Feasibility of using a semi standardised prognostic protocol in homeopathic treatment for premenstrual syndrome/symptoms: pilot study for a pragmatic randomised trial

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1. We will explore the feasibility of homeopathic treatment with a semi standardised homeopathic prognostic treatment protocol for PMS in daily homeopathic practice. 2. We will evaluate the prognostic validity of using a semi standardised prognostic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31118

Source
ToetsingOnline

Brief title
Homeopathic treatment of premenstrual syndrome

Condition

- Mood disorders and disturbances NEC
- Reproductive tract disorders NEC

Synonym
PMS, premenstrual syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Koninklijke Vereniging Homeopathie Nederland

Intervention

Keyword: feasibility, homeopathy, premenstrual syndrome, semi-standardised

Outcome measures

Primary outcome

Changes of complaints and general well being, measured separately by the AGOS,

an adjusted GHHOS-scale, a nine point Likert scale.

Changes in premenstrual symptoms will be measured by mean PMS-diary scores of

the last two weeks before the menstruation. The PMS diary is a modifcation of

the MDQ.

Secondary outcome

Days with use of conventional medicines and number of medicines,

days with absence from work

Study description

Background summary

A future pragmatic randomised trial could evaluate the effectiveness of homeopathic treatment for premenstrual syndrome/symptoms.

In research on individual homeopathy we face some specific challenges. Homeopathic treatment is individually targeted treatment and a complex intervention. In clinical research it would be convenient to limit the number of possible homeopathic prescriptions and minimise inter-rater variability. We also need to improve treatment results after first homeopathic precriptions. We

intend to achieve these goals with a semi standardised homeopathic prognostic protocol for PMS, targeting on larger, responsive subgroups.

Study objective

1. We will explore the feasibility of homeopathic treatment with a semi standardised homeopathic prognostic treatment protocol for PMS in daily homeopathic practice.

2. We will evaluate the prognostic validity of using a semi standardised prognostic protocol for homeopathic treatment of premenstrual syndrome/symptoms.

Study design

In phase 1 of the pilot study, an expert panel designs a patient questionnaire and diagnostic algorithm for homeopathic treatment of premenstrual syndrome/symptoms. They do this by Delphi procedures and focus group meetings.

In phase 2 we explore the feasibility of using the semi-standardised homeopathic prognostic protocol for premenstrual syndrome/symptoms in homeopathic practice. Patients with premenstrual syndrome/symptoms will be treated by homeopathic doctors, who use the semi standard protocol to decide about the prescription.

After intake and consent the patients keep a PMS diary during two months. The diary is needed to diagnose PMS/premenstrual symptoms. We also use this diary score as a baseline parameter.

After inclusion, the patient fills in the questionnaire for homeopathic treatment of PMS, with predictive characterisitics, prior to the first consultation. The history taking and examination is done as usual in homeopathic practice. The doctor selects a homeopathic medicine after the usual analysis of the case. Next he/she consults the diagnositc algorithm and selects one out of eleven homeopathic pre-selected medicines, according to the outcome of the algorithm. However, when the chracteristics of the patient don't match with one of the medicines, the doctor prescribes a homeopathic medicine as usual.

Follow up consultations will be planned after 1,2,3,5,7 and 9 months. The patient will keep the PMS diary during two periods of three months: 1,2,3 and 7,8,9.
Before every follow up consultation the patients fills in a score about change of complaints and general health.

We will compare the medicine prescription with one of the pre-selected

medicines after applying the algorithm with medicine prescription in the usual way. We will also compare the proportion of agreement/disagreement of the doctors first choice and the outcome of the algorithm. We will ask the opinion of the doctors about working with the protocol. We will aso evalaute the use of the questionnaire by patients.

Also, we will evaluate the predictive validity of the prognostic protocol. We will correlate results of treatment with the pre-selected medicines derived from the algorithm, as well as results of treatment with medicines otherwise prescribed, with patient-perceived changes of symptoms and well being.
We will assess the coverage of the protocol (what % of the women with PMS can we treat with one of the selected medicines?) and evaluate characteristics of subgroups of women who do or do not react well to homeopathic treatment.
We will explore the feasibility of conducting a future larger pragmatic randomised trial, comparing homeopathic treatment for PMS-patients with usual care, using the semi standardised protocol.

Study burden and risks

The extra burden is low. The patient fills in several questionnaires and has one to three extra consultations. Treatment is otherwise as usual in homeopathic practice.
There are no risks.

After intake and informed consent the patient keeps a diary to record PMS symptoms during two months.
After inclusion the patient fills in a patient questionnaire for homeopathic treatment.
There is a short evaluation form for this questionnaire. During homeopathic treatment she has a first consultation (1- 1 1/2 hours is usual in homeopathic practice). Follow up consultation will be at 1,2,3,5,7,9 months. The follow up consultations will take one half hour to three quarters of an hour, as usual.
The PMS diary will also be kept during the following treatment months: 1,2,3,7,8,9.
Before every follow up consultation the patints records change of complaints and well being seperately, on a 9 point Likert scale.

Contacts

Public
VU medisch centrum

Van der Boechorststraat 7
1081 BT Amsterdam

NL
Scientific
VU medisch centrum

Van der Boechorststraat 7
1081 BT Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Sex: female
Age: 18-50
Diagnosis premenstrual syndrome/symptoms

Exclusion criteria

pregnant or wanting to get pregnant
use of hormones, excl. contraceptive pill
use of antidepressants
recent homeopathic treatment (within the last two months)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17805.029.07