

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

Dr Julia Green

Contact details

286 Ashley Down Road

Ashley Down

Bristol

United Kingdom

BS7 9BQ

+44 (0)117 924 8133

julia.green@ukonline.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Greene Climacteric Scale

Secondary outcome measures

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

Overall study start date

01/01/2002

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

Age group

Adult

Sex

Female

Target number of participants

45

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

England

United Kingdom

Study participating centre

286 Ashley Down Road

Bristol

United Kingdom

BS7 9BQ

Sponsor information

Organisation

University of Central Lancashire (UK)

Sponsor details

Faculty of Health

Preston

England

United Kingdom

PR1 2HE

-

adenham@uclan.ac.uk

Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

National Institute of Medical Herbalists (UK) - Education Fund

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article		01/10/2007		Yes	No