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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

Registration date
03/08/2005

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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-
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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