A pragmatic, randomized controlled pilot study investigating the feasbility of an international study on individualized homeopathic add-on treatment and usual care only in women with premenstrual disorders

Published: 27-04-2012
Last updated: 19-03-2025

Phase I: To investigate whether it is feasible to organize an international multi-centre pragmatic trial on individualised homeopathic add-on treatment using a semi-standardised algorithm in women with premenstrual disorders and usual care only. We...

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

Summary

ID

NL-OMON37602

Source
ToetsingOnline

Brief title
Homeopathic add-on treatment versus usual care for PMD

Condition

- Mood disorders and disturbances NEC
- Reproductive tract disorders NEC

Synonym
premenstrual disorders; complaints/symptoms occurring before menses

Research involving
Human

Sponsors and support

Primary sponsor: Louis Bolk Instituut
Source(s) of monetary or material Support: International Scientific Committee for Homeopathic Investigations (ISCHI)

Intervention

Keyword: feasibility, homeopathy, premenstrual, usual care

Outcome measures

Primary outcome

Phase I·

-Time needed to recruit 114 women in three countries

-Preferences of the women for several treatment options

-Adherence of women to the therapy they are randomised to

-Numbers of complete patient records returned

-Numbers of complete reports returned by homeopaths/doctors

-Agreement between algorithm outcome and first homeopathic prescription

-Opinion about the semi standardised treatment protocol of the

homeopaths/homeopathic physicians in Germany and Sweden

-Mean percentage of change in PMS symptom scores after 4 menstrual cycles

measured through daily recording of patient rated symptoms scores by the Daily

Record of Severity of Problems (DRSP).

Phase II (if phase I has positive outcomes)

-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+II

-Changes of functional impairment score relating to work-productivity, social activities and relationships by the DRSP-FI.

-Changes in the Pre Menstrual Tension Syndrome Self-Rating Visual Analogue Scale (PMTS-VAS)

-Self-reported changes in main concern and well being by the Measure Yourself Concerns and Well-being (MYCaW)

-Changes in use of (pain) medication for premenstrual symptoms in a diary alongside the DRSP.

-Satisfaction with treatment and health care provider using the Patient Satisfaction Questionnaire (PSQ), a VAS-based scale.

-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.

-Participants* preferences for several treatment options will be documented by a short questionnaire (PPref)

-The participants* expectations about the treatment they will receive will be documented by short questionnaires (PE)

Study description

Background summary

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 and effect size (phase I) and investigate the possible added value (phase II) of a well-defined previously tested homeopathic intervention compared to usual care. The aim of phase I of this proposed pilot study is to investigate the feasibility of an international pragmatic study on an individualised homeopathic add-on treatment of women with premenstrual disorders and usual care. 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. For the homeopathic treatment we will use a previously developed semi-standardised algorithm with 11 homeopathic medicines. Women with premenstrual disorders will be recruited in the Netherlands (NL), Sweden (S) and Germany (G). Women will be randomly assigned to 4 months/cycles of homeopathic add-on treatment or usual care only.

Study objective

Phase I: To investigate whether it is feasible to organize an international multi-centre pragmatic trial on individualised homeopathic add-on treatment using a semi-standardised algorithm in women with premenstrual disorders and usual care only. We will describe the women*s preferences and expectations, recruitment and the nature of usual care in the participating countries. We will evaluate the adherence of the homeopaths and doctors to the study protocol and the opinion of the homeopathic professionals in Sweden and Germany about the semi standardised algorithm. We will measure effect size in both the usual care group and the homeopathic add-on treatment group by calculating changes in premenstrual symptoms, impact of health problems on social life and work productivity, use of conventional medicines (e.g. sedatives, painkillers) for premenstrual symptoms, disease-related costs and patient satisfaction. We will assess and evaluate the changes in disease burden expressed as main concern and

well being as reported by the participants. We will evaluate the use of the algorithm in daily homeopathic practice in Sweden and Germany.
Phase II: If the feasibility evaluation has positive results and preliminary results tend to be in favour of homeopathy, we will additionally evaluate the possible 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

A multi-centre, international, randomised, controlled pragmatic study with two parallel groups

Intervention

Usual care (UC): Depends on the treatment for PMS or PMDD that is usually provided by the GP or specialist doctor. This can differ in each country and between physicians in the same country, because there is no standard guideline for treatment of PMS/PMDD. Usual care may include advice about nutrition and lifestyle, vitamins, supplements, herbal products, OCPs, antidepressants, pain medication and diuretics. Referral to a psychiatrist or gynaecologist is possible.

Usual Care (UC) + Homeopathic add-on treatment (HT): In addition to usual care, women will receive individualised homeopathic add-on treatment, using a semi-standardized previously tested algorithm with 11 homeopathic medicines.

Women will receive 4 months/cycles of additional homeopathic treatment or usual care only. Follow-up consultations will be scheduled after 2 and 4 menstrual cycles. At follow-up consultations the physicians and homeopaths are allowed to change the treatment according to their professional judgment and the woman*s preferences.

Study burden and risks

Pulse, blood pressure, length and weight will be measured at intake and this procedure will be repeated (except length) after termination.
Before, during and after the treatment the women will complete diaries and questionnaires
Sometimes women will have to travel a bit further for the intake or the homeopathic treatment (travel costs will be reimbursed)
The treatments are not burdensome. The homeopathic and usual treament are as usual in daily practice.
Homeopathic treatments are reported as safe. In the usal care group medicines could be advised that have side-effects. However, women will not be forced to take those (or other) medicines.
We expect improvement of symptoms on both groups. Women who are randomised to

usual care will be offered the possibility to have homeopathic treatment after 4 months.
We expect that the benefits for the women will exceed the possible burdens.

Contacts

Public
Louis Bolk Instituut

Hoofdstraat 24
3972 LA Driebergen
NL
Scientific
Louis Bolk Instituut

Hoofdstraat 24
3972 LA Driebergen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age 18-50
diagnosis PMS or PMDD
written informed consent
accessible by telephone and internet
able to read and speak the native language of the participating country

Exclusion criteria

Major psychiatric co-morbidity or physical co-morbidity with large impact on general health
Absence of menses (after hysterectomy)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-12-2012
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-03-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26649
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL39087.028.12
OMON	NL-OMON26649