

A randomised controlled trial comparing psychological treatment and medical treatment for pre-menstrual syndrome (PMS)

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/12/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RDC00402

Study information

Scientific Title

Study objectives

The primary objective of the proposed study is to evaluate the relative effectiveness of psychological versus medical treatment of women diagnosed as having moderate pre-menstrual syndrome.

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Urological and genital diseases: Menstrual disorders

Interventions

1. Psychological treatment (Cognitive Behavioural Therapy [CBT])
2. Standard medical treatment (Selective Serotonin reuptake inhibitors [SSRIs]).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Improvement in quality of life of the patient, due to PMS being tackled in a more 'life-style' way
2. Reduction in physical and psychological symptoms premenstrually

- 3. Less disruption in daily activities/daily life/paid or unpaid work/leisure activities
- 4. Increases in patient satisfaction with care

Secondary outcome measures

Not provided at time of registration

Overall study start date

24/03/1996

Completion date

24/03/1999

Eligibility

Key inclusion criteria

Women will be recruited from a PMS clinic at the Elizabeth Garrett Anderson Hospital having been referred by their GP for treatment; between 20 and 45 years of age; having regular menstrual cycles (21-35 days); presently not taking hormonal or psychotropic medication, or currently experiencing a major psychiatric illness; not being pregnant or lactating within the previous 12 months; experiencing a 30% increase in two or more affective symptoms (e.g. depressed mood, irritability, anxiety/tension, aggressive feelings, and tiredness) on the Moss Menstrual Distress Questionnaire from pre and post menstruation in each of two adjusted menstrual cycles (a daily diary method of assessment).

These inclusion criteria are those recommended by the National Institute of Mental Health (NIMH). It is estimated that 40-50% of patients assessed will meet these criteria, and therefore 250-300 women may need to be assessed in order to obtain a sample of 120.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

120

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

24/03/1996

Date of final enrolment

24/03/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Psychology Department

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2002		Yes	No