

Developing effective interventions to help women to manage menopausal symptoms

Submission date 04/03/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 17/03/2009	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 29/08/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
PAXKAYT

Study information

Scientific Title

Managing menopausal symptoms: MENOS2 - a randomised controlled trial of cognitive behavioural interventions for menopausal symptoms

Acronym

MENOS2

Study objectives

1. To evaluate the effectiveness of two forms of cognitive behavioural treatment (CBT) (group CBT and self-help CBT) in reducing frequency and problem rating of hot flushes and night sweats in a sample of women seeking non-medical approaches to deal with menopausal symptoms
2. To evaluate secondary impacts of CBT upon an objective measure of hot flushes, mood, self esteem and health related quality of life
3. To investigate the factors mediating improvement in hot flushes/night sweats including stress, bodily preoccupation, beliefs about menopause and hot flushes

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kings College London Psychiatry, Nursing & Midwifery Research Ethics Sub-Committee gave approval on the 3rd March 2009 (ref: PNM/08/09-42)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Menopause

Interventions

The trial will include three groups:

Group CBT:

The group CBT treatment comprises 4 weekly sessions lasting 2 hours. Groups will comprise 8 - 10 women and a CBT therapist will run all the sessions. The approach is psycho-educational with individual treatment goals and an active focus upon cognitive and behavioural changes. The treatment targets cognitive and behavioural components:

1. Information and discussion about HF/NS and menopause
2. Monitoring and modifying precipitants, e.g. spicy food, alcohol
3. Relaxation and paced breathing
4. Behavioural strategies to reduce stress and deal with HF/NS
5. Cognitive therapy for unhelpful thoughts and beliefs about HF/NS and menopause

Self-help CBT:

The self-help CBT treatment comprises of a booklet containing the same information, participants work through this booklet over a 4 week period.

No treatment (control):

The no treatment group will receive no CBT treatment. They will be offered a form of CBT off-trial at the end of the trial.

Duration per participant:

3 months assessment and treatment, and 6 months follow-up post randomisation = approximately 9 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Problem rating and frequency of hot flushes and night sweats (physiologically measured and self reported) assessed at 12 weeks post-randomisation.

Key secondary outcome(s)

1. Problem rating and frequency of hot flushes and night sweats (self reported at follow-up, 6 months post-randomisation)
2. Mood, self-esteem, bodily preoccupation and health related quality of life, measured at baseline, 12 weeks post-randomisation and 6 months post-randomisation

Completion date

28/02/2011

Eligibility

Key inclusion criteria

1. Women seeking non-medical alternatives to manage hot flushes/night sweats
2. English speaking
3. At least 10 hot flushes per week for at least a month
4. Aged over 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Women who cannot understand English
2. Those who are currently have major health problems that would interfere with participation in the study
3. Women under 18 years of age

Date of first enrolment

01/04/2009

Date of final enrolment

28/02/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Psychology

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Biomedical Research Centre for Mental Health

Funder Name

South London and Maudsley NHS Foundation Trust (UK)

Funder Name

Institute of Psychiatry, King's College London (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 article	results	01/07/2013		Yes	No
Results article	results	01/11/2013		Yes	No
Results article	results	01/06/2014		Yes	No
Protocol article	protocol	23/02/2011		Yes	No