

# Developing effective interventions to help women to manage menopausal symptoms

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Myra Hunter

**Contact details**  
Department of Psychology  
Institute of Psychiatry (at Guys)  
King's College London  
5th Floor, Bermondsey Wing  
Guy's Campus  
London  
United Kingdom  
SE1 9RT  
+44 (0)20 7188 5408/5413/0189  
myra.hunter@kcl.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## 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  
London  
England  
United Kingdom  
WC2R 2LS

**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?
<a href="#">Protocol article</a>	protocol	23/02/2011		Yes	No
<a href="#">Results article</a>	results	01/07/2013		Yes	No
<a href="#">Results article</a>	results	01/11/2013		Yes	No
<a href="#">Results article</a>	results	01/06/2014		Yes	No