Homeopathic add-on treatment versus usual care for premenstrual disorders (PMD).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26649

Source
NTR

Health condition

Premenstrual syndrome (PMS)
Premenstrueeel syndroom (PMS)

Premenstrual dysphoric disorder (PMDD)
Premenstruele dysfore stoornis (PMDD)

Sponsors and support

Primary sponsor: Uitvoerder:
Louis Bolk Institute
Hoofdstraat 24
3972 LA Driebergen
The Netherlands
Source(s) of monetary or material Support: International Scientific Committee on Homeopathic Investigations (ISCHI)
and the Swedish Homeopathic Association

Intervention

Outcome measures

Primary outcome

Phase I:

1. Time needed to recruit 38 women in each country (114 women in 3 countries);

2. Preferences of the women for several treatment options;

3. Adherence of women to the therapy they are randomised to;

4. Numbers of complete patient records returned;

5. Numbers of complete reports returned by homeopaths/doctors;

6. Agreement between algorithm outcome and first homeopathic prescription;

7. Opinion about the semi standardised treatment protocol of the homeopaths/homeopathic physicians in Germany and Sweden;

8. Mean percentage of change in PMS symptom scores after 4 months, measured through daily recording of patient rated symptoms scores by the Daily Record of Severity of Problems (DRSP) before treatment and in the 2nd and 4th cycle after the start of the intervention.

Phase II (if phase I has positive outcomes):

1. Percentage of responders defined as ≥ 50% reduction of PMS symptom score after 4 menstrual cycles (4 months), through daily recording of patient rated symptoms scores by the Daily Record of Severity of Problems (DRSP).

Secondary outcome

Phase I and II:

1. Changes of functional impairment score relating to work-productivity, social activities and relationships by the DRSP-FI (after 2 and 4 months/cycles);

2. Changes in the Pre Menstrual Tension Syndrome Self-Rating Visual Analogue Scale (PMTS-VAS) after 4 months/cycles. (measured in 1st week of menses during all menstrual cycles);

3. self-reported changes in main concern and well being by the Measure Yourself Concerns and Well-being (MYCaW), measured at intake and after 4 months/cycles;

4. Changes in use of (pain) medication for premenstrual symptoms in a diary alongside the DRSP after 2 and 4 months/cycles, also assessed during an interview by phone, 1 and 3 months/cycles after the start of the intervention;

5. Satisfaction with treatment and health care provider using the Participants' Satisfaction questionnaire (PS), a VAS-based scale, presented after the last visit;

6. Disease related costs: Direct and indirect cost with a direct relation to PMS will be calculated in both groups. The calculation will be based on diaries and interviews;

7. The participants' expectations about the treatment they (will) receive will be documented by short questionnaires (PE), one before randomisation and one 2 months/cycles after the start of the intervention.

Study description

Background summary

Background:

Worldwide, a meaningful proportion (8-32%) of women suffers from moderate to severe premenstrual disorders. Moderate to severe PMS and Premenstrual Dysphoric Disorder (PMDD) seem to be associated with impaired work productivity and increased absenteeism, and thus pose a potential economic burden. At present, evidence-based pharmacological treatments of women with PMDD and severe PMS are the use of antidepressants of the Selective Serotonine Re-uptake Inhibitors (SSRI)-type and the Combined Oral Contraceptive (COC) drospirenone/ethinylestradiol. These treatments are often unsatisfactory and women have reported to prefer more 'natural and safe' treatment approaches.

A previous pilot study has shown that homeopathy may be a promising treatment strategy to improve symptoms and quality of life of women who suffer from premenstrual disorders. Therefore, we want to pilot the feasibility, effect size (phase I) and investigate the added value (phase II) of a well-defined previously tested homeopathic intervention compared to usual care.

Objectives:

The aim of phase I of this proposed pilot study is to investigate the feasibility of an international pragmatic study on the added value of an individualised homeopathic treatment of women with premenstrual disorders compared to usual care only. In case the recruitment for to the pilot study goes according to plan, the results are promising and implementation of the homeopathic treatment is evaluated as feasible in the three countries, we will enter

phase II of the study. For phase II, additional women will be recruited and randomised. A new sample size will be calculated based on the effect size of the pilot study, to be able to detect possible significant differences between the homeopathy-add-on and usual care group. The study will be extended by two years.

Interventions:

For the homeopathic treatment we will use a previously developed semi-standardised algorithm with 11 homeopathic medicines.

For usual care women will visit their general practitioner or specialist (depending on country) who will give care as usual.

Study population:

Women with premenstrual disorders will be recruited at primary care settings and outpatient clinics in the Netherlands, Sweden and Germany.

Duration:

Women will be randomly assigned to 4 months/cycles of homeopathic add-on treatment or usual care only.

Design:

Multi-centre, international, randomised, controlled pragmatic study with two parallel groups.

Countries of recruitment:

The Netherlands, Sweden and Germany.

Study objective

Phase I:

To investigate whether it is feasible to organise an international multi-centre pragmatic trial to study the value of individualised homeopathic add-on treatment using a semi-standardised

algorithm in women with premenstrual disorders, compared to usual care only.

Phase II:

If the feasibility evaluation has positive results and preliminary results tend to be in favour of homeopathy, we will additionally evaluate the added value of individualised homeopathic add-on treatment in women with PMD compared to usual care only in a larger sample of women.

Study design

Main measurements:

1. Before the start of the intervention;

2. 2 months after the start of the intervention;

3. 4 months after the start of the intervention.

Intervention

1. Individualised homeopathic treatment using a semi-standardised algortihm additional to usual care;

2. Usual care only.

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Eligibility criteria

Inclusion criteria

1. Women aged 18-50;

2. Written informed consent;

3. Diagnosis PMS or PMDD after keeping symptom diaries during two menstrual cycles;

4. Able to read and express themselves in language of country where the trial is done;

5. Access to phone and internet.

Exclusion criteria

1. Major psychiatric co-morbidity;

2. Physical co-morbidity with large impact on general health;

3. Absence of menses;

4. Improvement of pms symptoms of 50% or more after pre-treatment phase;

5. 75% or more missing diaries in pre-treatment phase;

6. Women who get pregnant during the study will be replaced.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	38
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-08-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37602
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3389
NTR-old	NTR3560
CCMO	NL39087.028.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37602

Study results

Summary results

Klein-Laansma CT, Jansen JC, van Tilborgh AJ, Van der Windt DA, Mathie RT, Rutten AL. Semi-standardised homeopathic treatment of premenstrual syndrome with a limited number of medicines: feasibility study. Homeopathy. 2010;99(3):192-204.
Klein-Laansma CT, Jansen JC, van Tilborgh AJ, Homeopathic treatment of PMS. Pilot study and call for collaboration. Abstract for poster presentation at the ISCMR-congress in Tromso, 2010.
Klein-Laansma C T, van Tilborgh A J W, Jansen J C H, Rutten A L B, Van der Windt D A W M, Labots-Vogelsang S M, Yakir M, Mathie R T, Relton C. Homeopathic treatment for PMS/premenstrual symptoms. Oral presentation at LMHI congress 2008, Oostende.