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A pilot patient cohort randomised controlled trial (RCT) of the effectiveness of an offer of treatment by a homeopath

Submission date 25/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/06/2008	**Overall study status** Completed	
Last Edited 27/09/2017	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol v8

Study information

Scientific Title
A pilot patient cohort randomised controlled trial (RCT) of the effectiveness of an offer of treatment by a homeopath

Study objectives
The objectives of the pilot study were to assess the following:
1. Willingness of patients to fill in questionnaires, consent to further questionnaires and consent to have data used
2. Willingness of participants to accept the intervention
3. Rate of compliance with the intervention
4. Suitability of the outcome measures chosen
5. Variance of the outcome variable
6. Changes in the health condition in the control group
Estimates of these parameters, especially the variance, will be used to recalculate the sample size to ensure that any main trial has sufficient power.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Sheffield NHS Research Ethics Committee. Date of approval: 30/01/2007 (ref: 06/Q2305 /181)

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hot flushes

Interventions
Intervention group: Offer of a course of treatment by a homeopath. A series of between one to five appointments with a homeopath, the first consultation being around one hour and subsequent appointments being 20 - 30 minutes in duration.
Control group: No treatment

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Hot flush frequency and severity score at baseline and 36 weeks.

Secondary outcome measures
The following outcomes were measured at baseline and 36 weeks:
1. Euro Quality of Life questionnaire (EQ-5D)
2. Measure yourself Medical Outcome profile (MYMOP2; a quality of life measure)
3. Medication Change questionnaire
4. Health economics information regarding the following:
4.1. Number of hospital admissions
4.2. GP visits
4.3. Time taken off work
4.4. Loss of earnings
4.5. Impact of hot flushes on household activities
4.6. Special diets

Overall study start date
01/02/2007

Completion date
01/11/2007

Eligibility

Key inclusion criteria
Participants for this trial were recruited from those participating in an observational study entitled "Women's Midlife Health Survey" conducted in Sheffield in 2005. The study was funded by a Research Capacity Development Award from the Department of Health.

Inclusion criteria:
1. Female, aged 45-65
2. Fourteen or more hot flushes or night sweats per week, or self rating of hot flushes or night sweats as severe or very severe

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
50

Key exclusion criteria
1. Taking Hormone replacement therapy (HRT) and not intending to stop
2. On immunosuppressant drugs
3. Currently undergoing chemotherapy

Date of first enrolment
01/02/2007

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Sheffield (UK)

Sponsor details
University of Sheffield Research Office
New Spring House
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Sponsor type
University/education

Website
http://www.shef.ac.uk

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Department of Health Training fellowship (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	study design	19/03/2010		Yes	No
Results article	results of pilot study	01/09/2012		Yes	No