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

Alison Denman[1]
Julia Green[2]
Sue Hawkey[3]

[1] University of Central Lancashire
[2] School of Life Sciences
[3]City of Bristol College

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Author names and affiliations:

Alison Denham[a]
School of Health, University of Central Lancashire, Preston, PR1 2HE. adenham@uclan.ac.uk

Julia Green [b]

Present address: School of Life Sciences, University of Westminster, 115 New Cavendish St, London, W1W 6UW. J.Green3@westminster.ac.uk

Sue Hawkey [c]
Faculty of Health and Social Care, University Centre, City of Bristol College, Ashley Down Centre, Bristol BS7 9BU. Sue.Hawkey@cityofbristol.ac.uk

Corresponding author: Alison Denham

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 five 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 support, 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.

Keywords Herbal Prescription; Western Herbal Medicine; Menopause; Complex Intervention; *Leonurus cardiaca* L.; Whole person treatment.

Trial registration: ISRCTN42406364

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) and 26% had used it within the last two years. One in twelve had consulted a practitioner of Western herbal medicine in the previous two years 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 tradition 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 forthcoming regulation of the practice of herbal medicine in the UK proposed, 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 sense before deciding on a treatment plan, including the herbal prescription (Conway 2011, Nissen 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 are progressively adapted at follow up consultations. The advice and discussion on, for example, diet, exercise or lifestyle varies with the individual. Depending 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. These participants initially had no treatment and acted as the control group, and then took up the offer of treatment after the main study was completed. Of the 35 participants, 30 (86%) completed the course of treatment, attending all 6 consultations offered over a five 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. In the waiting-list control 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, was between February 2003 to 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 and 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 5mL 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. 73% of the prescriptions were taken for 3 or 4 weeks.

3.1.1 Range of herbs in the main herbal prescriptions

A total of 80 herbs was used in the study (see Appendix A). The fourteen herbs prescribed most frequently are summarised in Table 1. *Leonurus cardiaca* (Motherwort) was the herb used most frequently: 109 times, as a part of 77% of the prescriptions, *Cimicifuga racemosa* syn. *Actaea racemosa* (Black Cohosh) was used in 80 prescriptions (57%) and *Salvia officinalis* (Sage) in 58 prescriptions (41%).

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)

For the 35 first prescriptions only, the reason for the inclusion of each herb was given. The actions were mainly described in broad terms which could be grouped into seven categories: for hot flushes (32 times), hormonal support (26 times), circulatory support (19 times), nervines (49 times), liver and digestive support (24 times), aches and pains (23 times), adaptogen and other categories (11 times).

3.1.2 Main herbal prescriptions for the treatment group

The aim of this study was not to evaluate the effectiveness of single herbs but, as the course of treatment was shown to be effective, the herbs used in the main prescriptions for the 14 women in the trial treatment group are summarized in Table 2. The table shows that the number of different prescriptions for each woman varied from 1 to 6. The total number of herbs prescribed for each woman varied between 5 and 13 over the full course of treatment. The combination of herbs in each prescription is not shown but the Table shows that 12 herbs were prescribed continuously throughout treatment for at least one of the women including: *Leonurus cardiaca* (6 women), *Salvia officinalis* (5 women) and *Cimicifuga racemosa* (4 women).

Table 2: Summary of 14 prescriptions for treatment group

Woman	Number of prescriptions	Total herbs	Number of prescriptions including *Leonurus cardiaca*	Herbs included in every prescription
1	6	13	6	*Leonurus cardiaca,Salvia officinalis*
2	4	9	4	*Leonurus cardiaca,Salvia officinalis*

3	3	11	3	*Leonurus cardiaca, Cimicifuga racemosa*
4	3	10	2	*Calendula officinalis, Lamium album, Salvia officinalis*
5	1	5	1	Disliked taste so treatment continued using proprietary tablets
6	4	10	1	*Salvia officinalis*
7	4	12	None	None
8	4	10	2	*Salvia officinalis.*
9	6	16	5	None
10	3	7	3	*Avena sativa, Leonurus cardiaca, Taraxacum officinale, Tilia* x *europaea*
11	5	11	5	*Cimicifuga racemosa, Glycyrrhiza glabra, Leonurus cardiaca, Trifolium pratense*
12	5	11	4	*Cimicifuga racemosa, Glycyrrhiza glabra, Trifolium pratense*
13	6	17	5	*Apium graveolens, Cimicifuga racemosa*
14	4	13	4	*Leonurus cardiaca, Trifolium pratense, Withania somnifera*

3.2 Example of herbal treatment

A representative example of treatment is given in Table 3. This summarises the treatment episodes of one woman during three consultations, and includes a summary of current symptoms, prescriptions and advice.

Table 3. Treatment given at three consultations including herbal prescriptions, advice and treatment rationale.

office worker, age 48, presenting with low energy, hot flushes, migraine, low libido, poor memory, poor concentration

Consultation	***Herbs***	**Volume**	**reason**	**Advice**
Consultation 1: Prescription 1	*Cimicifuga racemosa* (tincture, 1:5)	20	to help flushes and libido	reduce sugar, alcohol and dairy products; include legumes and essential fatty acids in diet; discuss possible dietary triggers including low blood sugar for migraines; relaxation.
	Turnera diffusa (tincture,1:5)	20	increase energy & libido	
	Salvia officinalis (tincture,1:5)	20	to help flushes	
	Taraxacum offic. Rad. (tincture, 1:5)	20	to clear hormonal load via liver, general detox	
	Ginkgo biloba (tincture, 1:5)	20	circulation to gynae areas & brain	
	Total dispensed=300mL	100 mL	Dose 5mL three times a day in cold water before meals	
Consultation 2	Repeat prescription Total dispensed=300mL		Dose as above	live yoghurt / L. acidophilus; Sage tea; discuss wider benefits of increased exercise.
Consultation 3: Prescription 2	*Avena sativa*	20	*	reiterate above advice; linseeds 1-2 tablespoons per day
	Tilia x europaea	20	*	
	Salvia officinalis	20	*	
	Taraxacum offic. rad	20	*	
	Leonurus cardiaca	20	*	

	Total dispensed=400mL	100	Dose as above	
Consultation 4: Prescription 3	(not included here)			Vitamin E
Consultation 5 and 6: Prescription 4	(not included here)			Discuss continuing the changes in diet, relaxation and exercise, which had generally been maintained.

3.3 Additional treatment and advice

Both prescriptions additional to the main prescription and advice on food supplements were also part of the herbal treatment. These were noted at 111 (56%) out of the total of 198 consultations. Two herbs were prescribed separately for symptoms related to the menopause, and these were *Vitex agnus castus* (11 times) and *Salvia officinalis* (9 times).

Additional herbal medicines and food supplements are summarised in Table 4.

Table 4: Additional prescriptions given in addition to the main herbal prescription

Type of prescription or recommendation	Number of times prescribed or noted	Details
Sleeping mixes	11	
Colds, Coughs etc	9	
External remedies	9	
Others:	6	Teas: *Urtica dioica, Apium graveolens; Psyllium ovata*; Bach flower remedies; proprietary tablets; constipation mix
Supplements	24	Oils, essential fatty acids, Vitamin E, linseed

Discussion and advice on other factors was noted at 105 (53%) of consultations. Factors that were discussed included diet (50 consultations), fluid intake (most commonly to reduce coffee, 17 consultations), emotional factors (20 consultations) and exercise (16 consultations). Suggestions were made about consulting other practitioners 9 times (acupuncture, Alexander technique, allergy testing, general practitioner, osteopath, shiatsu/massage, yoga/meditation). In some cases, this advice and discussion was wide-ranging. To take one example of the practitioner summary of the notes at the first consultation: “diet sheet given; 2 teaspoons Psyllium seeds on porridge; increase fruit; eat ginger; try rice cakes and oatcakes; replace wheat cereal with oats; drink more water; reduce coffee gradually; consult osteopath”.

4. Discussion and Conclusions

This study documents herbal prescribing in usual practice, amongst a client group that frequently consults Western herbal practitioners. Prescriptions designed by the herbal practitioners were found to be mainly liquid ethanolic mixtures of 4-9 individual herbs, typically modified after follow up consultation (71%). Additional herbal prescriptions and discussion about diet and lifestyle took place in over half the consultations, a feature of practice also noted in a survey of herbalists in Australia (Casey et al. 2007).

In contrast to most research on herbal medicines used in the menopause (Borrelli and Ernst 2008), this study documents herbal practice which is more involved and complex than over the counter use of herbal medicinal products (Evans 2008). Prescriptions were formulated after in-depth consultations, which is similar to the findings of Casey et al. (2007, 2008) who reported similar results in a survey of 378 herbal practitioners in Australia. The details of prescribing and advice add to the description of usual care, which is not always adequately described in pragmatic trials (Smelt et al. 2010). As the original study showed treatment of menopausal symptoms by herbal practitioners to be effective (Green et al. 2007), closer examination of usual care in this instance is of interest. By reporting not only the prescriptions but the practitioners’ rationale for selecting herbs in the context of treating women with menopausal symptoms, we begin to explore their clinical reasoning (Bissessur et al. 2009) which is a neglected area of practice research (Higgs et al. 2008).

While the context of the study would suggest treatment was addressing menopausal symptoms, this was not necessarily the sole treatment aim. Prescriptions were formulated in response to individual circumstances including symptoms not necessarily due to menopause. For example, in the representative prescription given in Table 3, a woman complaining of migraine and poor memory was given *Ginkgo biloba* "to increase circulation to brain and pelvic organs".

The 141 prescriptions formulated during this clinical trial contained a range of 80 individual herbs (See Appendix A). The herbs used most frequently in formulations were *Leonurus cardiaca, Cimicifuga racemosa* and *Salvia officinalis* and these were amongst five used most frequently in an earlier survey of 38 practitioners in the UK (Beatty and Denham 1998). These three herbs have been reported to treat menopausal symptoms, although *Leonurus cardiaca* is referred to less widely in the literature, and they are discussed here.

Leonurus cardiaca (Motherwort) was selected by practitioners to control hot flushes, as a gynaecological tonic and as a relaxant. According to Culpeper (1995, p.171), writing in 1652, "there is no better herb to take melancholy vapours from the heart...and make a merry, cheerful blithe soul..." Traditional use is further described by Cook (1985, p.506), writing in 1869, as an antispasmodic nervine tonic useful in "the sufferings peculiar to women" and "habitual restlessness". The British Herbal Pharmacopoeia (BHMA, 1983) lists the action of *Leonurus cardiaca* as sedative, antispasmodic and indications as cardiac debility, simple tachycardia, effort syndrome, amenorrhoea. *Leonurus cardiaca* is specified as a herbal remedy used to treat menopausal symptoms in a recent US survey (Williams et al. 2007).

Cimicifuga racemosa (Black cohosh) was included by practitioners for treating hot flushes, aches and pains, dry vagina, low libido and tinnitus, and used for "hormonal buffering" and as a relaxant. It is widely used in self-prescribing in the menopause (Shams et al. 2010, Borrelli and Ernst 2008) and by practitioners (Beatty and Denham, 1998). However in 10 out of the 18 first prescriptions containing *Cimicifuga racemosa* practitioners specify aches and pains or anti-rheumatic as the treatment rationale. 4 participants had underlying health conditions that might have caused such symptoms and in addition these symptoms could reflect underlying osteoarthritis. However, an 8-year study of 438 women in Australia, of whom 56% were postmenopausal by the end, found the most commonly reported symptom was "aches and stiff joints" which occurred in over 60% of women whether or not osteoarthritis was identified by X-ray of the knee and/or hand (Szoeke et al. 2008). The British Herbal Pharmacopoeia (BHMA, 1983) lists the indications for *Cimicifuga racemosa* as muscular rheumatism, rheumatoid arthritis, intercostal myalgia, sciatica, whooping cough, chorea, tinnitus, dysmenorrhoea, and uterine colic. Thus, *Cimicifuga racemosa* may have been selected to suit treatment to the individual woman rather than simply for menopausal symptoms.

Practitioners were consistent in describing *Salvia officinalis* as useful for treating hot flushes, in some cases describing it as an aid to digestion. *Salvia officinalis* was also prescribed as a simple, a single herb, in additional prescriptions either as a tincture or a tea. The British Herbal Pharmacopoeia (BHMA, 1983) lists the indications for *Salvia officinalis* as flatulent dyspepsia, pharyngitis, uvulitis, stomatitis gingivitis, glossitis, hyperhidrosis and galactorrhoea. A review of practice found 45 of 47 UK practitioners used *Salvia officinalis* in prescriptions for menopausal problems and it was chosen not only for hot flushes but to increase mental clarity, as a general tonic for debility and fatigue, and for antiseptic actions, particularly to the mouth and throat (Beatty and Denham 1998). A recent open label clinical trial, using fresh *Salvia officinalis* on 69 women for 8 weeks, found a reduction in menopausal symptoms (Bommer et al. 2010).

How do practitioners make a choice of herbs in a prescription? Traditional usage for herbs acknowledges several actions and indications for each one (BHMA 1983, Walker 2006). The practitioner's aim is to match these to the unique presentation of the patient, often within particular philosophical or cultural traditions (Evans 2009, Nissen 2008). The language used by practitioners to describe their clinical reasoning is typically functional ("hormonal support", "liver support", "for hot flushes and palpitations", "for energy and libido"). Whilst common language within herbal practice, this "shorthand" may not be explicit to a wider audience, and further research to explore the practitioner's clinical reasoning would benefit from articulating tacit knowledge, in particular to explore the role of traditional knowledge and vitalist philosophy in the practice of herbal medicine (Evans 2008). It is a limitation of this study that the underling rationale for the prescribing has not been adequately described as it would be useful to understand more about the linkage between the clinical history and the process of composing the prescription (Bissessur et al., 2009). In a future study, it would be important to ensure that the clinical reasoning underlying the prescriptions was recorded at the time.

It is a limitation of this study that it discusses the prescriptions and practice of only three practitioners who trained on the same course at a similar time so, despite congruence with an older review of practice (Beatty and Denham 1998), it may not be representative of wider herbal prescribing. Discussion has been limited to a small number of the herbs used.

As the prescription is only one component in the treatment process, which includes diet and lifestyle advice, and listening to the patient narrative set in evolving therapeutic relationship it is not possible to equate effectiveness with the herbs used. In particular, although the extent to which each woman followed the advice is unknown, the volume and variability of the discussion of diet and food supplements was such that it makes characterisation of the intervention unclear. This discussion is integral to herbal practice, but would require more consideration if designing a further clinical trial using the Medical Research Council guidance on the evaluation of complex interventions (Craig et al. 2008).

Much literature on the modelling of complex interventions has been published (Boon et al. 2007, Craig et al 2008). There is an argument that such complex holistic practice cannot be deconstructed but is best viewed as a whole process (Nissen 2008). There has been some relevant investigation of the nature of the intervention in traditional acupuncture. Paterson & Dieppe (2005) question whether it is possible to separate the characteristic elements of a therapy from the incidental elements such as practitioner, clinical setting and patient expectation. They argue that when the consultation is a process that gradually engenders the diagnosis, in the sense of the rationale for treatment, the incidental and characteristic elements of the intervention cannot be separated

Future investigation of herbal practice should take the complex and evolving nature of herbal prescribing and herbal treatment into account. Qualitative investigation of clinical reasoning would clarify prescribing and treatment choices (Higgs et al 2008). To evaluate usual care continues to be a valid goal, in that a recent study of 19 patients who consulted herbalists found the collaborative relationship between patient and practitioner to be a crucial element underpinning the success of herbal medicine as a therapeutic intervention. The results of this qualitative study suggest that it was the variability and individuality of the consultations and treatments that patients regarded as important (Little 2009).

From within this diversity, emerges frequent and consistent use of *Leonurus cardiaca, Cimicifuga racemosa* and *Salvia officinalis*, within a prescription designed to meet individual health needs of the women. Herbal practice included additional prescriptions and advice and discussion of diet and lifestyle which was set within evolving therapeutic relationships. Thus herbal prescriptions were complex in themselves, and part of the larger complex intervention that is herbal practice.

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Contributors: AD carried out this part of the study, and is main author; JG was the trial co-ordinator; SH entered the data. JG and SH contributed to the revision of the manuscript. AD acts as guarantor.

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Appendix A.	
Herbs prescribed during the study (n=80)	Number of prescriptions (Total=141)
Leonurus cardiaca	109
Cimicifuga racemosa	80
Salvia officinalis	58
Glycyrrhiza glabra	48

Taraxacum officinalis Radix	34
Borago officinalis	27
Rumex crispus, Trifolium pratense	26
Avena sativa, Verbena officinalis	25
Hypericum perforatum, Scutellaria lateriflora	23
Ginkgo biloba	20
Tilia x *europaea*	19
Achillea millefolium, Apium graveolens	18
Viburnum prunifolium	17
Crataegus monogyna, Stachys officinalis	16
Berberis vulgaris	15
Eleutherococcus senticosus, Turnera diffusa	13
Withania somnifera	12
Angelica sinensis, Citrus aurantium, Lamium album, Tussilago farfara	11
Euphrasia rostkoviana, Matricaria recutita, Rosmarinus officinalis	10
Filipendula ulmaria, Melissa officinalis	9
Centella asiatica, Dioscorea villosa, Vitex agnus castus, Zanthoxylum americanum	7
Plantago lanceolata	6
Galega officinalis, Harpagophytum procumbens	5
Arctium lappa, Calendula officinalis, Galium aperine, Glechoma hederacea, Sambucus nigra, Urtica dioica, Viburnum opulus	4
Chionanthus virginicus, Humulus lupulus, Jasminum officinale, Scrophularia nodosa	3
Agrimonia eupatoria, Astragalus membranaceus, Centaurium erythraea, Codonopsis pilosula, Cynara scolymus, Fucus vesiculosus, Iris versicolor, Passiflora incarnata, Rosa damascena, Swedish bitters (treated as one herb), *Vinca major, Viscum album*	2
Acorus calamus, Aesculus hippocastanum, Althaea officinalis, Capsella bursa-pastoris, Carduus marianus, Guaiacum officinale, Lobelia inflata, Marrubium vulgare, Melilotus officinalis, Panax ginseng, Peumus boldo, Phytolacca decandra, Salix alba, Solidago virgaurea, Symphytum officinalis Herba, *Thymus vulgaris, Valeriana officinalis, Verbascum thapsus*	1