Living to the full during pregnancy: Increasing resilience during pregnancy to prevent peripartum depression

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON52869

Source
ToetsingOnline

Brief title
Resilient during pregnancy

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Mood disorders and disturbances NEC

Synonym
melancholy, mood disturbances

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, pregnancy, prevention, resilient

Outcome measures

Primary outcome

primary maternal outcomes:

- mood disturbances

- resilience

Secondary outcome

secundary maternal psychosocial outcomes:

- depression incidence

- *flourishing*

- quality of life

- anxiety

- PTSS symptoms

- experience of birth

- mother-child bonding

- parenting skills (mindful parenting)

secundary maternal biological outcomes:

- pregnancy outcomes

- stresshormone cortisol

secundary child outcomes:

- birth outcomes

- developmental landmarks

- temperament

Study description

Background summary

Depression is an increasing major public health problem in the Netherlands. Between 10 to 20% of pregnant women experience depressive symptoms. Moreover, in 60% of the cases these symptoms are not recognized by healthcare providers. Antepartum depressive symptoms are associated with peripartum depression, low quality of life, prematurity and long-term developmental and behavioral problems.
This emphasizes the need to prevent the consequences of antepartum depressive symptoms for both mother and child. Current evidence regarding the effectiveness of antepartum psychological interventions is inconsistent and mainly based on face-to-face interventions with high rates of drop-out and low rates of adherence. Therefore, an alternative, non-stigmatizing and accessible approach to prevent peripartum depression is necessary. Resilience, the ability to deal with challenges, setbacks, and misfortune, is inversely associated with depressive symptoms and can be trained. Previously, a self-help resilience training, based on Acceptance and Commitment Therapy (ACT), has repeatedly been shown to effectively reduce depressive symptoms among non-pregnant populations. The current project is the first randomized clinical trial (RCT) with 6 months follow-up which evaluates the efficacy of a pregnancy-specific guided self-help resilience training, based on ACT, designed to reduce depressive symptoms and improve resilience.
Correspondingly, there is a need for more knowledge of the underlying mechanisms of the possible relationship between maternal prepartum resilience, peripartum psychological functioning and perinatal and infant development outcomes. One of the neurobiological mechanisms underlying the associations between maternal antenatal psychological dysfunction such as depression and adverse maternal and child outcomes may be an altered hypothalamic-pituitary-adrenal (HPA) axis, reflected by increased or decreased maternal cortisol levels in pregnancy and henceforth transmitted to the fetus. There is, however, a need for more research into haircortisol as a (potential) valid indicator of prenatal depression.
To consider possible effects of experiences of respondents during the *Corona crisis*, information regarding these experiences will be taken into account.

Study objective

Aims of the study:

1. To evaluate the effect of a guided self-help resilience training for pregnant women with depressive symptomatology on:
a) primary outcomes: maternal depressive symptoms and resilience; and
b) secondary outcomes including maternal psychosocial functioning and developmental outcomes of the (unborn) child.
2. To identify psychosocial factors (e.g., anxiety) that predict which pregnant women with depressive symptomatology do or do not benefit from the guided self-help resilience training.
3. To identify psychosocial factors (e.g., psychological flexibility) that mediate the possible effect of the antepartum guided self-help resilience training on depressive symptoms, resilience and infant developmental outcomes.
4. To examine experiences of pregnant women that participated in the guided self-help resilience training, their e-mail coaches and midwives.
Cohort study:
5. To explore the psychosocial profiles (based on, e.g., maternal prenatal stress) and demografic profiles of pregnant women with absent/low, subclinical and clinical depressive symptoms and flourishing
6. To identify a) longitudinal trajectories of different levels of depressive symptoms in the peripartum period and b) to identify maternal psychosocial characteristics (e.g. maternal prenatal stress), infant characteristics and the level of resilience characterizing these trajectories.
7. To study the relationship between resilience and different levels of peripartum depressive symptoms during time.
8. (a) To study the association of maternal prepartum factors associated with resilience (e.g. psychological flexibility, mindfulness) and maternal prenatal stress (due to the Corona-crisis) with pregnancy and birth outcomes, perinatal outcomes, and infant behavioral and cognitive developmental outcomes; and (b) to study whether maternal prenatal resilience and experienced continuity of midwifery care ameliorate the influence of maternal prenatal stress on peripartum depressive symptoms and infant behavioral and cognitive difficulties.
9.To assess the cortisol concentration from scalphair of pregnant women with a low, moderate or severe lvel of depressive symptoms in the second trimester of pregnancy.
10. To study the association between haircortisol and the level of depressive symptoms, resilience, anxiety and birth-outcomes and infant development.

Study design

A RCT with two conditions: A guided self-help resilience training (intervention) versus care as usual (control group = regular perinatal care)
An observational longitudinal cohort study. Additional analysis of haircortisol from randomly selected participants of the main study with varying symptomlevels of antenatal depression.

Intervention

The resilience training includes multiple components designed to increase resilience and to reduce depressive symptoms.
The training is based on a self-help book *Living to the full*, applying Acceptance and Commitment Therapy (ACT) via 9 modules that will be followed by the participants during a 9-weeks period (Bohlmeijer & Hulsbergen, 2008). In line with ACT this self-help book uses multiple components and strategies, i.e. acceptance, commitment, and mindfulness based strategies and behavior change strategies to increase both psychological flexibility and resilience (Hayes et al., 2006). During the 9-weeks training participants will follow 9 modules as described in the self-help book *Living to the full* (Bohlmeijer & Hulsbergen, 2008). These modules are clustered into three parts. In the first part of the book, participants are asked to reflect on their avoidance and control strategies and whether these strategies are effective on the long run. In the second part, participants learn how to come into contact with their present experiences without trying to avoid or control them. In addition, they practice cognitive defusion and experiencing self as context. In the third part, participants learn to become aware of the most important personal values and to make decisions based on these values. Each module includes experiential exercises and metaphors for illustrating the processes of ACT. Moreover, the participants were asked to do daily mindfulness exercises, based on mindfulness-based stress reduction (Kabat-Zinn, 1990, 1994). The mindfulness exercises lasted on average 10-15 minutes and were on an audio CD which was included in the book. Next to the book, participants receive a pregnancy-specific supplement describing in a positive and non-stigmatizing manner how pregnant women with depressive symptomatology can use to the self-help book.
Each week during the training period participants receive an e-mail by their trained coach referring to the content of the respective module participants followed in the week before, in line with the approach by Fledderus et al. (2012). In this e-mail participants are asked about their experiences with the respective module and about their progress. The purpose of the e-mail support is to motivate and to support participants while following the training and modules. To follow the development of the depressive symptomatology, participants will be asked to fill in the PGIC. The e-mail support will be supervised by a trained clinical psychologist.

Study burden and risks

During 5 measurement periods participants will be asked to fill in digital questionnaires. Those with a score >=11 on the Edinburgh Depression Scale (EPDS) during T0 (baseline measurement) will be asked to partcipate in a short psychiatric interview (MINI; 10-15 minutes) to further assess the severity of depressive symptomatology. The half of the participants will follow a guided self-help resilience training whereas the other half participates in the control group (i.e., regular perinatal care).
There are no risks involved for the participants of this study.
The intervention will be supervised by a clinical psychologist and the

development of depressive symptomatology will repeatedly be monitored during the intervention period. The intervention concerns a guided self-help intervention asking participants to carry out experiential practices. They will receive e-mail support from their coaches. Such support is known to increase participants* motivation and adherence levels. The study population concerns a subclinical population with depressive symptomatology.
Pregnant women will participate in a preventative intervention for which they will be selected based on a two-steps psycho-diagnostic recruitment procedure. As the current intervention has already been proven to be effective in other populations, it is likely that included pregnant women may benefit from the intervention (even on the long run).
Hairsampling for cortisol is non-invasive and will take place via one homevisit of a trained researchnurse- or researchassistant. Only a small randomly selected subpopulation will be approached for the hairsampling substudy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- pregnant <18 weeks
- RCT: Edinburgh Postnatal Depression Scale (EPDS) score >= 11 (Bergink et al., 2011)
- Haircortisol: a hairlength of at least 3 cm. and sufficiënt hair growth at the posterior vertex position of the head.

Exclusion criteria

- poor literacy in Dutch
- functional illiteracy
- RCT: severe clinical depression
- RCT: psychopharmacological and/or psychological therapy started within the last three months
- Haarcortisol: cortisocosteroids intake in the past 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2019
Enrollment:	3800
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2022

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20234
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64740.029.18
OMON	NL-OMON20234