

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
Registration date 09/06/2008	Overall study status Completed	☐ Statistical analysis plan ☒ 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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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Randomised controlled trial.

Study type(s)

Treatment

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(s)

Hot flush frequency and severity score at baseline and 36 weeks.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

University of Sheffield

Sheffield

United Kingdom

S1 4DA

Sponsor information

Organisation

University of Sheffield (UK)

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Government

Funder Name

Department of Health Training fellowship (UK)

Results and Publications

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?
	results of pilot study				

Results article		01/09/2012	Yes	No
Other publications	study design	19/03/2010	Yes	No