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

No registrations found.

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

Summary

ID

NL-OMON20793

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: We are currently applying to different funding organisations

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

1. Cost effectiveness of the intervention

2. Quality of life

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

problem solving therapy through the internet

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2014
Enrollment:	286
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-12-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
N/A