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A study to look at the effects of a hydrolat spray to palliate hot flushes in women being treated for breast cancer

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 18/10/2011	**Condition category** Signs and Symptoms	

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
N0258184657

Study information

Scientific Title

Study objectives
Hot flushes are a common side effect of treatment for breast cancer. Research has shown that having more problematic hot flushes and night sweats was associated with more anxiety and sleep problems, poorer emotional and social functioning and worse body image. Current advice suggests cool sprays and moist wipes to lower skin temperature. Although anecdotal evidence for the beneficial effects of hydrolats is quoted in text books and aromatherapy teaching programmes, no research into specific effects for hot flushes has been found. The principle research question is to establish whether a peppermint and neroli hydrolat spray is preferred by woman over a distilled water spray to help palliate the unpleasant effects of hot flushes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomized single blinded crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Hot flushes

Interventions
Randomized single blinded crossover study of two sprays

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The number of women choosing a hydrolat spray in preference to a water spray to palliate hot flushes.

Key secondary outcome(s)
Not provided at time of registration

Completion date
15/01/2007

Eligibility

Key inclusion criteria
Any woman suffering from hot flushes as a result of treatment for breast cancer.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/08/2006

Date of final enrolment
15/01/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nutrition and Dietetic Department
London
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SW3 6JJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust (UK)

Funder Name
NHS R&D Support Funding

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	01/11/2008		Yes	No