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

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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,...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26649

Bron
NTR

Aandoening

Premenstrual syndrome (PMS)
Premenstrueeel syndroom (PMS)

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

Ondersteuning

Primaire sponsor: Uitvoerder:
Louis Bolk Institute
Hoofdstraat 24
3972 LA Driebergen
The Netherlands
Overige ondersteuning: International Scientific Committee on Homeopathic Investigations (ISCHI)
and the Swedish Homeopathic Association

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

2. Usual care only.

Contactpersonen

Publiek

Louis Bolk Institute

Hoofdstraat 24
M. Jong
Driebergen 3972 LA
The Netherlands
+31 (0)343 523860

Wetenschappelijk

Louis Bolk Institute
Hoofdstraat 24
M. Jong
Driebergen 3972 LA
The Netherlands
+31 (0)343 523860

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	38
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37602
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.