

# A randomised controlled trial of light therapy in the treatment of premenstrual syndrome (PMS)

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/09/2014	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
N0158108034

## Study information

**Scientific Title**

**Study objectives**

To assess the efficacy of light therapy in the treatment of PMS.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Urological and Genital Diseases: Premenstrual syndrome (PMS)

**Interventions**

Women will be recruited from PMS clinics, GP surgeries and through the media. They will record symptoms daily for two cycles. A structured clinical interview for DSM IV personality disorders (SCID) will be carried out 1 month single blind, to exclude placebo responders.

Randomised to either actual or placebo light masks. They will continue to keep a daily diary.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Reduction in the overall score for PMS symptomatology

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/06/2005

**Eligibility****Key inclusion criteria**

Women between 18 and 45 years of age with regular menstrual cycles who meet the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV) criteria for premenstrual dysphoric disorder (PMDD). They need to be able to write and read English.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

45 Years

**Sex**

Female

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/06/2002

**Date of final enrolment**

01/06/2005

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Obstetrics and Gynaecology Academic Department

Stoke-on-Trent

United Kingdom

ST4 6QG

**Sponsor information****Organisation**

Department of Health (UK)

# **Funder(s)**

## **Funder type**

Government

## **Funder Name**

North Staffordshire Research and Development Consortium (UK)

# **Results and Publications**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration