0.013$; Figure 5) and anxiety ($p = 0.005$; Figure 6) domains all reached statistical significance, whilst the sexual domain did not (data not shown). *Post-hoc* pairwise comparisons of scores among phases for the somatic domain showed differences between pre- and post-intervention ($p = 0.025$). Differences in scores between phases for the vasomotor and anxiety domains did not attain *post-hoc* pairwise significance.

Data collected via the hot flush diary showed between-stage differences in the intensity (Figure 8; $p = 0.02$) and a trend for this in the frequency (Figure 7; $p = 0.05$) of flushes. Percentage changes from pre- to post-intervention averaged 37.2% and 62.2% respectively. Neither of these two domains attained *post-hoc* pairwise significance.

Table 1

Individual Characteristics of study population

	Age[a]	Age at perimenopause[a]	Stage of Perimenopause[b]	Age at start of hot flushes[a]	Number of Pregnancies	Number of living children	BMI[c]	Smoker
Participant 1	47	45	Late	46	2	2[d]	42.8	No
Participant 2	48	45	Late	45	0	0	25.8	No
Participant 3	46	44	Late	45	0	0	24.6	No
Participant 4	54	50	Late	53	6	5	43.0	No
Participant 5	50	39	Late	40	2	0	29.4	Yes
Participant 6	49	45	Late	46	2	2	27.1	No
Mean ± SD	49.0 ± 2.8	44.7 ± 3.5		45.8 ± 4.2	2 ± 2.2	1.3 ± 2.0	32.1 ± 8.5	

Abbreviation: BMI, Body Mass Index

[a] Years

[b] Determined during questioning using Female Reproductive History sheet

[c] Calculated as weight in kilograms divided by the square of height in meters Kg/m^2.

[d] Twins from one pregnancy

Table 2

Effect sizes of change in symptoms

Symptom Domains	MENoQL	Greene Climacteric Scale	Hot Flush Diary
Physical	2.96* (76.7%)		
Somatic		2.48* (56.4%)	
Psychological	5.67* (32.0%)		
Anxiety		1.00* (31.9%)	
Depression		0.26 (15.0%)	
Vasomotor	3.54 (34.2%)	5.00* (38.5%)	
Sexual	5.32 (35.7%)		
Frequency			1.34 (62.2%)
Intensity			5.81 (37.2%)

Effect size was calculated as the difference in mean symptom score from pre- to post-intervention divided by the pre-intervention standard deviation. * indicates $p < 0.05$. The difference from pre- to post-intervention expressed as a percentage of pre-intervention values are also included in brackets.

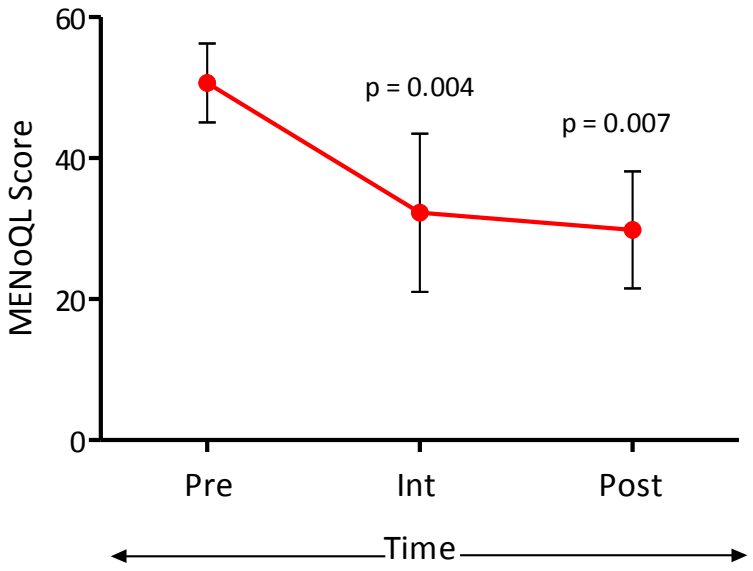


Figure 2. Menopause Quality of Life Questionnaire (MENoQL). Physical domain scores against study phase. Pre, Int and Post represent the 2-week pre-intervention, 4-week intervention and 2-week post intervention phases respectively. Error bars show standard deviations.

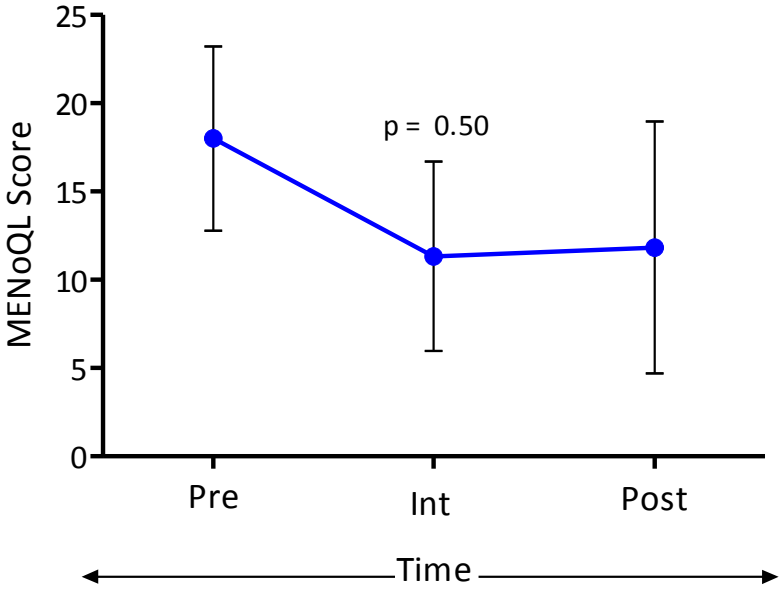


Figure 3. Menopause Quality of Life Questionnaire (MENoQL). Psychological domain scores against study phase. Pre, Int and Post represent the 2-week pre-intervention, 4-week intervention and 2-week post intervention phases respectively. Error bars show standard deviations.

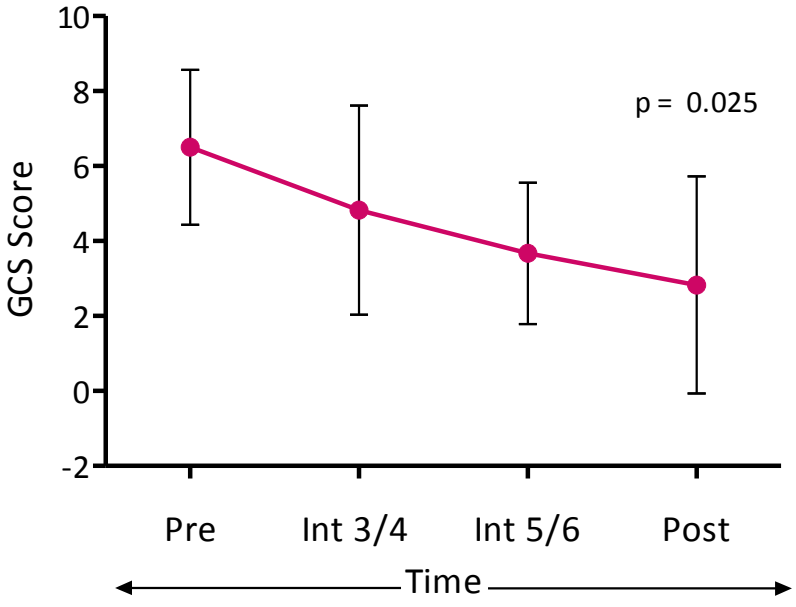


Figure 4. Greene Climacteric Scale (GCS). Somatic domain scores against study phase. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively. Error bars show standard deviations.

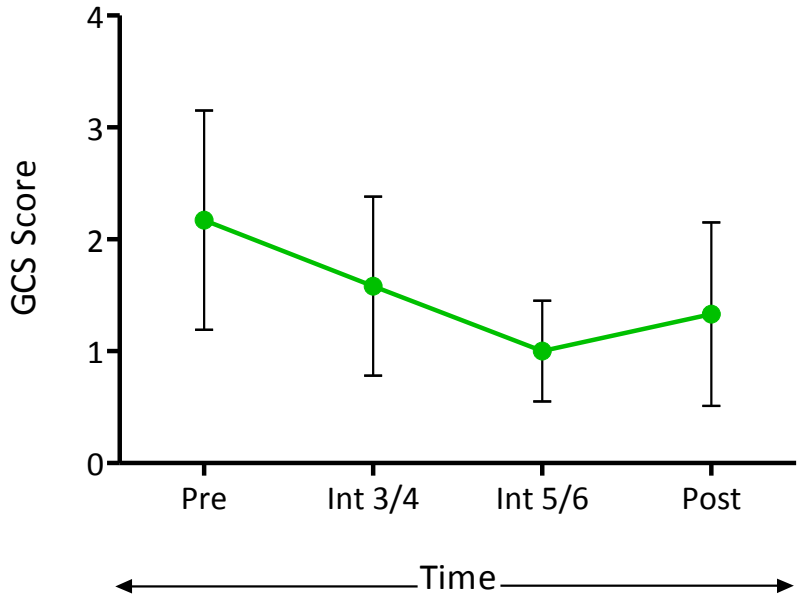


Figure 5. Greene Climacteric Scale (GCS). Vasomotor domain scores against study phase. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively. Error bars show standard deviations.

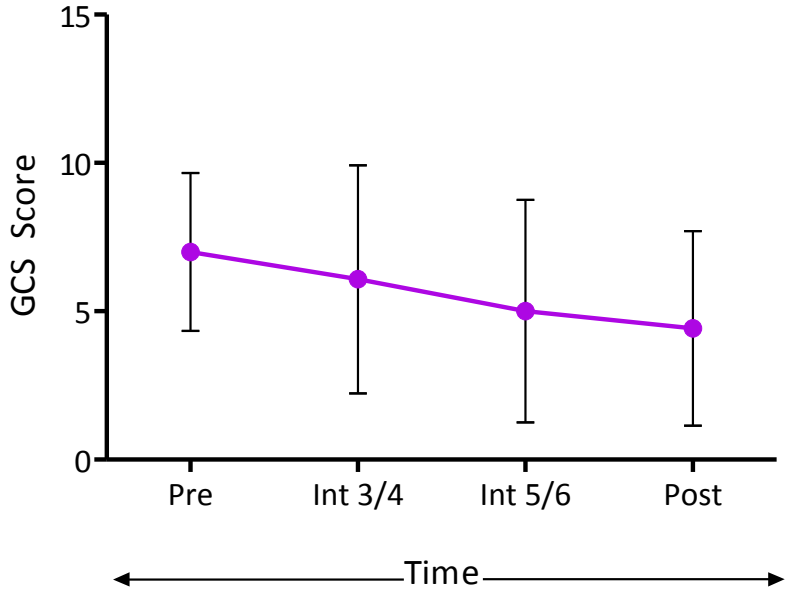


Figure 6. Greene Climacteric Scale (GCS). Anxiety domain scores against study phase. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively. Error bars show standard deviations.

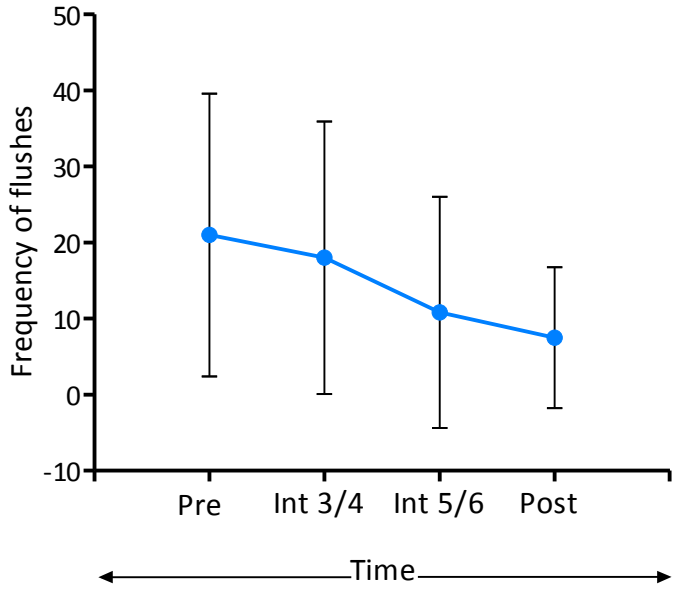


Figure 7. Hot flush frequency against study phase. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively. Error bars show standard deviation.

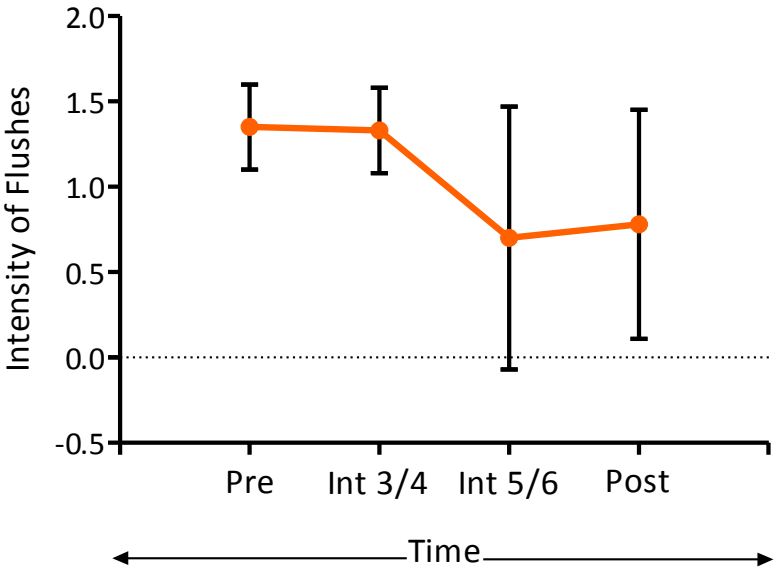


Figure 8. Hot flush intensity against study phase. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively. Error bars show standard deviations.

Individual Data

The most reported MENoQL (figure 9a) symptoms were those that fell into the physical domain, of which there were 16 different symptoms. Participant 4 showed the most dramatic decrease in physical symptoms, notable across all three phases of the study. In most cases, participants stabilised following a significant decrease in symptoms during the early part of the intervention. It was common to see a slight increase in symptoms during the post intervention phase (e.g. Participants 3 and 6). See Appendix [L] for graphs illustrating change in all MENoQL symptom domains for each participant.

Results from the Greene Climacteric Scale (figure 9b) illustrated no obvious trend with respect to most reported group of symptoms. Symptoms that fell into the anxiety domain, of which there were six, followed a similar trend to the MENoQL physical symptoms and tended to decrease followed by a stabilisation or a more gradual decrease. Participant 5 responded differently to others, showing a slight worsening in symptoms before a decrease and plateau that equalled the initial baseline measure. See Appendix [M] for graphs illustrating change in all Greene Climacteric Scale symptom domains for each participant.

Data from the hot flush diary showed a decreasing trend in the frequency of hot flushes (figure 10a) over the 4-week intervention period. Participants 3 and 5 showed an increase in the number of flushes between the pre-intervention phase and weeks three and four of the intervention phase. Reductions in their number of flushes were reported in the second half of the intervention phase; Participant 3 illustrating a sudden decrease while participant 5 demonstrated a more gradual decrease. Only one participant reported an increase in frequency of flushes following the conclusion of the intervention phase.

Similarly to hot flush frequency, the majority of participants experienced an initial decrease in the average intensity of each hot flush (figure 10b). Two participants, (1 and 3) both showed a slight increase before reporting a reduction in the intensity of their flushes. In contrast to changes in frequency of hot flushes, 3 of the 6 participants reported that following the intervention phase the intensity of their hot flushes began to increase again. See Appendix [N] for graphs illustrating change in both the frequency and intensity of hot flushes for each participant.

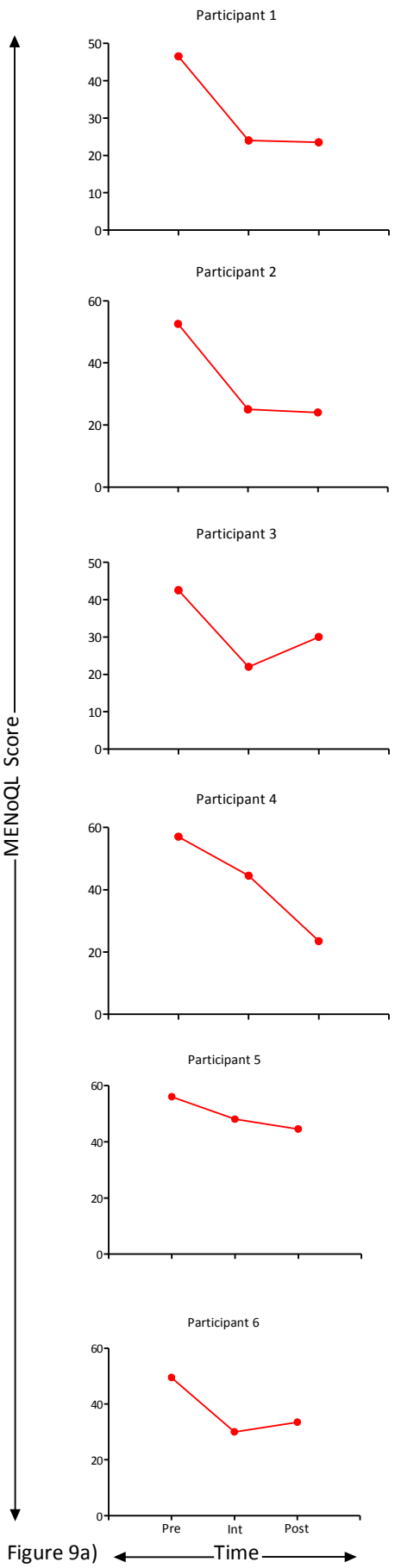


Figure 9a)

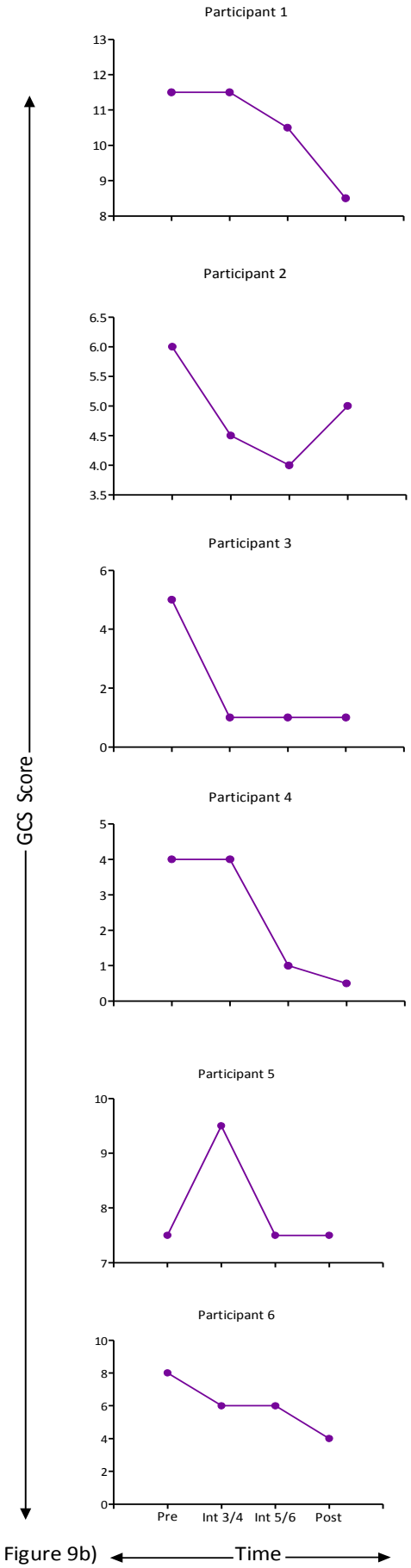
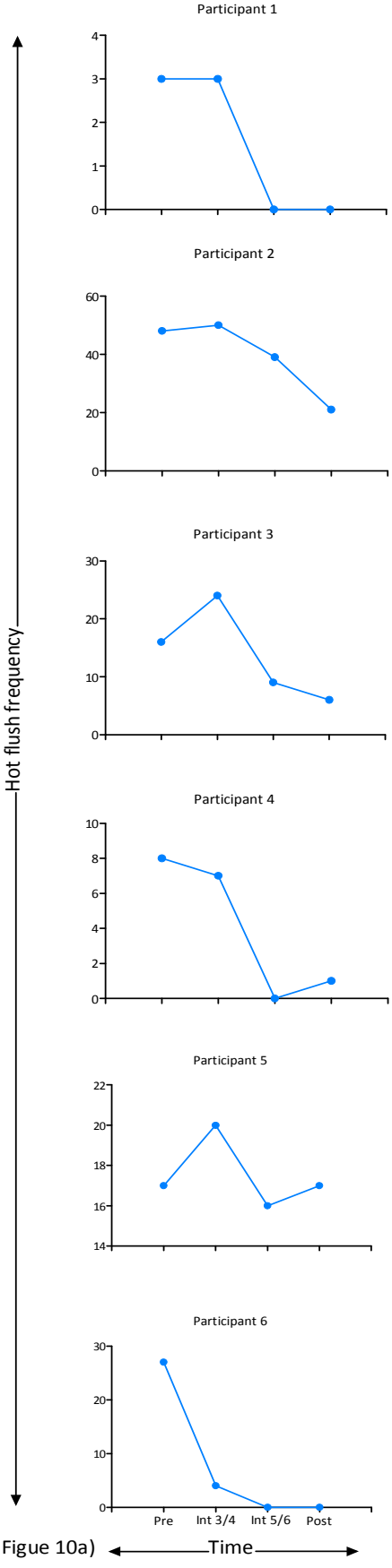


Figure 9b)

Figure 9a & b. a) Menopause Quality of Life Questionnaire. Physical Domain. Pre, Int and Post represent the 2-week pre-intervention, 4-week intervention and 2-week post intervention phases respectively. **b)** Greene Climacteric Scale (GCS). Anxiety domain. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively.



Figue 10a)

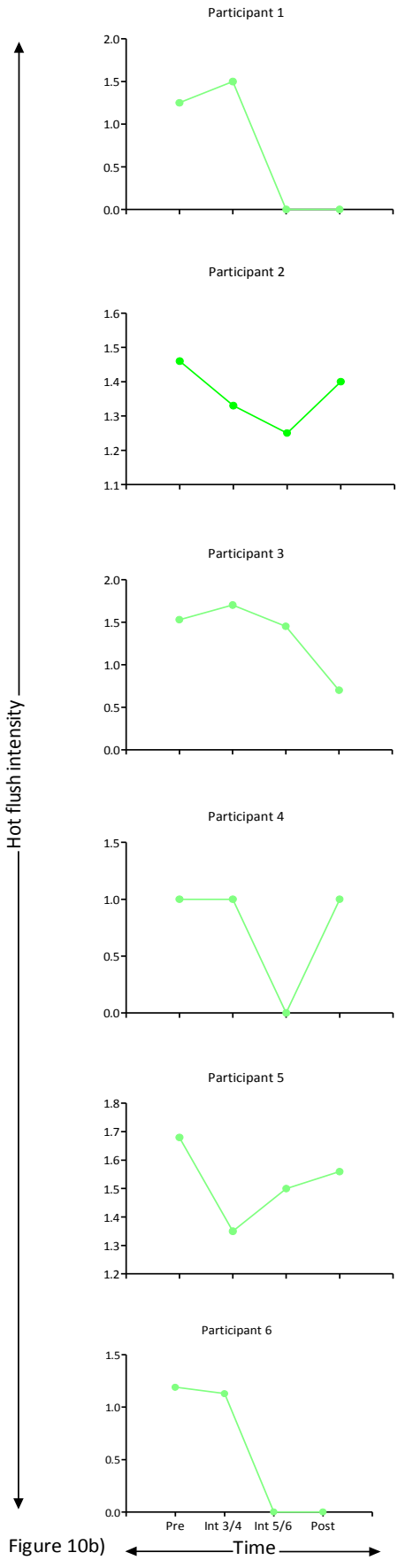


Figure 10b)

Figure 10a & b. a) Hot flush frequency against study phase. b) Hot flush intensity against study phase. Pre, Int 3/4, Int 5/6 and Post represent the 2 week pre-intervention phase, weeks 3 and 4 of the intervention phase, weeks 5 and 6 of the intervention phase and the 2 week post-intervention phase respectively.

Qualitative Results

The analysis of the qualitative data indicated a number of topics that were common to the interviews with the participants. These were grouped into three themes and two sub-themes.

The first theme, **Communication**, illustrated the importance of the verbal interaction between the patient and practitioner, especially since the majority of women were unsure of what osteopathy was. Communication that was perceived to be good by the participant helped to reduce stress and anxiety associated with seeking treatment from a relatively unknown modality and, talking to a student practitioner about personal matters such as those relating to menopause.

> *"The practitioner would always ask my permission and explain what she was doing. She was very polite" Participant Two - Line 79*
>
> *"I loved the way the practitioner explained every single little thing she was doing. I felt like I was getting the best" Participant Four - Line 68*

The **Empathic Relationship** between the patient and practitioner arose as a sub-theme to Communication. Strong empathic communication was shown to enhance the effectiveness of the therapeutic relationship between the patient and practitioner. The positive interactions appeared to be of of key importance to the overall success of the treatments.

> *"She was great, we got on really well" Participant Two - Line 46*
>
> *"She had really good rapport with me; I trusted her totally and believed what she told me" Participant Four - Line 62*
>
> *"I felt very safe with the practitioner and that was partly to do with the great rapport we had" Participant Five - Line 65*

The second theme, **Overall Wellbeing**, reveals the impact of the transition from pre-menopausal to perimenopausal on both the mental and physical aspects of female wellbeing. Menopause as an entity does not have a distinct beginning or end thus, the drawn-out and unpredictable nature does produce negative outcomes for some women.

This theme focused on the positive ramifications that came with seeking help from an osteopathic practitioner.

> *"I've felt a lot more positive in my own life. It hasn't just affected me physically it's affected me mentally too" Participant Four - Line 131*

> *"It made me feel like someone was really thinking about how I felt and took an interest in what was happening with me" Participant Five - Line 49*

Empowerment developed as a sub-theme of Overall Wellbeing. It became apparent that optimism that stemmed from having a positive patient-practitioner relationship led to a change in the motivational status. The encouragement and support received from the practitioner enabled several participants to make positive steps in changing their lifestyle for the better.

> *"I'm now thinking about what I can do to help myself and I've just jointed the gym. I think exercise might help in several areas of my life" Participant Three - Line 88*

> *"It's just given me that zest back again to get out there and try something instead of feeling sorry for myself and not wanting to do anything" Participant Three - Line 190*

> *"I felt that someone taking an interest and giving me a little bit of information has motivated me a bit more to get out and do positive things for myself" Participant Five - Line 183*

The third and final theme, **Lack of Knowledge**, illustrated an absence of understanding of what osteopathy was and how it could potentially help ease perimenopausal complaints. It is likely that a lack of knowledge is not only applicable to women reporting perimenopausal symptoms, but to members of the general public seeking osteopathic treatment.

> *"Having never been to an osteopath I wasn't sure what to expect or what they did and had no idea how it would help me" Participant Two – Line 67*

Discussion

Data from this study shows that Osteopathic Manual Therapy delivered over a four-week period can reduce the perceived intensity of perimenopausal complaints and improve psychological well-being. The greatest effects were noted for symptoms in the musculoskeletal and psychological domains, with smaller changes occurring in the vasomotor domains. Symptoms that were encompassed by the musculoskeletal domains, referred to as *somatic* in the Greene Climacteric Scale and *physical* in the Menopause Quality of Life Questionnaire, included complaints such as headaches, low back pain and muscle aches and pains. In the Greene Climacteric Scale psychological symptoms such as palpitations and crying spells, were broken into two domains, *anxiety* and *depression* respectively. In the Menopause Quality of Life Questionnaire there was only one domain that encompassed all psychological-type complaints.

Improvement in musculoskeletal symptoms has been shown once before in an osteopathic investigation that sought to determine the effect of osteopathy on the symptoms associated with perimenopause. Cleary and Fox (1994) found that in a cohort of 30 menopausal women, physical complaints such as neck pain reduced over a 15-week period when compared to the control group. Menopausal-related symptoms were measured using an unnamed symptom questionnaire that graded symptoms from 1 to 10 (1 being no pain and 10 being unbearable). In the treatment group, 4 participants of 8 reported a 100% reduction for neck pain compared to 1 participant of 6 reporting the same reduction in the control group (Cleary & Fox, 1994). In the current study the most noteworthy finding was in the physical domain of the Menopause Quality of Life Questionnaire, in which a 77% reduction from pre- to post-intervention was observed. It is difficult to draw direct comparisons between the studies as Cleary and Fox analysed symptoms individually, whereas in the current study symptoms were grouped into domains and examined as a whole. Additionally, it is difficult to tell if the reported changes in the unnamed symptom questionnaire used by Cleary and Fox correlates with a change in the Menopause Specific Quality of Life Questionnaire used in the current study. A further disparity between the studies is the time-frame utilised for the intervention period. Although both studies treated

participants weekly, Cleary and Fox continued treatment for ten weeks (compared to four weeks of treatment in the current study), and reported no interim outcome data to allow comparison. However, the results of both osteopathic studies may have been expected as osteopaths readily employ mobilisation, manipulation, stretching and soft tissue techniques when treating musculoskeletal complaints. The primary aim in most cases is to improve function and rebalance homeostasis altered by the presence of dysfunctional tissue (Lucas & Moran, 2007).

Another study that has observed changes in the physical Menopause Quality of Life Questionnaire domain, reported on the effects of an intervention of aerobic and resistance exercise. Ağıl, Abıke, Daşkapan, Alaca and Tüzün (2010) utilised a Single System Research Design, similar to the current study, to determine the effect of exercise on menopausal symptoms, psychological health and the quality of life in menopausal women across an 8-week intervention. The aerobic exercise training was performed on a cycle ergometer 3 times per week, under the supervision of a physiotherapist. The resistance exercise programme was not detailed. Ağıl et al. reported small effect sizes in both the aerobic (0.8) and resistance (0.5) exercise groups for changes in symptoms in the physical domain of the Menopause Quality of Life Questionnaire. In the current study, after four weekly osteopathic treatments, symptoms in the physical domain displayed an effect size of 3.0. The large disparity demonstrates that Osteopathic Manual Therapy provides a more effective treatment of the symptoms associated with menopause than exercising. Direct comparisons between the studies can be drawn as the same outcome measure was utilised and a very similar methodological process was undertaken in the current study, including the absence of a control group.

All domains encompassing depression or anxiety based symptoms consistently displayed a general improving trend. The anxiety domain of the Greene Climacteric Scale and the psychological domain of the Menopause Quality of Life Questionnaire measure displayed large effect sizes (1.0 and 5.7 respectively), whereas the depression domain in the Greene Climacteric Scale displayed a smaller effect size which did not attain statistical significance (0.3; refer Table 2).

The relationship between functional communication and the changes in the psychological symptoms associated with perimenopause became evident during analysis of the qualitative follow-up interviews. “Communication” arose as a primary theme as many participants felt that verbal interaction regarding the scope of osteopathy and the process of menopause helped to relieve stress-related anxiety associated with the unknown. Further to this, compassion and understanding have been shown to exert a positive influence not only on the emotional health of the patient but also on symptom resolution, functional and physiological status and pain control (Stewart, 1995). The importance of rapport between the patient and practitioner was encapsulated in a sub-theme of communication, the “Empathetic Relationship”. Without rapport a harmonious patient-practitioner relationship is hard to establish and difficult to maintain (Leach, 2005). Moreover, the degree of responsiveness of a patient in relation to any health practitioner will ultimately depend on the degree of rapport established between them (Leach, 2005; Martyn, 2007). The rapport that developed between each participant and practitioner may have had an influence on their attentiveness when information or advice was being given, and their willingness to embrace exercise or lifestyle changes. It is not possible in the present study to separate patient-practitioner communication from the techniques used on each participant given the lack of control group. It is, however, reasonable to suggest that the encouraging atmosphere and relaxed settings that enabled free dialogue had a direct effect on the psychological and therefore, physical outcomes associated with the study.

The vasomotor domain in the Greene Climacteric Scale displayed a large effect size (5.0) and the frequency and intensity of flushes reported in the Hot Flush Diary decreased 62% and 37% respectively. The vasomotor domain in the Menopause Quality of Life Questionnaire, whilst illustrating a noteworthy effect size (3.5), did not attain statistical significance. The small effect size may have been because general sweating was included in the domain alongside hot flushes and night sweats, whereas in the Greene Climacteric Scale, only the latter two were represented.

In a recent study, Kim et al. (2010) conducted a randomised controlled trial in which 175 peri- or postmenopausal participants were allocated to either acupuncture plus usual care (n = 116) or usual care alone (n = 59) groups. Acupuncture points used in the intervention

were selected according to the recommendations of Traditional Chinese Medicine clinical experts. The primary outcome measure was the mean change in the average 24 hour hot flush score at week four from baseline. Hot flush scores were measured by multiplying the frequency by severity of hot flushes recorded in a daily dairy, similar to the one used in the current study. Following an intervention period of four weeks, throughout which participants received three treatments per week, the mean number of flushes reduced with an effect size of 2.4 compared to 1.9 in the control group. These effects were larger than those observed for frequency of flushes in the current study (1.3 following 4 osteopathic treatments)**.** It is difficult to draw direct comparisons given the differences in analysis and outcome measures. While Kim et al. used the product of frequency and severity as the overall hot flush score, the current study looked at frequency and intensity of flushes as separate entities. Further to this, the current study observed large effect sizes for relief of symptoms in the vasomotor domains of both the Greene Climacteric Scale (5.0) and the Menopause Quality of Life Questionnaire (3.5). Kim et al. used the Menopause Rating Scale which has similar characteristics to the Greene Climacteric Scale but did not report data on the vasomotor domain. Overall, it is difficult to determine if one or other modality is more effective however, it is reasonable to suggest that osteopathy provides a faster and less invasive treatment for perimenopausal symptoms when compared to acupuncture.

Even though there are distinct differences between osteopathy and acupuncture, both modalities aim to improve function through restoring the balance of structure within the body (Bonnie, 2008; Lucas & Moran, 2007). Whilst the mechanisms behind vasomotor symptoms are unclear it is possible that osteopathic therapy delivered to the thoracic spine could be advantageous to women suffering from vasomotor symptoms. The primary aim of treatment in this area consists of addressing hypertonicity, increasing mobility and blood flow. It may be that a secondary effect is that of reducing the output of the sympathetic ganglia. These ganglia deliver information about stress and impending danger, and are responsible for the fight or flight response (Craven, 2011; Waterhouse & Campbell, 2011). Some osteopathic authors suggest that dysfunction of the tissues in which these ganglia are located may increase their output because of their close proximity to their overactive tissues, thus leading to constant stimulation of the sympathetic nervous system (Craven, 2011; Parsons & Marcer, 2006). This type of continuous demand on the body can lead to

chronic overstimulation and blunted responses to new stressors (Crockett & Panickar, 2011; Fisher, Young, & Fadel, 2009; McCarty, Horwatt, & Konarska, 1988). If the activity of the ganglia is reduced by way of manual technique, it may improve the body's capability to deal with the external triggers thought to set off the cascade of events that lead to a hot flush.

With only 6 participants it may be difficult to generalise the results of this study to the wider cohort of women going through perimenopause. The final sample size cannot be considered a true representation of the total population as the inclusion and exclusion criteria focused on a small proportion of women who were currently experiencing perimenopausal-related symptoms. The inclusion criteria encompassed parameters that ensured that participants were experiencing moderate symptoms associated with perimenopause, but the exclusion criteria prohibited the participation of women who were currently using HRT or hormone based oral contraceptives or had done so in the preceding six months. Further research is warranted to determine the effects of osteopathic manual therapy in conjunction with hormone replacement therapy or hormone based contraceptives.

In the current study a Single System Research Design was employed primarily in response to the lack of literature surrounding the treatment of perimenopausal symptoms with Osteopathic Manual Therapy. However, in the absence of a control group it is not possible to identify the mechanism by which the perimenopausal symptoms were affected. It is particularly difficult to separate the verbal interaction between the patient and practitioner from the hands-on treatment given by the practitioner. What can be stated is that the overall effect of treatment reduced muscular aches and pains, muscular hypertonicity, vasomotor and psychological symptoms as well as increasing range of movement, all of which reduced stress on the neurological system. In order to uncover the specific mechanisms by which these reported changes occurred, further research in this field needs to utilise the standardised process of a randomised controlled trial. This methodology is the widely accepted standard in determining the efficacy of a clinical intervention, whether it be medicinal or physical in nature.

The current study did not seek to recognise the efficacy of one single technique, but rather encompassed the holistic and individualised nature of osteopathy by means of a semi-

standardised treatment protocol. Collaboration took place with registered osteopaths to develop a representative treatment approach for use on perimenopausal women. Each participant was given a treatment that focused on their primary complaint and took into consideration factors that contributed to their personal group of symptoms. As a result the internal validity associated with the study was traded-off in favour of external validity, treatment was thus more representative of that occurring in private osteopathic practice.

There is no doubt that further research into the effect of osteopathy for women experiencing menopausal-related complaints needs to be conducted, primarily with larger scale controlled and blinded studies to confirm the results of this investigation. In addition, the effect of an extended treatment regime should be investigated as the initial reduction of somatic, psychological and vasomotor symptoms suggest that a longer intervention period may further reduce or completely alleviate symptoms associated with perimenopause. Women would be more likely to utilise osteopathic medicine for perimenopausal complaints if it was clear that they could obtain a similar reduction in symptoms as that associated with conventional treatments. Finally, the effect of the patient-practitioner relationship and communication on the overall well-being of perimenopausal women may provide further information to determine the most effective practice when treating women with menopausal-related symptoms.

The results of this study suggest that structural osteopathic techniques, employed within the treatment protocol, may be an effective way of reducing physical, psychological and vasomotor symptoms that are common to women who are going through menopause. These results, although preliminary, will help to further practitioners' knowledge surrounding perimenopause and may have a wider positive impact on clinical outcomes for women of this age group. Further research that; confirms the effectiveness of the treatment protocol utilised in this research, includes a control group, and establishes the longer-term effect of osteopathic treatment is warranted, in order to completely understand the role of osteopathic medicine for the treatment of symptoms associated with perimenopause.

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Section Three

Appendices

Appendix

(A) Eligibility Questionnaire

Female Reproductive History – Eligibility

1. How old are you?

2. Have you had a hysterectomy — Yes / No

   2a. Were your ovaries left after the operation? — Yes / No

3. Have you had hot flushes? — Yes / No

   3a. What age did they start?

4. Have you used hormone replacement therapy since the onset of perimenopause? — Yes / No

   4a. When was the last time you took the medication?

   4b. Please list hormone preparations and the dose you are taking or have taken:

Hormone	Daily Dose	Date Started	Date Stopped

5. Have you had any osteopathic treatment in the last 6 months? — Yes / No

6. Have you had cancer? — Yes / No
   If 'YES' please specify type, treatment and outcome

(B) Quantitative Information Sheet

INFORMATION SHEET

The effectiveness of osteopathic treatment for reducing perimenopausal symptoms: a pilot study

About this research:
My name is Kate Bone and I'm currently in my 5th and final year of my Master of Osteopathy. As partial fulfilment of this qualification I am required to complete a research thesis on a topic of my choice. I have decided to investigate whether Osteopathic Manual Therapy is an effective treatment for women suffering from perimenopausal symptoms.

If you have noticed a change in your menstrual cycle of 7 days or more, with or without irregular menses, and are currently experiencing disturbing symptoms that may be associated with perimenopause then we invite you to participate in this study. Your participation would help us to understand the role osteopathy may be able to play in the treatment of women experiencing discomfort from perimenopausal symptoms. We recognise that talking about menstruation may be uncomfortable for some people. We'd like to reassure you that participating in any part of this study is your choice and you may withdraw or chose not to respond to a question without reproach.

Taking part:
Your involvement in the study would be for eight consecutive weeks. You will be asked to come into the osteopathy clinic during that period for treatment. The first visit will involve signing the consent form and taking a detailed history of your health. In the following visits you will receive an osteopathy treatment of approximately 60 minutes relating to your primary perimenopausal by a senior student practitioner in the final year of their 5 year Osteopathy qualification who has been specifically trained in the techniques performed. In accordance with normal clinic practice the student practitioner will be overseen by a registered osteopath. You may choose to withdraw from the study without any consequence however, due to project time restrictions you will only be able to remove yourself for up until two weeks after the data collection period has finished.

Information:
In addition to your medical history, you will be asked to complete two different questionnaires several times that assess the frequency and severity of symptoms associated with perimenopause. Both take around 5 -7 mins to fill out and will be emailed to you to complete in the comfort of your own home. You will also be asked to record each hot flush as mild, moderate or severe in a provided diary.

Any concerns:
If you have any further questions or concerns please don't hesitate to contact me directly on 021 303 991 or at kate.bone1@gmail.com. If you wish, you may also contact any of my research supervisors at Unitec Drs Catherine Bacon, Andrew Stewart, or Clive Standen on 09 815 4321 ext 519

Thank you for reading this information sheet please keep it for your records

This study has been approved by the **Unitec Research Ethics Committee** from (29/06/2011) to (29/06/2012). If you have any complaints or reservations about the ethical conduct of this research you may contact the committee secretary on 09 815 4321 extn 6162. Any issues you raise will be treated in confidence and investigated fully and you will be informed of the outcomes.

(C) Quantitative Consent Form

PARTICIPANT CONSENT FORM

The effectiveness of osteopathic manual therapy for reducing perimenopausal symptoms

This research will investigate the effectiveness of osteopathic manual therapy for reducing perimenopausal symptoms. The research is being conducted by Kate Bone, a Master of Osteopathy student at Unitec and is supervised by Dr Catherine Bacon and Clive Standen.

Name of participant: _____

I have seen the information sheet for women taking part in the research into the effectiveness of osteopathic manual therapy for reducing perimenopausal symptoms.

I have had the opportunity to read the information sheet and discuss the project with the primary supervisor and I am satisfied with the explanations I have been given.

I understand that I may seek further information if I wish.

I understand that taking part in this study is my choice and I may withdraw from the study any time up until 2 weeks following the end of the data collection period.

I understand that everything I say is confidential and none of the personal information I give will be displayed in public documents in a way that could identify me. The only persons who will have access to my individual data are the researcher and their academic supervisors.

I also understand that all hardcopy information will be stored in a locked cabinet and the electronic data will be stored by both the researcher and supervisors in password protected files and that the data will be stored for up to five years as per Unitec policy. Any treatment notes made will be available only to treating practitioners and their clinical supervisors if they are students.

I understand that I will be asked to come into the Unitec student clinic for four treatment sessions of approximately 60 minutes which may either be with a registered osteopath or a senior, specifically trained and supervised student practitioner.

I understand that the techniques used will reflect those used routinely in osteopathic medicine.

I understand that I can obtain a summary of the study results.

I have had enough time to consider whether I wish to partake.

I know who to contact if I have any concerns or questions regarding the study.

Participant Signature: _____ **Date:** _____

Project explained by: _____

Signature: _____ **Date:** _____

UREC REGISTRATION NUMBER: (2011-1173)
This study has been approved by the UNITEC Research Ethics Committee from (28/9/2011) to (28/6/2011). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

(D) Ethical Approval

Kate Bone
23 Medowland Dr
Somerville 2014

20.7.2011

Dear Kate,

Your file number for this application: 2011-1173
Title: *The effectiveness of osteopathic treatment for reducing peri-menopausal symptoms: A pilot study.*

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 28.6.2011
Finish date: 28.6.2012

Please note that:

1. **The above dates must be referred to on the information AND consent forms given to all participants.**

2. **You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.**

You may now commence your research according to the protocols approved by UREC. We wish you every success with your project.

Yours sincerely,

P.P. Kjonla

Scott Wilson
Deputy Chair, UREC

cc: Catherine Bacon
Cynthia Almeida

study@unitec.ac.nz
Tel +64 9 849 4180
Fax +64 9 815 2901
www.unitec.ac.nz

Postal address
Private Bag 92025
Victoria St West
Auckland 1142
New Zealand

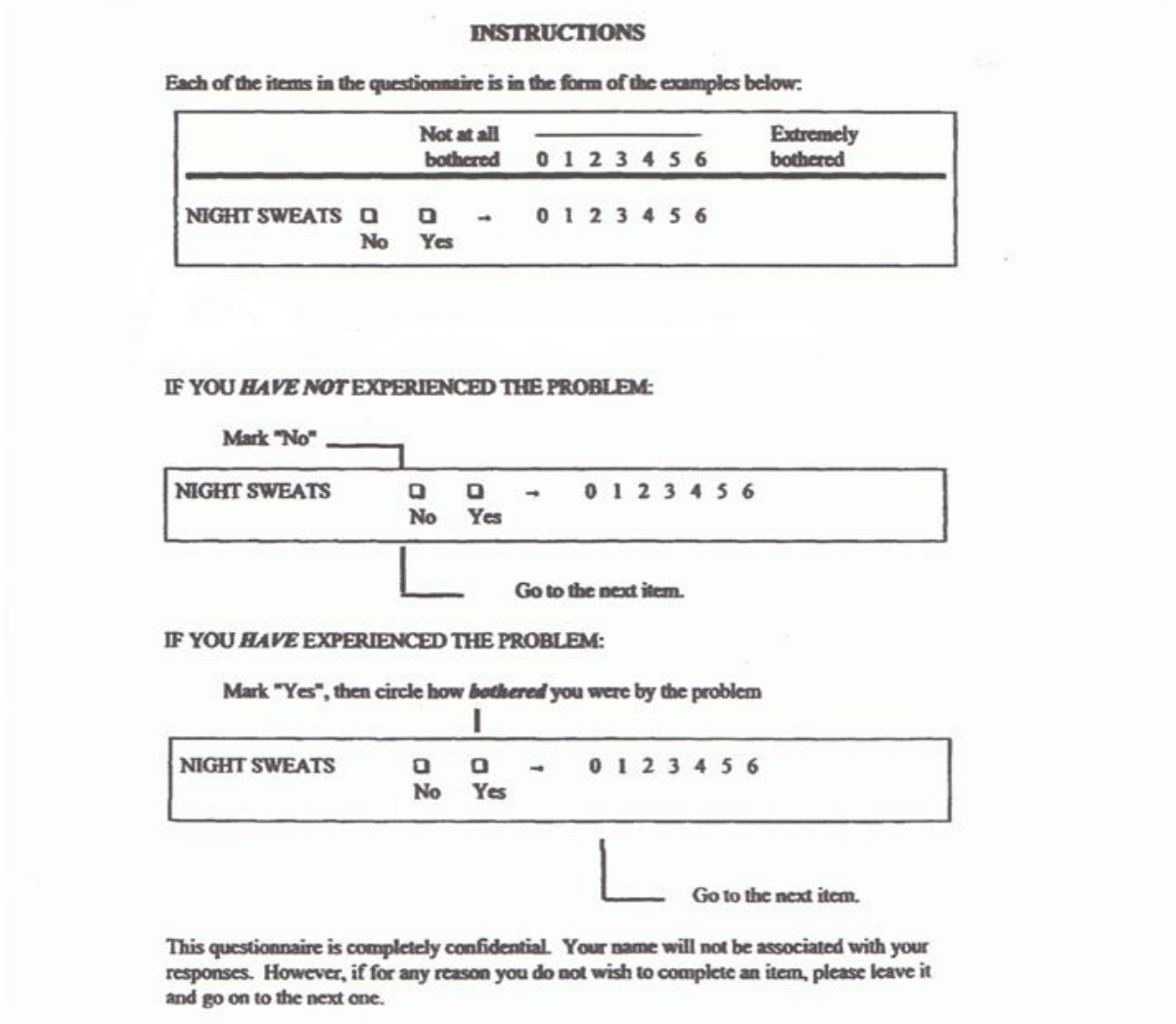
Mt Albert campus
139 Carrington Rd
Mt Albert
Auckland 1025
New Zealand

Newmarket campus
277 Broadway
Newmarket
Auckland 1023
New Zealand

Northern campus
10 Rothwell Ave
North Harbour
Auckland 0632
New Zealand

Waitakere campus
5-7 Ratanui St
Henderson
Auckland 0612
New Zealand

(E) Menopause Quality of Life Questionnaire



INSTRUCTIONS

Each of the items in the questionnaire is in the form of the examples below:

	Not at all bothered	0 1 2 3 4 5 6	Extremely bothered
NIGHT SWEATS ☐ No ☐ Yes	→	0 1 2 3 4 5 6	

IF YOU *HAVE NOT* EXPERIENCED THE PROBLEM:

Mark "No"

NIGHT SWEATS	☐ No ☐ Yes	→	0 1 2 3 4 5 6

Go to the next item.

IF YOU *HAVE* EXPERIENCED THE PROBLEM:

Mark "Yes", then circle how *bothered* you were by the problem

NIGHT SWEATS	☐ No ☐ Yes	→	0 1 2 3 4 5 6

Go to the next item.

This questionnaire is completely confidential. Your name will not be associated with your responses. However, if for any reason you do not wish to complete an item, please leave it and go on to the next one.

		Not at all bothered			0	1	2	3	4	5	6	Extremely bothered
1.	HOT FLUSHES OR FLASHES	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
2.	NIGHT SWEATS	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
3.	SWEATING	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
4.	BEING DISSATISFIED WITH MY PERSONAL LIFE	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
5.	FEELING ANXIOUS OR NERVOUS	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
6.	EXPERIENCING POOR MEMORY	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
7.	ACCOMPLISHING LESS THAN I USED TO	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
8.	FEELING DEPRESSED, DOWN OR BLUE	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
9.	BEING IMPATIENT WITH OTHER PEOPLE	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
10.	FEELINGS OF WANTING TO BE ALONE	☐ No	☐ Yes	→	0	1	2	3	4	5	6	
11.	FLATULENCE (WIND) OR GAS PAINS	☐ No	☐ Yes	→	0	1	2	3	4	5	6	

The Menopause-Specific Quality of Life Questionnaire

	Not at all bothered		0	1	2	3	4	5	6	Extremely bothered
12. ACHING IN MUSCLES AND JOINTS	☐ No	☐ Yes	→	0	1	2	3	4	5	6
13. FEELING TIRED OR WORN OUT	☐ No	☐ Yes	→	0	1	2	3	4	5	6
14. DIFFICULTY SLEEPING	☐ No	☐ Yes	→	0	1	2	3	4	5	6
15. ACHES IN BACK OF NECK OR HEAD	☐ No	☐ Yes	→	0	1	2	3	4	5	6
16. DECREASE IN PHYSICAL STRENGTH	☐ No	☐ Yes	→	0	1	2	3	4	5	6
17. DECREASE IN STAMINA	☐ No	☐ Yes	→	0	1	2	3	4	5	6
18. FEELING A LACK OF ENERGY	☐ No	☐ Yes	→	0	1	2	3	4	5	6
19. DRYING SKIN	☐ No	☐ Yes	→	0	1	2	3	4	5	6
20. WEIGHT GAIN	☐ No	☐ Yes	→	0	1	2	3	4	5	6
21. INCREASED FACIAL HAIR	☐ No	☐ Yes	→	0	1	2	3	4	5	6
22. CHANGES IN APPEARANCE, TEXTURE OR TONE OF YOUR SKIN	☐ Yes	☐ No	→	0	1	2	3	4	5	6
23. FEELING BLOATED	☐ No	☐ Yes	→	0	1	2	3	4	5	6

The Menopause-Specific Quality of Life Questionnaire

	Not at all bothered		0	1	2	3	4	5	6	Extremely bothered
24. LOW BACKACHE	☐ No	☐ Yes	→	0	1	2	3	4	5	6
25. FREQUENT URINATION	☐ No	☐ Yes	→	0	1	2	3	4	5	6
26. INVOLUNTARY URINATION WHEN LAUGHING OR COUGHING	☐ No	☐ Yes	→	0	1	2	3	4	5	6
27. CHANGE IN YOUR SEXUAL DESIRE	☐ No	☐ Yes	→	0	1	2	3	4	5	6
28. VAGINAL DRYNESS DURING INTERCOURSE	☐ Yes	☐ No	→	0	1	2	3	4	5	6
29. AVOIDING INTIMACY	☐ No	☐ Yes	→	0	1	2	3	4	5	6

(F) The Greene Climacteric Scale

THE GREENE CLIMACTERIC SCALE

NAME: ..... DATE: .....

NUMBER: .....

Please indicate the extent to which you are bothered at the moment by any of these symptoms by placing a tick in the appropriate box.

SYMPTOMS	Not at all	A little	Quite a bit	Extremely	Score 0-3
1. Heart beating quickly or strongly					
2. Feeling tense or nervous					
3. Difficulty in sleeping					
4. Excitable					
5. Attacks of panic					
6. Difficulty in concentrating					
7. Feeling tired or lacking in energy					
8. Loss of interest in most things					
9. Feeling unhappy or depressed					
10. Crying spells					
11. Irritability					
12. Feeling dizzy or faint					
13. Pressure or tightness in head or body					
14. Parts of body feel numb or tingling					
15. Headaches					
16. Muscle and joint pains					
17. Loss of feeling in hands or feet					
18. Breathing difficulties					
19. Hot flushes					
20. Sweating at night					
21. Loss of interest in sex					

(G) Hot Flush Diary

Hot Flush Diary

Please record the occurrence and severity of each hot flash, categorizing it as mild, moderate or severe. A mild hot flush is defined as a fleeting warm sensation without sweating and which does not disrupt activity. A moderate hot flush is defined as a warm sensation (with or without sweating) which has a transient and insignificant impact on your activity. A severe hot flush is defined as a hot sensation with sweating that significantly disrupts the your activity. Please separate hot flushes that occur during the day or wakeful period from those that occur during the nocturnal sleep period.

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

Date/Time

Mild Moderate Severe

(H) Treatment Protocol

Treatment Protocol

The techniques used and the area treated in each session will be recorded by the practitioner on the Unitec Student Osteopathic Clinic case history forms.

Rhythmic techniques – including kneading, stretching, articulation, inhibition, and traction. Rhythmic techniques involve repetitive movements to musculoskeletal structures (joints, muscles, tendons, ligaments, and fascia) in an attempt to re-establish movement, circulation and remove barriers that may be restricting joints.

Muscle-energy technique – the practitioner first finds the initial barrier to movement within a joint then asks the patient to apply a small force whilst the practitioner resists the movement. Muscle-energy technique is thought to improve range of motion in a joint, increase circulatory flow, decrease muscle tonicity, and to help strengthen weak muscles.

High-velocity-low-amplitude thrust (HVLA) – a short thrust applied at high velocity and low amplitude to a restricted joint in the spine or peripheral joint, including ribs. HVLA is used to improve range, quality and functionality of a restricted joint.

Harmonic technique – rhythmic movement of a joint applied until a dynamic, harmonic rhythm is found. Harmonic technique is thought to improve quality of movement, relaxation of muscle, and improve fluid dynamics in the area.

Strain – Counter-strain technique – involves the application of pressure to a trigger point within a dysfunctional muscle, followed by the practitioner placing the patient in a position where the trigger point is no longer felt as painful. This position is held for up to 90 seconds or until the time that a sense of relaxation is felt. This technique is used to relax and improve function to a dysfunctional muscle.

Advice – the practitioner may advise on exercises or activity modifications believed to be a factor in the development and/or maintenance of the presenting complaint.

(I) Non Disclosure Form

NON DISCLOSURE OF INFORMATION

Student Practitioners

I _____ agree not to disclose the name of, or any information that would lead to the identification of the participants in the research study being undertaken by Kate Bone, Masters of Osteopathy Student at Unitec, New Zealand.

The treatment notes will not be made available to anyone other than the primary researcher and will be kept securely while in my possession.

I will not retain any copies of participant treatment notes.

Signed: _____

Name: _____

Date: _____

(J) Female Reproductive History Form

Female Reproductive History

1. How old were you when you started having periods?

2. Have you used the oral contraceptive pill?
   # of years

3. Do you have endometriosis? Yes ☐ No ☐
   Treatment

4. How many pregnancies have you had?

5. How many live births have you had?

6. Did you breast feed your children? ☐ ☐

   5a. For what total period of time?
   Please tick

   ☐ <6 months ☐ >6 months – 1 year ☐ 1 -2 years ☐ 2 – 3 years ☐ 3+ years

7. How regular was your mesntrual cycle during your reproductive years?

   ☐ Not regular ☐ Reasonably regular ☐ Very regular

8. What age did you notice a change in you menstrual cycle?

9. Are you experiencing hot flushes? ☐ ☐

   8a How long have you been experiencing hot flushes?

10. Are you a smoker? ☐ ☐

11. How tall are you?

12. How much do you weigh?

(K) Qualitative Information Sheet

Hello

In addition to the components of the study you have already taken part in I would like to collect a little further information. This element of the study will explore your attitudes and experiences during the treatment of your perimenopausal symptoms.

This aspect of the research will be conducted through a brief phone interview that will take no longer than 20 minutes. The interview will be done by myself at a time convenient to you.

During the interview I will be asking a few questions about your experiences through the duration of the study. All information conveyed during the interview will be confidential, and will be kept anonymous. The interview will be recorded via voice recording software and a copy of the transcript will be sent to you as soon as possible after the interview, to give you an opportunity to give me any further comments.

The questions that will be asked are listed below:

1. Looking back, what were your expectations prior to participating in this study?

2. Can you tell me a bit about your experience of having the treatment at the osteopathic clinic?

3. Can you describe to me how you feel since the treatments were completed?

4. Can you give me an example of any ways in which the treatment seems to have made a lasting difference to how you feel?

Taking part in this part of my study is entirely your choice, and you may choose not to participate.

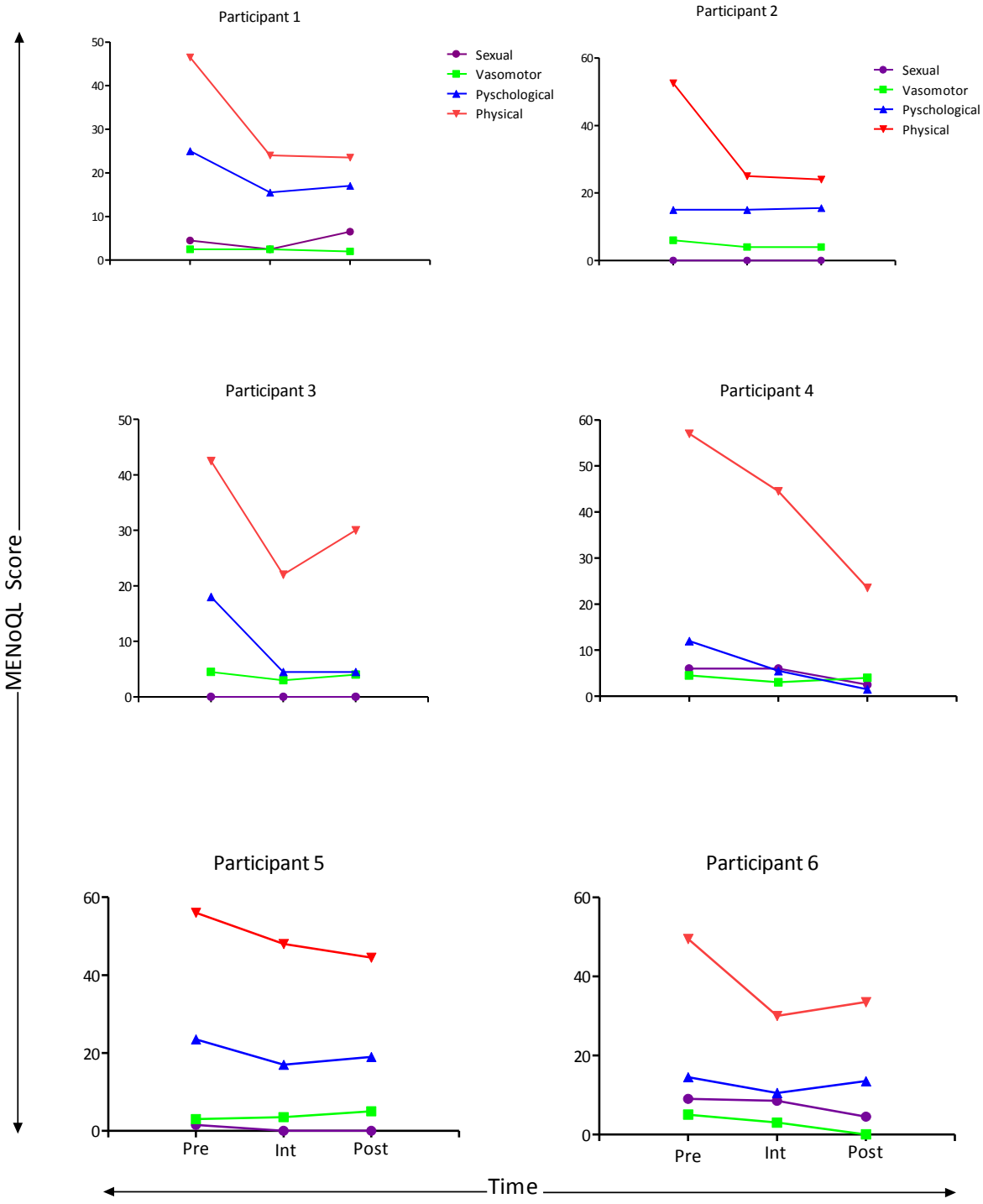
If you agree to take part in the short phone interview please send me an email saying that you consent to me contacting you to do a telephone interview that will include the questions listed above.

If you have any further questions or concerns please don't hesitate to contact me directly on 021 303 991 or at kate.bone1@gmail.com. If you wish, you may also contact any of my research supervisors at Unitec Dr Catherine Bacon, or Clive Standen on 09 815 4321 ext 8475

UREC REGISTRATION NUMBER: (2011-1173)
This study has been approved by the UNITEC Research Ethics Committee from (28/6/2011) to (28/6/2012). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

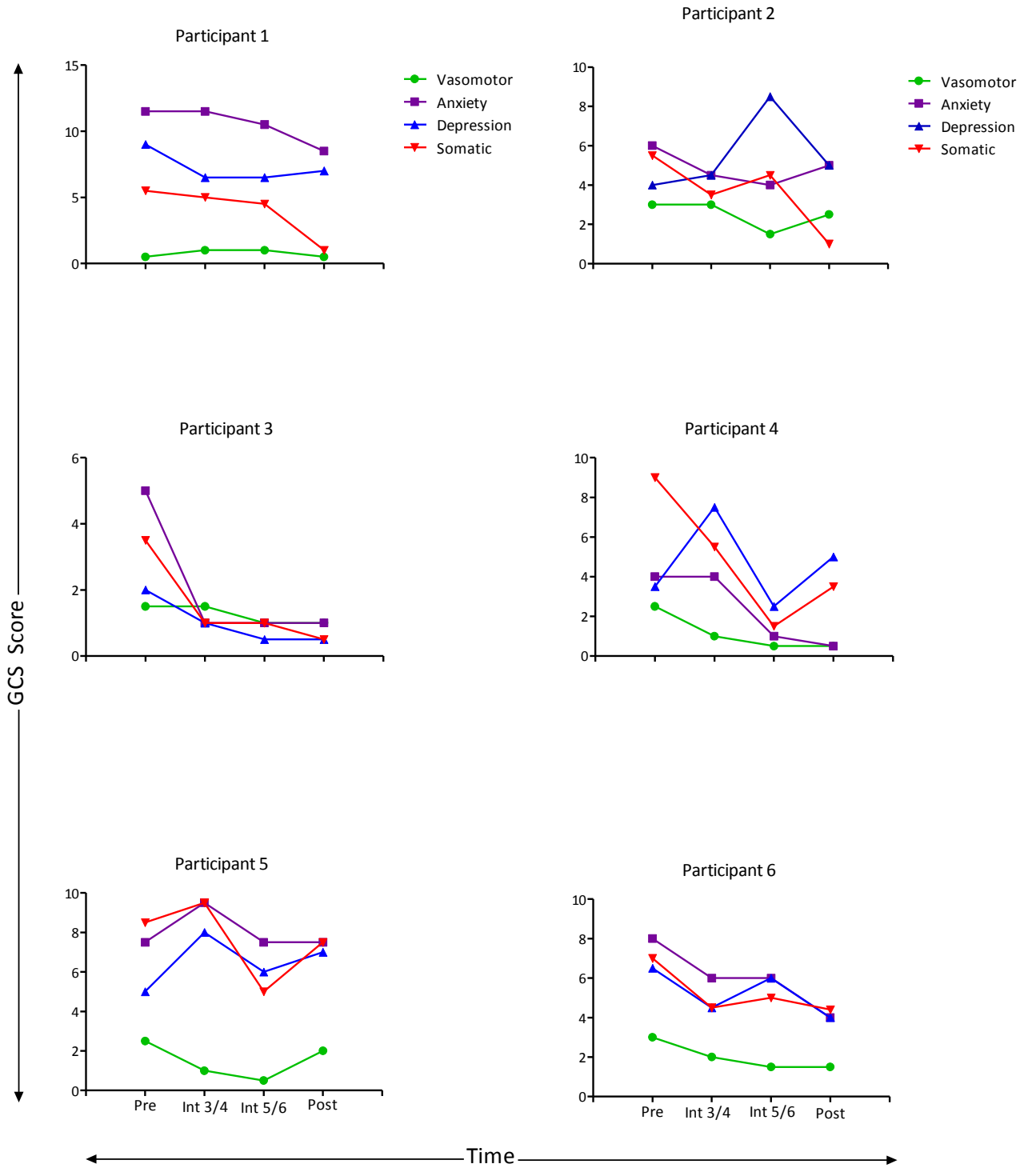
(L) MENoQL – Individual Symptom Domains

Average change in the symptom categories in the Menopause Quality of Life Questionnaire across the 8-week study



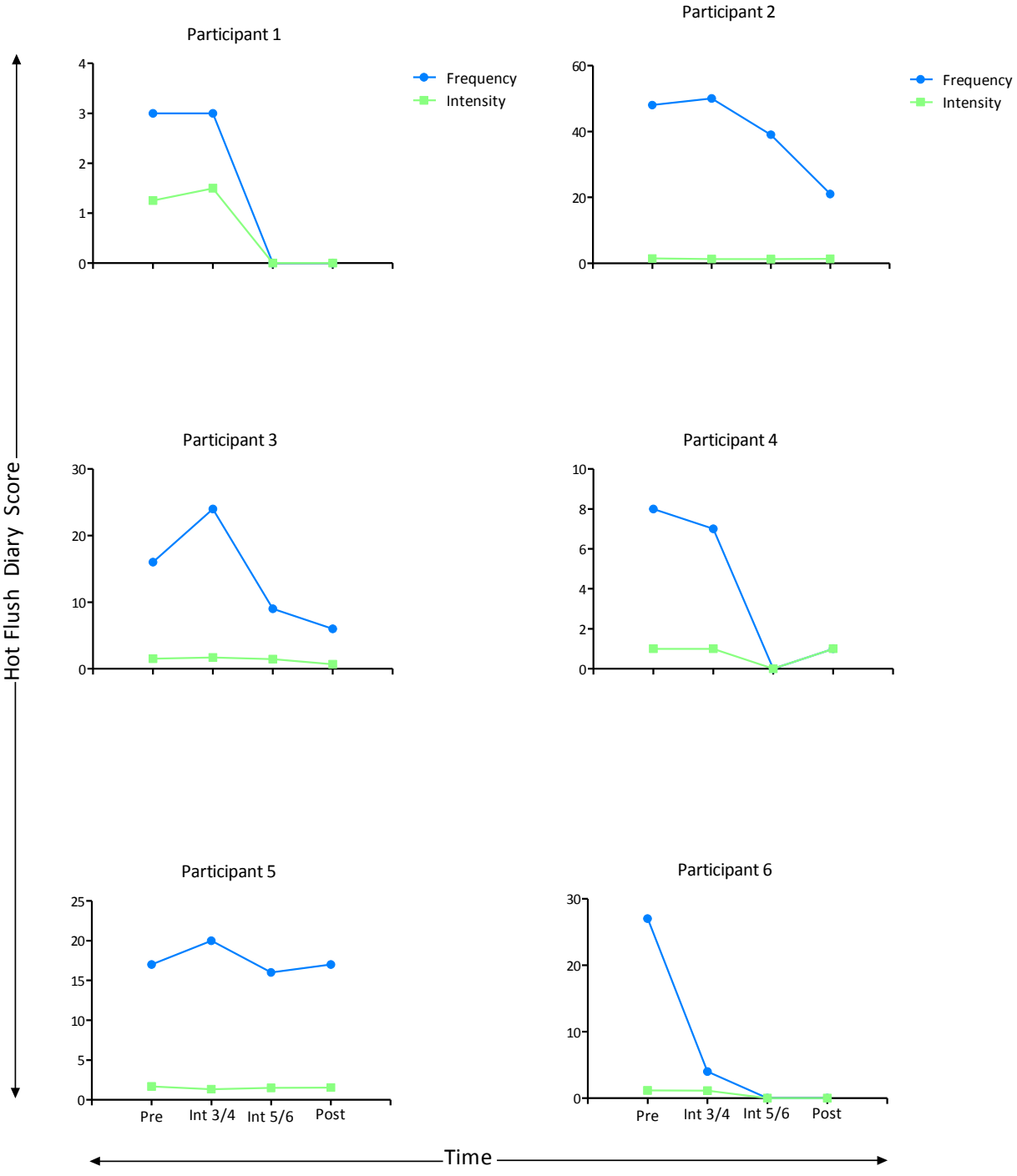
(M) Greene Climacteric Scale – Individual Symptom Domains

Average change in the symptom categories in the Greene Climacteric Scale across the 8-week study



(N) Hot Flush Frequency and Intensity

Average change in the frequency and intensity of hot flushes as recored in the Hot Flush Diary across the 8-week study



(O) Author Information – *IJOM*

See:
http://www.journalofosteopathicmedicine.com/authorinfo