Maturitas 80 (2015) 179–186

Contents lists available at ScienceDirect

Maturitas

journal homepage: www.elsevier.com/locate/maturitas

Chinese medicine treatment for menopausal symptoms in the UK health service: Is a clinical trial warranted?

Volker Scheid[a,*], Veronica Tuffrey[b], Thomas Weijburg[a], Mark Bovey[c], Trina Ward[a]

[a] EASTmedicine, Faculty of Science and Technology, University of Westminster, 115 New Cavendish Street, London W1W 6UW, United Kingdom
[b] Faculty of Science and Technology, University of Westminster, 115 New Cavendish Street, London W1W 6UW, United Kingdom
[c] Faculty of Health and Social Care, London South Bank University, London SE1 0AA, United Kingdom

ARTICLE INFO

Article history:
Received 14 July 2014
Received in revised form
10 November 2014
Accepted 11 November 2014

Keywords:
Menopause
Menopausal symptoms
Chinese medicine
Acupuncture
Herbal medicine
Personalized health care

ABSTRACT

Objectives: The aims of this pilot study were to evaluate treatment effects, ascertain safety and formulate best practice Chinese medicine protocols relevant for London women suffering from menopausal symptoms.
Study design: This clinical pilot study employed a case series design within a wider action-based research project. 117 perimenopausal women between 45 and 55 years of age recruited from the general population were treated for menopausal symptoms by six experienced practitioners of Chinese medicine at the Polyclinic of the University of Westminster. Practitioners were instructed to treat as near to their usual practice style as possible. This involved using Chinese herbal medicine and/or acupuncture along with dietary and lifestyle advice. A maximum of 12 treatments over 6 months was allowed per patient.
Outcome measures: The menopause specific quality of life questionnaire (MenQoL), the Greene climacteric scale, and flushing diaries were used to evaluate treatment outcomes. Liver and kidney function tests were carried out at intake and after 1, 6 and 12 treatments to evaluate the safety particularly in relation to the use of herbal medicines.
Results: Patients showed significant improvement across all domains measured by the MenQoL and Greene climacteric scales. Reduction on the MenQoL scale between first and last visit was from 4.31 to 3.27 ($p < 0.001$) and on the Green climacteric scale from 21.01 to 13.00 ($p < 0.001$). Study participants did not reliably complete their flushing diaries. No adverse events or abnormal liver or kidney function values were observed during the course of the study.
Conclusions: Further research that seeks to investigate the effects observed in more detail and to evaluate them against other forms of treatment and/or no-treatment controls is warranted. This could be achieved by way of a pragmatic randomized controlled trial that evaluated Chinese medicine against orthodox medical care.

1. Introduction

Nearly 50% of women experiencing symptoms during the menopausal transition find these symptoms distressing [1]. With conventional hormone replacement therapy (HRT) viewed as problematic by both experts and the public [2] women increasingly look for alternative solutions [3], including the use of complementary and alternative medicine (CAM) [4,5]. Chinese medicine (CM), with its claims to have successfully treated menopausal symptoms for hundreds or even thousands of years, is a popular choice in both China and abroad and consequently has attracted considerable research interest. Chinese medicine is increasingly popular in the West and thought to offer a personalized alternative to HRT. There is some high quality evidence to support this popularity [6] but the overall picture for both acupuncture and Chinese herbal medicine is variable and problematic [7]. Besides issues relating to the quality of research design, we contend that in most of the studies carried out to date the interventions lack validity, as their therapeutic processes are not rooted in an appropriate theoretical framework [8,9]. In addition, they have failed to engage with the cross-cultural variation known to exist in women's experience of menopausal symptoms [7,11–14,38].

Chinese medicine intrinsically lends itself to diagnostic and treatment approaches that are sensitive to local and individual

* Corresponding author. Tel.: +44 07734 252993.
E-mail addresses: scheidv@wmin.ac.uk (V. Scheid), tuffrev@wmin.ac.uk (V. Tuffrey), thomas@innerqi.co.uk (T. Weijburg), markb@acupuncture.org.uk (M. Bovey), trinaward@gmail.com (T. Ward).

http://dx.doi.org/10.1016/j.maturitas.2014.11.006
0378-5122/

variation in symptoms [9]. However, starting in the 1950s, institutionalized 'traditional Chinese medicine' or TCM developed standardized treatment protocols. The predominant TCM menopause protocol, based on a simplified biomedical understanding of the symptoms and their cause, has delivered a one-size-fits-all model into Chinese textbooks and thence into Chinese medicine teaching and practice in the West [7]. This model takes no account of the different experiences of menopause between China and Western countries [7,11] and does not reflect current practice even in East Asian countries, where the prescribing of Chinese medicinals for menopause is not constrained by textbook standards but draws on a much wider variety of medical formulas and clinical strategies [12].

Hence on the one hand there is a need for clinical evidence on the effectiveness of Chinese medicine for women with menopausal symptoms in the West, but on the other hand there are no credible best practice guidelines, nor accepted expert consensus, to inform a trial protocol. The Westminster menopause study was therefore conceived to test a radically different process for ascertaining treatment protocols that can reliably represent best clinical practice for the treatment of menopausal symptoms in given locales.

Altogether the Westminster menopause study consists of three distinct phases. This paper relates to the second phase of the project, which is clinical study with an action-research approach [10]. The aims of this study are to provide a preliminary evaluation of treatment effects, ascertain safety and formulate best practice Chinese medicine protocols relevant for London women suffering from menopausal symptoms. We have previously shown [12] that London women's experience of menopause differs significantly from that of women in other locales, hence a similar focus on London women was employed for the present study.

This paper relates specifically to the treatment effects and safety issues. Phase 1 of the project consisted of a large-scale survey of symptoms experienced by menopausal women in London [11] as well as extensive archival research documenting the historical emergence and variability of approaches to menopausal symptoms within the CM tradition [7,12–15]. Phase 3 is planned to be a randomized controlled trial (RCT) evaluating the effectiveness of the best practice protocols derived from Phase 2.

2. Methods

2.1. Design

The study was a practice-based pre-post design with no control group. Participants were recruited from the general population. 117 menopausal women were treated in the University of Westminster Polyclinic in central London by six experienced practitioners of Chinese medicine.

2.2. Participants

The study included 117 menopausal women residing in London. Participants had to be aged between 45 and 55 years to be included in the study. Data was collected between May 2008 and October 2011. A sample size calculation indicated that 119 participants were needed to detect an effect size of 0.3 with a power of 90% and probability of Type 1 error of 5% [16].

Participants were recruited from the general population. The initial design was to do so via delegation by general practitioners (GPs) in two London boroughs (Westminster, Lewisham). However, GPs were extremely reluctant to delegate patients to the study. Ethics permission was therefore obtained to change the study design and recruit via advertisements in a free London newspaper, and on the University of Westminster intranet site. Interested potential respondents contacted the research administrator, who sent them relevant documents to take to their GP or consultant who could then delegate them to the study. These documents included an introductory letter, a research summary, an invitation and explanatory letter, inclusion and exclusion criteria and a delegation pack. Once their GP or consultant had signed the delegation letter, the woman could arrange an appointment at the polyclinic. The administrator allocated a practitioner to each participant ensuring that each practitioner treated approximately the same number of women over the course of the study. Once recruited, the practitioner informed the participant's GP of their patient's inclusion in the study. GPs were also sent a final letter when the woman was discharged from the study.

Menopause is most commonly experienced by woman aged 45–55, though it may also occur earlier or later. As the presence or not of menopausal symptoms appears mediated by a range of personal and cultural factors rather than being strictly the result of the biological cessation of periods [12,38], for the purpose of this study we selected women between 45 and 55 years who experience menopausal symptoms such as night sweats and mood changes. Women were excluded from the study if they had one or more of the following characteristics: receiving HRT treatment; with surgically or drug induced menopause; menopause occurring before age 45 or unnatural menopause; already receiving Chinese medicine or acupuncture and not willing to suspend such treatment for the duration of the study; on warfarin or other drugs with a very narrow therapeutic dosage that required constant monitoring; suffering from severe systemic disorders such as cancer or multiple sclerosis who were receiving immunosuppressive treatment, radiation treatment, or chemotherapy; suffering from severe psychiatric disorders who were being treated with lithium or neuroleptic medication and required constant psychiatric supervision; with known allergies to herbal products; diagnosed during their initial assessment interview as requiring treatment for the Chinese medical disorders *diankuang* 癲狂 (mania and withdrawal) or *benglou* 崩漏 (uterine bleeding), or were already participating in another medical study. If potential participants had abnormal liver or kidney function detected in the course of routine monitoring during the first visit, they were excluded from the study and referred back to their GP for investigation.

2.3. Study intervention

Patients were offered 12 sessions of Chinese medicine for free over a 6-month period. Based on discussions within the research team, we considered this to corresponds to the average frequency of treatments Chinese medicine practitioners would deliver across a range of conditions in normal practice. The frequency of treatments was not fixed; some received weekly treatments, some fortnightly and others less frequently, according to the practitioner's usual style and the patient's individual circumstances In order to achieve a high level of external validity, each practitioner treated their patients based on their knowledge and experience as well as their personal approach to clinical practice. This is representative of the complexity of CM in practice and its varied traditions [9]. Practitioners were instructed to treat as near to their usual practice style as possible; this involved using Chinese herbal medicine and/or acupuncture along with dietary and lifestyle advice. Owing to fire safety regulations at the University of Westminster Polyclinic moxibustion could not be employed. There was no standardized protocol to guide their clinical decisions besides being limited to the maximum of 12 sessions.

Chinese medicine is geared to relieving patient distress by making use of a range of different clinical tools in an integrated fashion. There is evidence that the combined use of acupuncture and herbal medicine in the treatment of menopause related symptoms