ISRCTN57302613 https://doi.org/10.1186/ISRCTN57302613

Developing effective interventions to help women to manage menopausal symptoms

Submission date	Recruitment status	[X] Prospectively registered
04/03/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2018	Urological and Genital Diseases	

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Secondary outcome measures
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

Overall study start date
01/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
120

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
England

United Kingdom

Study participating centre
Department of Psychology
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Strand
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.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

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?
Protocol article	protocol	23/02/2011		Yes	No
Results article	results	01/07/2013		Yes	No
Results article	results	01/11/2013		Yes	No
Results article	results	01/06/2014		Yes	No