ISRCTN14743304 https://doi.org/10.1186/ISRCTN14743304

Validation of PreMentricS smartphone app: patient and clinician acceptability of using an electronic method for measuring premenstrual symptoms

Submission date
12/06/2018

Recruitment status
No longer recruiting

Registration date
14/06/2018

Overall study status
Completed

Last Edited
15/05/2019

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to compare a smartphone application (PreMentricS app) for recording premenstrual symptoms against the currently recommended and used paper-based method. PreMentricS was developed for recording premenstrual symptoms and intends to support clinicians in diagnosing premenstrual disorders (PMS). PMS has a major impact on primary and secondary care time and referrals, patient health, well-being, work performance, interests and social activity, interpersonal relationships, aggressive acts, divorce and suicide. Poor diagnostic and quantification tools have hampered medical care because the recognised methods are too cumbersome for use. PreMentricS will overcome these difficulties and provide validated tools for data capture, diagnosis, classification, clinical trials and treatment monitoring.

Who can participate?
Women from the general public aged 18 -50 and qualified gynaecology doctors (male and female)

What does the study involve?
Participating women from the general public are randomly allocated to one of two groups. One group records their symptoms (or absence of symptoms) daily for the duration of one menstrual cycle (about one month) using the Royal College of Obstetricians and Gynaecologists (RCOG) recommended paper charts, Daily Record of Severity of Problems (DRSP charts). The group records their symptoms daily using the PreMentricS app. All participants complete questionnaires regarding their method of symptom scoring at the end of the month. The completed scores (paper and app scores) and the questionnaires are collected and the data is analysed. The questionnaires are used to assess the acceptance and usability of the app among the public. Participating gynaecologists are provided with anonymised versions of the above collected scores (paper and app) and suggest a diagnosis based on the scores. They then complete questionnaires to determine the acceptance and usability of the app among the clinicians.

What are the possible benefits and risks of participating?
Participants receive free access to the PreMentricS app either during or after the study depending on the group they are allocated to. This study may or may not benefit participants by helping with diagnosis of previously undiagnosed PMS. If participants are experiencing symptoms, they can provide their healthcare provider with the collected information which could help identify and treat their symptoms. There are no known risks involved in this study. The only inconvenience may be the daily recording of symptoms on a paper chart or the app. It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant.

Where is the study run from?
University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
October 2017 to May 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Deepthi Lavu

Contact information

Type(s)
Scientific

Contact name
Dr Deepthi Lavu

Contact details
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Additional identifiers

Protocol serial number
Pro00077340_AME3

Study information

Scientific Title
Validation of PreMentricS smartphone app: patient and clinician acceptability of using an electronic method for premenstrual symptom quantification

Study objectives

Smartphone Applications (Apps) are being developed to quantify a spectrum of gynaecological disorders. These intend provide diagnostic and treatment monitoring tools from patient-recorded symptom documentation. Initially, these Apps were particularly focused on the disorders of the menstrual cycle; premenstrual disorders (PMS), heavy menstrual bleeding (HMB) and menstrual pain (MP) but might subsequently encompass polycystic ovarian syndrome (PCOS), endometriosis, symptoms of the climacteric (menopause) and ultimately any gynaecological disorder requiring large quantities of numerical data capture.

This study aims to initiate validation of the PreMentricS App which was developed for recording premenstrual symptoms and for assisting clinicians' (clinician's tool) in diagnosing and classifying premenstrual disorders.

Participant and clinician acceptability of this electronic method of symptom quantification would be the first step in validating this app.

Early work published in 2001, demonstrated for the first time that electronic symptom data acquisition could be achieved using relatively primitive personal digital assistants (Amstrad PDA) – Menstrual Symptometrics. Subsequent advances in technology have permitted electronic data acquisition to be achieved online from laptop, PC, tablet or mobile phone but none of these provided the ideal format until technology permitted the simpler self-contained and readily modifiable use of Smartphone Applications - Apps.

These potentially invaluable clinical tools for patients and health professionals are expected to replace cumbersome established methods, validated paper-based method for Premenstrual Syndrome. Existing paper-based methods to quantify PMS require tedious completion of paper questionnaires by patients and subsequent transfer of huge volumes of data into the central database. This is exceedingly time-consuming and patient scoring is frequently incomplete.

This new PreMentricS application produces a numerical representation of all these symptoms for diagnosis, statistical calculation and graphical representation for patient feedback, clinician diagnostics, clinical trials and treatment monitoring in the clinical arena.

The trialists hypothesise that PreMentricS app will be a more user friendly method of symptom scoring and will assist clinicians in arriving at a reliable diagnosis at ease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Ethics Board - Health Panel, University of Alberta, Edmonton, 07/02/2018, Study ID: Pro00077340

Study design
Interventional single-centre randomised control trial with no masking

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Premenstrual disorders

Interventions
The study is a user acceptability and usability study which will enable us to move on to validate the PreMentricS app.

The study will:
1. Determine numbers and power calculation if a larger study is needed.
2. Determine if this electronic method of symptom quantification is acceptable to women and clinicians (the users)
2. Inform the trialists on what advice to seek (statistical/methodological) based on the problems encountered in this study

There are two parts to this project:

Participant acceptability:
Participants (100) will include members of the general public (women) including staff and faculty of the Department of Family Medicine at the University of Alberta. Following consent, the participants will be randomised at arm's length using methods like the coin flip or computer randomisation to one of two groups. Based on which arm of the study they are allocated to, the participants will be given standard paper-based booklets for recording their symptoms on paper or be given access to download the PreMentricS app on their smartphone. One arm of the study will record their symptoms (or absence of symptoms) daily for the duration of one menstrual cycle (approximately one month) using the Royal College of Obstetricians and Gynaecologists (RCOG) recommended paper charts, Daily Record of Severity of Problems (DRSP charts). The other arm will record their symptoms daily using the PreMentricS app. Although participants may or may not suffer from premenstrual symptoms, all participants will be required to complete all components of the symptom scoring daily for the duration of the study.
All participants will complete questionnaires regarding the acceptability and ease of use of their method of symptom scoring at the end of a month of symptom scoring. The completed scores (paper and app scores) and the questionnaires will be collected and data analysed. The questionnaires will allow determination of the acceptance and usability of the app among the public.

Clinician acceptability:
10 gynaecologists, qualified in diagnosing premenstrual disorders, will be recruited to participate in the study. Following consent they will be provided with anonymised versions of the above collected participant’s scores (paper and electronic). Each clinician will get at random get 1 paper score and 5 electronic scores to analyse. This will be achieved using coin flip or random computer generated sequences. The clinicians will be required to suggest a diagnosis on the basis of the ISPMD classification (which will be provided to them) for their sets of scores. Classification suggested by the app will not be available to the clinicians for their set of scores. On completion of suggesting diagnosis for their sets of scores, as clinicians will have the whole DRSP chart to view when making diagnosis but not the PreMentricS app, the clinicians will be shown the app on one of the research member’s phone to understand how data is collected and how a classification of the premenstrual disorder is displayed.They will then complete questionnaires which will determine the acceptance and usability of the app among the clinicians. The suggested diagnosis for anonymised scores (hard copies) and questionnaires will be collected by the research team members. Data collected will then be analysed.

The success criteria for the study will be determined by:
1. User (participant and clinician) acceptability
2. Practicality of running a larger study. Further studies will be designed by the power calculated from this study and any methodological changes determined by the study.

The study is a validation study. The study will inform what specific questions we need to seek advice on for further studies based on the problems encountered during the study.

Intervention Type
Other

Primary outcome(s)
The primary objective is to initiate the validation of the PreMentricS app against the current paper method of recording premenstrual symptoms, Daily Record of Severity of Problems (DRSP) charts. The current Royal College of Obstetricians and Gynaecologists Clinical Guideline on premenstrual disorders recognises the new PreMentricS app but also implies that it should be validated against the DRSP. Determination of the user (participant and clinician) acceptability and usability of PreMentricS app is the first step in this validation process.

Acceptability will be measured using the affective attitude of the participants towards the methods (both women using the methods and clinicians using data collected by those methods) and the burden of the method on the participants. The data will be captured in the questionnaires which seek information on the participants' perception of the different methods. This will be analysed in the data analysis stage (Dec 2018 - Jan 2019).

Key secondary outcome(s))
1. Perceived concurrent validity measured from answers provided in the study questionnaires (completed by all participants - women using the methods and clinicians who will use those methods to make a diagnosis of premenstrual disorders). This will be measured in the data analysis stage (Dec 2018 - Jan 2019)
2. Construct validity of the app: concordance of the clinician's diagnosis with the diagnosis suggested by the app. Sensitivity, specificity, positive and negative predictive values will be assessed. This will be measured in the data analysis stage (Dec 2018 - Jan 2019)
3. Difference in proportion of days of prospective symptom recording completed between both methods. The app does not allow retrospective recording and women given the paper forms will be informed not to fill in information retrospectively. This will be measured in the data analysis stage (Dec 2018 - Jan 2019)
4. Proportion of women returning the paper forms and app results. This will be measured in the data analysis stage (Dec 2018 - Jan 2019)

Completion date
30/05/2019

Eligibility

Key inclusion criteria
1. Women from the general public between 18 -50 years age will be included in the study.
We will be recruiting from the public as we intend to see which method of symptom recording is preferred in the general population (paper vs electronic method of data capture).
The women recruited will be over the age of 18 years and under 50 years. Above 18 years is to ensure that recruited women have regular cycles and ovulation. The upper age limit exists as

most women experience menopause around the age of 50 and we are studying disorders surrounding menstruation.

2. For the second part of the study:
Qualified gynaecology doctors (male and female) will be recruited as they are specialists in the area and will have experience in being able to diagnose premenstrual disorders.

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
115

Key exclusion criteria
1. Males
2. Women < 18 years of age
3. Pregnant women
4. Post menopausal women
5. Women on gonadotrophin releasing hormone analogues
6. Women who have used either method of symptom scoring previously
7. Women who lack capacity
8. Women who have special communication needs/who do not understand written English

For the second part of the study:
1. Doctors (male or female) who are in training and not completed their qualifying exams (junior doctors in gynaecology)

Date of first enrolment
18/03/2018

Date of final enrolment
03/04/2019

Locations

Countries of recruitment
United Kingdom

Australia

Canada

France

India

United States of America

Study participating centre
University of Alberta
Edmonton
Canada
T6G 2R3

Sponsor information

Organisation
University of Alberta

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the study will not be made publicly available due to planned analyses and publications, but are available from the corresponding author (Dr Deepthi Lavu) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes