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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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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