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A trial of a non-medical treatment for menopausal symptoms in women with breast cancer

Submission date 23/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2009	**Overall study status** Completed	
Last Edited 24/03/2022	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-a-way-of-reducing-menopausal-symptoms-after-treatment-for-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
C8303/A6130

Study information

Scientific Title
A randomised controlled trial of a cognitive behavioural intervention for women who have menopausal symptoms following breast cancer treatment

Acronym
MENOS1

Study objectives
Primary objective:
To determine the efficacy of group cognitive behavioural therapy (CBT) compared to usual care in reducing the problem rating of menopausal symptoms (hot flushes and night sweats), 12 weeks post-randomisation, in women who have had treatment for breast cancer.

Secondary objectives:
1. To investigate the efficacy of group CBT compared to usual care in reducing the problem rating of menopausal symptoms of hot flushes and night sweats, up to 6 months (26 weeks) post-randomisation, in women who have had treatment for breast cancer
2. To investigate the efficacy of group CBT compared to usual care in reducing the frequency (subjective and objective) of hot flushes and night sweats, 12 weeks post-randomisation, in women who have had treatment for breast cancer
3. To investigate the efficacy of group CBT compared to usual care in reducing the frequency (subjective) of hot flushes and night sweats, 6 months (26 weeks) post-randomisation, in women who have had treatment for breast cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas' Hospital Research Ethics Committee (South London REC Office 3) gave approval on the 23rd July 2008 (ref: 08/H0802/106)

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer and menopause

Interventions
Cognitive behavioural therapy encompassing stress management, cognitive restructuring and sleep hygiene for treatment of hot flushes and night sweats.

Group CBT:
The treatment comprises 6 weekly sessions lasting 1.5 hours. Groups will comprise 8 - 10 women and a CBT therapist will run all the sessions. A proportion of sessions will be taped and evaluated by an independent assessor to ensure that Group CBT strictly follows the manual. 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 respiration, to lower levels of stress and apply at onset of HF/NS
4. Behavioural strategies to reduce stress and deal with HF/NS
5. Cognitive therapy for unhelpful thoughts and beliefs about HF/NS and menopause
6. Managing sleep and NS, drawing upon CBT for insomnia
7. Managing menopausal symptoms and maintaining changes the context of breast cancer

Usual care:
The control arm will receive standard care - they will have access to their oncologist and clinical nurse specialist, as well as cancer information and support services, and be offered a form of CBT off-trial at the end of the trial.

Duration per patient: 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 of hot flushes and night sweats, measured at 12 weeks post-randomisation

Key secondary outcome(s))
1. Frequency of hot flushes and night sweats (physiologically measured and self reported)
2. Mood, sleep and quality of life
3. Treatment cost-effectiveness

Measured at 12 weeks post-randomisation (all measures) and 6 months post-randomisation (except physiological measure of frequency of hot flushes and night sweats).

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged 18 years and older and have had early stage breast cancer
2. Have completed radiotherapy and chemotherapy
3. No evidence of distant metastatic disease
4. May have had ductal carcinoma in situ (DCIS)
5. English speaking
6. Have had problematic hot flushes (HF)/night sweats (NS) for at least 2 months

7. Having completed active treatment and being in remission
8. Prior medical treatment for HF/NS will be recorded. If women have derived partial benefit and are stable on a treatment, they can be included if they have been on this treatment for 2 months or longer.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Depression or general cancer concerns are the main problem that the woman is seeking help for, not HF/NS
2. Unable to commit time to attend the sessions

Date of first enrolment
01/03/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Unit of Psychology
London
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C8303/A6130)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/01/2011		Yes	No
Results article	results	01/03/2012		Yes	No
Plain English results			24/03/2022	No	Yes