ISRCTN73540150 https://doi.org/10.1186/ISRCTN73540150

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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
03/12/2008

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jane Ussher

Contact details
Psychology Department
UCL
Gower Street
London
United Kingdom
WC1E 6BT

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