

Voluit zwanger - Veerkracht tijdens en na de zwangerschap

No registrations found.

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

Summary

ID

NL-OMON20234

Source

NTR

Brief title

Voluit zwanger

Health condition

Antepartum depression

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: AVAG Midwifery Academy Amsterdam
Groningen

Intervention

Outcome measures

Primary outcome

- depressive symptoms
- resilience

Secondary outcome

Secondary maternal psychosocial outcomes:

- depression incidence
- 'flourishing'
- quality of life
- anxiety
- PTSS symptoms
- experience of birth
- mother-child bonding
- parenting skills (mindful parenting)

Secondary maternal biological outcomes:

- pregnancy outcomes

Secondary child outcomes:

- birth outcomes
- developmental milestones
- temperament

Study description

Background summary

Depression among pregnant women is a prevalent public health care problem related to poor maternal and offspring outcome. Up to 20% of women experience depressive symptoms during their pregnancy. Prenatal depressive symptoms are associated with peripartum major depression, low maternal quality of life, premature birth, low birthweight and long-term emotional, cognitive and behavioral problems in the child. Therefore, early detection and intervention is crucial.

However, psychological interventions generally offered to pregnant women, as cognitive behavioural therapy (CBT) or inter personal therapy (IPT), are shown to have inconsistent and only moderate effects in preventing and treating prenatal depression partly due to high drop-out rates. Acceptance and Commitment Therapy (ACT) may be suitable as early easy accessible non-stigmatizing intervention for peripartum depressive symptoms because of its proven effectiveness on mild to moderate depressive symptoms and in the promotion of positive mental health. In this RCT, the effectiveness of a self-guided resilience training based on ACT and mindfulness, Living to the full during pregnancy (Voluit zwanger), will be evaluated.

This RCT is embedded in an observational cohort study investigating the underlying mechanisms of the possible relationship between maternal peripartum resilience, psychological functioning and perinatal and infant development outcomes.

Study objective

The primary aim of the RCT is to evaluate the effect of a guided self-help resilience training

for pregnant women with depressive symptomatology on maternal depressive symptoms and resilience and secondary outcomes including maternal psychosocial functioning and developmental outcomes of the (unborn) child.

We expect the intervention group to be superior in outcomes on depression, resilience and secondary outcomes in comparison with the CAU control group at the end of the intervention during pregnancy and follow-up at 6 and 18 weeks postpartum.

Exploratively, we want to examine to what extent certain baseline characteristics are predictive of treatment outcome (effect modification) and to what extent changes in psychosocial factors (e.g. psychological flexibility) mediate the intervention effects.

Experiences of pregnant women that participated in the guided self-help resilience training will be evaluated.

Study design

- second trimester
- third trimester
- 6 weeks postpartum
- 18 weeks postpartum

Intervention

The intervention is based on a self-help book 'Living to the full', applying Acceptance and Commitment Therapy (ACT) via 9 chapters that will be followed by the participants during a 9-weeks period. 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.

Contacts

Public

Amsterdam UMC
Annika Walker

0031204442386

Scientific

Amsterdam UMC
Annika Walker

0031204442386

Eligibility criteria

Inclusion criteria

- Women with singleton pregnancies <18 weeks
- RCT: Edinburgh Postnatal Depression Scale (EPDS) score ≥ 11

Exclusion criteria

- Poor literacy in Dutch
- Functional illiteracy
- RCT: severe clinical depression
- RCT: psychopharmacological and/or psychological therapy started within the last three months

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2019
Enrollment:	290
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 05-02-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52869

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7499
CCMO	NL64740.029.18
OMON	NL-OMON52869

Study results