

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/10/2011	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Clare Shaw

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

### Study design

Randomized single blinded crossover study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

The number of women choosing a hydrolat spray in preference to a water spray to palliate hot flushes.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

16/08/2006

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

44

**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**

England

United Kingdom

**Study participating centre**  
**Nutrition and Dietetic Department**  
London  
United Kingdom  
SW3 6JJ

## **Sponsor information**

### **Organisation**

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

### **Sponsor details**

The Department of Health, Richmond House, 79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

### **Sponsor type**

Government

### **Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

The Royal Marsden NHS Foundation Trust (UK)

### **Funder Name**

NHS R&D Support Funding

## **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="#">Results article</a>	results	01/11/2008		Yes	No