

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

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 measure

Problem rating of hot flushes and night sweats, measured at 12 weeks post-randomisation

Secondary outcome measures

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).

Overall study start date

01/03/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

96

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

England

United Kingdom

Study participating centre

Unit of Psychology

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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United Kingdom

WC2R 2LS

Sponsor type

University/education

Website

<http://www.kcl.ac.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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

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	31/01/2011		Yes	No
Results article	results	01/03/2012		Yes	No
Plain English results			24/03/2022	No	Yes