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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/09/2014	Urological and Genital Diseases	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Reduction in the overall score for PMS symptomatology

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Obstetrics and Gynaecology Academic Department
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Research and Development Consortium (UK)

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