Probiotics in Pregnancy pilot study

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

Samenvatting

ID

NL-OMON26403

Bron
Nationaal Trial Register

Verkorte titel
PIP pilot study

Aandoening

anxiety, depression, pregnancy, probiotics

Ondersteuning

Primaire sponsor: Behavioural Science Institute, Radboud University, Nijmegen
Overige ondersteuning: Radboud University
Clinical Research Rotterdam (CR2O)
Winclove Probiotics B.V. (supply of probiotics and placebo)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the number of successfully met
feasibility criteria linked to the intervention and study design.

• feasibility of recruitment pathways (the ACCEPT checklist);
• participant retention;
• acceptability of study measures;
• number of women in Wageningen region (the Netherlands) eligible for this pilot trial.

Toelichting onderzoek

Achtergrond van het onderzoek

Maternal prenatal depression or anxiety during late pregnancy are risk factors for adverse health and behaviour outcomes in offspring.

With prevalence rates of prenatal depression or anxiety ranging between 10-20%, attempts to identify feasible and effective interventions to reduce symptoms are priority in the prenatal care and clinical setting.

There are indications that probiotics, as a food supplement, by improving the intestinal microbiota, can improve mental wellbeing.

The probiotic mixture used in this study has been shown
to significantly reduce negative thoughts associated with sad mood in healthy adults.

Probiotics, with their anti-inflammatory and neuroregulatory properties, may improve intestinal microbiota in pregnant mothers and consequently their mood. Additionally, prenatal ingestion of probiotics by mothers may improve their vaginal microbiota, which may in turn positively influence their offspring’s developing microbiota.

This study assesses the feasibility of a multispecies
probiotic intervention in pregnant women, to reduce symptoms of depression and anxiety, in preparation for a larger randomised controlled trial (RCT).

Doel van het onderzoek

This randomized controlled pilot study evaluates the feasibility of probiotic food supplement intervention in pregnant women, as an adjuvant therapy, to reduce prenatal maternal depression and anxiety.

Our first hypothesis is that all feasibility criteria linked to the intervention and study design will be met (e.g feasibility of recruitment pathways, participant retention, acceptability of study measures).

Our second hypothesis is that probiotic consumption will lead to a reduction of levels of prenatal maternal anxiety, depression and stress.

Onderzoeksopzet

Baseline/T0: week 26 gestation

T1: week 34 gestation

T2: day 7 post partum

T3: week 4 post partum

Onderzoeksproduct en/of interventie

Subjects will be randomly allocated to either control group (placebo) or intervention probiotic group. Probiotic/placebo intake once daily for 8 up to 14 constituent weeks.

Contactpersonen

Publiek

Pamela
Browne

Wetenschappelijk

Pamela
Browne

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy pregnant women (>18 years) in obstetric care in the Netherlands with at least elevated symptoms of depression and/or anxiety (resp. EDS ≥ 10; STAI-S > 40)

2. Women who can start daily probiotic intake from ≥26 weeks gestational age until delivery (Gestation is based on last menstrual period and early ultrasound)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Multiple pregnancy (increased obstetric risk);

2) High suicidal risk according to suicidality subscale score on the MINI International Neuropsychiatric Interview;

3) Illegal drug use;

4) Having a psychiatric history on psychoses and bipolar disorder;

5) Medically diagnosed with inflammatory bowel disease; 6) History of major gastro-intestinal surgery (e.g. colectomy);

7) Hypersensitivity or allergy to any ingredients in the probiotic product;

8) History of using the interventional product;

9) Presently using food containing probiotics (Actimel etc.) and not willing to stop these at least 2 weeks prior to the start of the interventional product intake;

10) No mastery of the Dutch language;

11) Generalized autoimmune disorder (e.g. artritis, SLE, ulcerative colitis, Crohn’s disease, Bechterew’s disease etc.) and/or treatment with immunosuppressive therapy (e.g. radiation, chemotherapy).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-03-2017
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-02-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43160
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6072
NTR-old	NTR6219
CCMO	NL57780.091.16
OMON	NL-OMON43160

Resultaten