

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

☐ Prospectively registered

☐ Protocol

Registration date
23/01/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/12/2008

Condition category
Urological and Genital Diseases

☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre**Psychology Department**

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

Results and Publications

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