Pregnancy Outcomes after Maternity Intervention for Stressful EmotionS (PROMISES)

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To assess the effects of Cognitive Behavioral Therapy (CBT) in pregnant women with symptoms of anxiety or depression on the child*s behavioral/emotional problems. In addition, we aim to study its effects on the child*s development, maternal mental...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON38046

Source
ToetsingOnline

Brief title
Maternity intervention for stressful emotions

Condition

- Neonatal and perinatal conditions
- Psychiatric and behavioural symptoms NEC

Synonym
prenatal anxiety/depression, prenatal stressful emotions

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cognitive behaviour therapy, fetal programming, negative emotions, pregnancy outcome

Outcome measures

Primary outcome

Behavioral/emotional problems at age 1.5 as assessed by the total problems

scale of the Child Behavior Check List 1.5 - 5 years.

Secondary outcome

- Mental, psychomotor and behavioral development of the child at age 18 months

according to the Bayley scales

- Maternal anxiety and depression during pregnancy and 6 weeks postnatal

- Maternal attachment style

- Neonatal outcomes: birth weight, gestational age and Apgar score

- Health care consumption and general health status (economic evaluation).

Study description

Background summary

There is ample evidence from observational prospective studies that maternal depression or anxiety during pregnancy is a risk factor for adverse psychosocial outcomes in the offspring. To date, however, no previous study has demonstrated that treatment of depressive or anxious symptoms in pregnancy actually could prevent psychosocial problems in children. Preventing psychosocial problems in children will eventually bring down the huge public health burden of mental disease.

Study objective

To assess the effects of Cognitive Behavioral Therapy (CBT) in pregnant women with symptoms of anxiety or depression on the child*s behavioral/emotional problems. In addition, we aim to study its effects on the child*s development,

maternal mental health, and neonatal outcomes, as well as the cost-effectiveness of CBT relative to usual care.

Study design

A randomized controlled single-blind trial in primary, secondary and tertiary obstetric care.

Intervention

The cognitive behavioral therapy consists of 10-14 individual sessions, 6-10 sessions during pregnancy and 4-8 sessions after delivery (once a week). The CBT will be conducted by registered psychologists, specialized in conducting CBT.
The first session will focus on the rationale of cognitive behavioral therapy, i.e. the influence of (irrational or dysfunctional) cognitions and attitudes on feelings and behaviors. Additionally, goal setting will be initiated. These therapy goals will be unique for each patient. Subsequent sessions will be targeted at identifying and amending irrational cognitions and attitudes related to pregnancy, delivery, concerns about the (unborn) child and the future family situation. Each session will address specific pregnancy-related cognitions. Additionally, patients will be taught how dysfunctional cognitions and attitudes affect adversely feelings and behaviors. These dysfunctional cognitions and attitudes will be challenged and replaced by functional cognitions and attitudes. After each session, patients will be given home work. For example, patients will be asked to register negative experiences, and accompanying cognitions, feelings and behaviors. Finally, in the last two to four sessions, the newly learned cognitions and attitudes will be consolidated.

Study burden and risks

There are no risks associated with participating in this study.
Women will be asked to fill in some questionnaires; 9 questionnaires of which a few will have to be filled in a few times spread over 2 years. Besides that, the child born from this pregnancy will be tested on psychosocial development at the age of 1.5.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Having at least moderate depression and/or anxiety symptoms during pregnancy.

Exclusion criteria

Women fulfilling one or more of the following criteria will be excluded from participation:
1. High suicidal risk according to the suicidality subscale score on the MINI (defined as a positive response on the question on concrete suicide plans)
2. Presently receiving psychotherapy at a higher than twice a month rate
3. Substantial physical disease or illegal substance abuse

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	13-10-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	09-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-06-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL29578.042.09