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

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

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 231 Glossop Road Sheffield England United Kingdom S10 3GW g.pearman@sheffield.ac.uk

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 |