The effectiveness of een internet course for pregnant women with depressive and anxiety symptoms

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An online intervention will be an effective intervention for treating affective symptoms in pregnancy and their complications by reaching more women and making therapy easier accessible

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

Samenvatting

ID

NL-OMON20793

Bron
NTR

Aandoening

pregnancy, affective symptoms, depressive symptoms, anxiety symptoms, depression, anxiety, online interventions, low birth weight, prematurity and breastfeeding, zwangerschap, depressie, angst, prematuriteit, borstvoeding, internet interventie.

Ondersteuning

Primaire sponsor: VU medical center
Overige ondersteuning: We are currently applying to different funding organisations

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. reduction of depressive and anxiety symptoms post intervention and 6 weeks postpartum

2 improvement in perinatal outcome (e.g.pre-term birth, growth restriction and breastfeeding initiation)

Toelichting onderzoek

Achtergrond van het onderzoek

Women in pregnancy and postpartum have an increased vulnerability to develop an affective disorder.
Affective disorders in pregnancy are associated with an increased risk of prematurity, dysmaturity and the development of postpartum depressive disorder. Untreated affective disorders and their complications may also result in considerable costs. Recent meta-analysis showed that interventions during pregnancy are less effective than postpartum interventions probably because of high attrition due to the barriers pregnant women experience withattending sessions outside their homes.
An internet-based self-help intervention may overcome these barriers as it can be followed at home, and also in one’s own time. Such internet interventions showed to be effective for decreasing affective symptoms in general.
This study examines whether an internet-based self-help intervention is effective in reduction of affective symptoms in pregnancy and postpartum and results in an improvement in the perinatal outcome. We will also determine the cost-effectiveness of the intervention.
We present a study protocol to investigate the effectiveness of a 6 week internet-based self-help problem solving treatment (PST) for affective symptoms in pregnancy in a randomized controlled trial. We aim to include 286 women with mild tot severe affective symptoms who will be randomly assigned to an internet-based intervention or waiting list control group. Primary outcome measures are affective symptoms and the perinatal outcome Secondary outcome measures are quality of life, and economic costs. Assessments will take place at baseline (T0), after completion of the intervention (T1), 4 weeks before the expected day of birth (T2), and 6 weeks after delivery (T3). The control group will be measured at the same moments in time with the exception of T1. Analysis will be based on the intention-to-treat principle.
If shown effective, internet-based PST will offer new possibilities to treat pregnant women for affective symptoms, to improve their perinatal outcome and to prevent the development of postpartum depressive disorders. It will also improve quality of care and cost effectiveness.

Doel van het onderzoek

An online intervention will be an effective intervention for treating affective symptoms in pregnancy and their complications by reaching more women and making therapy easier accessible

Onderzoeksopzet

T0 baseline assessment

T1 10 weeks after inclusion (only for intervention group)

T2 4 weeks before expected delivery date

T3 6 weeks after delivery.

Women who start late in their pregnancy will not be asked to participate in T2

Onderzoeksproduct en/of interventie

problem solving therapy through the internet

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

participants of 18 years and older,
who are pregnant at any stage of pregnancy, but not later than 10 weeks before the expected delivery date,
Who have at least mild symptoms of depression and/or anxiety, defined by Center for Epidemiological Studies Depression scale (CES-D) higher than 16 and /or a score higher than 8 on the Hospital Anxiety and Depression scale (HADS-A)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Participants who indicate that they either intend to harm themselves or to attempt suicide (as assessed by one question [210]) will be excluded and advised to consult their general practitioner to obtain more tailored care.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	286
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-12-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4162
NTR-old	NTR4321
Ander register	: 2013.275 (METC VUMC)
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A