

# Randomised controlled open outcome study of treatment of menopausal symptoms by medical herbalists (pilot study)

**Submission date**  
12/07/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
03/08/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
28/10/2022

**Condition category**  
Urological and Genital Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

NUX018

## Study information

### Scientific Title

Randomised controlled open outcome study of treatment of menopausal symptoms by medical herbalists (pilot study)

**Study objectives**

To demonstrate whether the well-being of a sample of menopausal women is improved by treatment from practicing medical herbalists.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration.

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Menopausal symptoms or problems

**Interventions**

Intervention group of 15 women: 6 consultations and treatment with individual prescriptions of a mixture of herbal medicines over a 5 month period by one of 3 local qualified herbal practitioners who are Members of the National Institute of Medical Herbalists.

Control group of 30 women: offered equivalent series of consultations and treatment after acting as controls for 5 months.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Greene Climacteric Scale

**Key secondary outcome(s)**

Measure Yourself Medical Outcome Profile (MYMOP2), Hot flush Visual Analogue Scale (VAS)

**Completion date**

30/12/2004

**Eligibility**

**Key inclusion criteria**

1. Women aged 46 - 59 registered on database of one general practice in Bristol
2. Over three months since last menstrual period
3. Experiencing self-defined menopausal problems of over three months duration

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

45

**Key exclusion criteria**

In the previous three months:

1. Taken hormone replacement therapy
2. Taken any other hormone treatment including 'natural progesterone cream'
3. Taken tamoxifen
4. Surgery requiring a general anaesthetic

Current:

Complementary treatment for menopausal problems; psychiatric treatment or medication; advised by a doctor to take hormone replacement therapy because of osteoporosis or high risk of developing osteoporosis.

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

30/12/2004

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

286 Ashley Down Road  
Bristol  
United Kingdom  
BS7 9BQ

## Sponsor information

### Organisation

University of Central Lancashire (UK)

### ROR

<https://ror.org/010jbqd54>

## Funder(s)

### Funder type

Research organisation

### Funder Name

National Institute of Medical Herbalists (UK) - Education Fund

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/10/2007   |            | Yes            | No              |