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What's in the bottle? Prescriptions formulated by medical herbalists in a clinical trial of treatment during the menopause

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ABSTRACT

This paper reports on the complex prescriptions designed by practitioners of western herbal medicine in a pilot randomised, waiting-list controlled trial carried out in primary care in the UK. Herbal practitioners recorded their prescriptions and advice contemporaneously during the pragmatic trial investigating 5 months of treatment for symptoms associated with the menopause. Treatment was modified so that the 35 participants received 141 prescriptions between them during the course of their treatment. These complex prescriptions were shown to contain varying combinations of a total of 80 herbs. Between 4 and 9 herbs were used in each prescription. The three most commonly prescribed herbs were *Leonurus cardiaca*, *Cimicifuga racemosa* and *Salvia officinalis*. Care included not only herbal prescriptions but also dietary and lifestyle advice and discussion of self care in an evolving therapeutic relationship. The care was individually reviewed and adjusted at each consultation over the course of treatment.

1. Introduction

The practice of Western herbal medicine has been defined as a healing modality which centres on plants native to Europe, prescribed within a philosophical tradition arising from European thought (Evans, 2009; Nissen, 2010). Herbal medicine is commonly used in the UK: a survey of 2032 adults, commissioned by the Medicines and Healthcare products Regulatory Agency in 2008, found that 35% had used herbal medicine at some time in the past (over the counter or from a practitioner). Women were more frequent users than men and 9% of women, compared with 6% of men, had used medicines supplied by a herbal practitioner which were not traditional Chinese herbal medicines (Ipsos Mori/MHRA, 2009). Western herbal practitioners report menopausal symptoms (Beatty and Denham, 1998) and women's health issues (Nissen, 2010) as a frequent reason for patient consultations. While there is an established research base in clinical and pharmacological studies of individual herbal medicines, investigation into contemporary herbal practice is limited (Evans, 2008; Green et al., 2007; Hamblin et al., 2008; Walker, 2006). With the proposed regulation of the practice of herbal medicine in the UK, an understanding of herbal practice is pertinent (Department of Health, 2011).

Herbal practitioners take a detailed clinical history, examine the patient and discuss diet and lifestyle in the broad

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sense before deciding on a treatment plan, including the herbal prescription (Conway, 2011; Nissen et al., 2008). The first consultation generally takes an hour (Casey et al., 2008) and each consultation may take a different course depending on the particular practitioner and patient. A survey of 378 herbal practitioners in Australia found that 97% dispensed their own prescriptions, and 87% formulated individualised herbal prescriptions (Casey et al., 2007). The prescription is based on the clinical history and discussion but the choice of herbs for the individual patient relies on the clinical judgment of the practitioner who considers the overall health of the patient (Walker, 2006). Prescriptions formulated by herbal practitioners are complex in the sense that the prescription has more than one component herb, and is progressively adapted at follow up consultations. The advice and discussion on, for example, diet, exercise or lifestyle varies with the individual. Dependent on the wishes of the patient, it is common for there to be some discussion of emotional factors, so there is substantial diversity both between individual consultations and between practitioners.

This paper contributes to the investigation of herbal prescribing, a defining feature of Western herbal practice, by reporting on the herbal prescriptions formulated by three herbal practitioners during a pilot randomised, waiting-list controlled trial of the effectiveness of herbal practice in the treatment of menopausal symptoms (Green et al., 2007). The herbs used and treatment rationale are discussed together with some exploration of the discussion and advice which formed part of the consultations.

2. Methods

Records were made of the herbal prescriptions and advice offered by three practitioners of Western herbal medicine during a pilot pragmatic randomised controlled trial of care of women experiencing self-defined menopausal symptoms (Green et al., 2007). Individualised herbal prescriptions, formulated by the herbal practitioners, were adjusted if required at each consultation. The practitioners were experienced members of the National Institute of Medical Herbalists who trained at a similar time; they were asked to prescribe as they would in usual practice with no limit imposed on their choice of herbs.

For this part of the study, the practitioners used their patient records for each consultation to enter information about their prescriptions onto a data sheet, recording the main prescription plus any additional prescriptions, food supplements and advice. Each individual prescription was numbered, and entered in anonymised form on a database. For the first prescription only, the reason for the inclusion of each herb was given, and this was the one item completed in retrospect rather than from the contemporaneous patient records.

Prescriptions were analysed for 35 participants: 14 in the treatment group and 21 in the waiting-list control group. Of the 35 participants, 30 (86%) completed the course of treatment, attending all 6 consultations offered over a 5 month period.14 participants out of 15 in the treatment group completed the course of treatment. One participant in the treatment group was excluded early in the trial as post-operative complications meant that she was unable to attend for treatment. Her prescription is not included in this study. The waiting-list control group initially had no treatment and acted as the control group, and then took up the offer of treatment after the main study was completed. In this group of 30 women, 21 women took up the offer of treatment. 4 of these women did not complete the full course of treatment but their prescriptions are included in this study. Thus, the records of 35 women are included in this part of the study. The women were aged 46-58 at the date of their first consultation, which was between February 2003 and July 2004.

At the first consultation, all participants were given a diet sheet which made recommendations on foods to include in the diet such as oats, soya and other beans, fresh vegetables and fruit, seeds, nuts and sprouted grains. The sheet also advised participants to drink plenty of water and cut down on coffee, cola, tea, hot spices, sugar, salt, chocolate, alcohol and smoking.

3. Results

Primary outcomes of change in menopausal symptoms are reported elsewhere (Green et al., 2007). Here we report the herbal prescriptions and advice offered to participants in the study. Findings are presented as an overview of prescriptions, some examples of herbal treatment, and additional treatment and advice.

3.1. *Prescriptions*

All women received a main herbal prescription. Most formulations were of liquid ethanolic tinctures taken at a dose of 5 mL three times daily. For the 35 women, there was a total of 198 consultations, and there were 141 different herbal prescriptions, each containing between 4 and 9 herbs (mean 6.4). At follow up consultations, the prescriptions were reviewed and either adjusted to some extent (71%) or repeated without change (29%). Prescriptions were therefore taken for between 2 and 14 weeks before adjustment. About 73% of the prescriptions were taken for 3 or 4 weeks.

Table 1 – Top 14 herbs included in the main herbal prescriptions.

Herbs	Proportion (%) of total prescriptions (n = 141)
Leonurus cardiaca	77% (n = 109)
Cimicifuga racemosa	57% (n = 80)
Salvia officinalis	41% (n = 58)
Glycyrrhiza glabra	34% (n = 48)
Taraxacum officinale Rad	24% (n = 34)
Borago officinalis	19% (n = 27)
Trifolium pratense	18% (n = 26)
Rumex crispus	18% (n = 26)
Verbena officinalis	18% (n = 25)
Avena sativa	18% (n = 25)
Scutellaria lateriflora	16% (n = 23)
Hypericum perforatum	16% (n = 23)
Ginkgo biloba	14% (n = 20)
Tilia x europaea	14% (n = 19)