Stress Reduction Intervention during Pregnancy, Length of Gestation, Infant Cognition and the Maternal and Infant Stress System.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32860

Source
ToetsingOnline

Brief title
Pregnancy and Mindfulness

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions
- Cognitive and attention disorders and disturbances

Synonym
attention problems, Stressregulationproblems

Health condition

aangeboren kwetsbaarheid gerelateerd aan het stresssysteem (HPA-as en autonoom zenuwstelsel)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: March of Dimes (USA); aanvraag ingediend op 16 september 09

Intervention

Keyword: infant cognition, late preterm birth, pregnancy, stresssysteem

Outcome measures

Primary outcome

1. Part 1 (sample 1 : measuring at 10-14, 24 and 34 weeks of pregnancy)

-Measures of anxiety, stress, and mindfulness with self-report questionnaires:

Stress (Cohen Self Perceived Stress Scale), general anxiety (Spielberger State

Trait Anxiety Scale), specific pregnancy anxiety (Pregnancy Anxiety

Questionnaire-R) en Mindfulness (Five Factor Mindfulness Questionnaire)

-basal HPA-as activity: saliva samples to measure cortisol awakening response

and diurnal cortisol profile

-basal ANS activity: saliva samples to measure alpha-amylase; 24 hrs ambulant

monitoring with VU-ambulant monitoring system

-stress-related HPA-axis activitity: saliva samples to measure cortisol before

and after a stress-inducing arithmetic Pc-task

-stress-related ANS-activity: heart rate variability (HRV) measures with

commercial equipment (BIOPAC systems Inc,) before during and after a

stress-inducing arithmetic Pc-task

2. Part 2 (sample 2 : measures in the four month old infant)

-measuring of cognitive functioning with AERPs-paradigma

-stress-related ANS activity: measures of HRV before, during and after AERPs-paradigma (with BIOPAC software)

-stress-realated HPA-activity: saliva samples to measure cortisol before and after AERPs

3. Part 3 (sample 1: measure in the mother and her infant when the infant is four months old)

-for the baby: the infants are tested with the protocol that is set up and fine tuned in part 2.

-for the mother: well-being of the mother (psychological measurements) and basal HPA-axis activity as described in part 1; There are no ambulant recordings of ANS and no stress-induced HPA-axis of ANS activity measures.

-some aspects of cognitive and socio-emotional development of the infant will be measured with subscales of the Ages and Stages Questionnaire (ASQ) and the ASQ: Social- Emotional version and an infant temperament scale (IBQ-R). These measures will be used as covariates and in some analyses also as moderators.

-length of gestation, birth weight, birth length, obstetrical characteristics are taken from the medical file

Secondary outcome

covariates

mother: maternal age, parity, gravidity, body mass index, education, SES,

ethnicity, smoking, alcohol, glucocorticoid exposure, prescription drug use

(i.e., SSRI, anti-hypertensive, anti-asthmatic, anti-epileptic, steroids..)

Study description

Background summary

A large body of research provides empirical evidence for the hypothesis that the risk of a shorter length of gestation and of late preterm birth is increased when maternal chronic stress is present. The interaction between the maternal stress system and the physiology of pregnancy and parturition is seen as one of the pathophysiological mechanism explaining preterm birth. There is also evidence for an association between maternal stress and anxiety during pregnancy and birth defects in the offspring, including cognitive functioning. Moreover it is hypothesized that antenatal exposure to maternal chronic stress may induce morphological and functional changes in the hippocampus, amygdala and prefrontal cortex by which a neurobiological vulnerability is acquired already prenatally. There still is, however, a lack of knowledge about the underlying mechanisms. On the one hand a better understanding of the biology of preterm parturition and of (subtle) birth defects and their underlying pathophysiological processes is necessary to set up preventive and curative treatment of women at enhanced risk for giving birth to babies with birth defects and/or for preterm parturition. On the other hand, by examining in pregnant women the effectiveness of a standardized stress reduction intervention program on maternal stress systems and also the infant stress system and cognitive functioning, hypotheses about the proposed underlying mechanisms will have a chance to be tested

Study objective

Our objective is to test the following hypotheses :
- Hypothesis 1 (part 1 of the study): The stress reduction intervention has beneficial effects on subjective maternal emotional well-being, on objective maternal stress system measures (i.e., HPA-axis and/or ANS measures) and on length of gestation.
- Hypothesis 2 (part 2 of the study): In normal four months old infants the maturity of its stress system (as measured with HPA-axis and ANS measures) is associated with their cognitive functioning (as measured with auditory event-related evoked potentials (AERPs).
- Hypothesis 3 (part 3 of the study): The association between the infant stress system and its cognitive functioning (as measured with AERPs in the four month

old infant) is moderated by the maternal stress system during pregnancy. Hypothesis 3 is the most explorative one. We assume that: (a) the moderating influence of the maternal system may occur independently of whether the mother participated in the stress reduction intervention or not; (b) if the intervention is associated with a reduction of birth defects, this most probably is related to benefical effects of the intervention not only on subjective well-being but also on the maternal stress system.

Study design

The first part of our proposed study involves a randomized controlled trial (sample 1, n=140) in which 70 women receive a stress reduction intervention, weekly between week 15 and 23 of gestation, and 70 matched women receive normal prenatal care. It will be examined whether the intervention has an influence on subjective well-being and on maternal autonomic regulation and HPA-axis function as well as on length of gestation. We hypothesize that, if the provided intervention is effective, it may indeed influence the length of gestation and eventually lower the chance for premature delivery (hypothesis 1). As a recent study showed that there is a 23% decrease in adverse outcomes with each week of advancing gestational age between 32 and 39 completed, even a gain of one gestational week is an important goal to obtain.
In the second part of our study, we design a protocol to study the association between the autonomic regulation (i.e., heart rate variability measures), HPA-axis (i.e., cortisol responsiveness) and cognitive functioning (i.e., attention to auditory events and cortical auditory processing as measured with auditory event-related potentials) in a sample of four months old infants (sample 2, n=60). Positive associations between these systems are expected (hypothesis 2).
Finally, in the third part, with the protocol tested in the second part, an eventually enhanced vulnerability acquired during gestation in the offspring of the stressed or anxious women of sample 1 will be examined when the offspring is four months old. It plausible to hypothesize that the maternal stress system during pregnancy moderates this effect (hypothesis 3, the most explorative one). This moderating influence may occur independently of whether the mother participated in the stress reduction intervention or not. If the intervention is associated with a reduction of birth defects, this most probably is related to beneficial effects of the intervention not only on subjective well-being but also on the maternal stress system.

Intervention

A stress reduction intervention is given to the experimental group, weekly between week 15 and 23 of gestation and each session lasts 150 minutes,

Study burden and risks

Completing the questionnaires takes 15 to 30 minutes; taking the saliva samples takes a few minutes every time; to attach and detach the VU-ambulant monitoring system will take 10 minutes.
The observations in the university lab (3 times during pregnancy) take about 60 minutes
For the Mindfulness-training (to reduce stress) therer are 8 sessions that last 150 minutes each
The final observation in the lab takes 60 to 75 minutes and completion the questionnaires takes 30 minutes.

Contacts

Public
Universiteit van Tilburg

Postbus 905153
5000 LE Tilburg
NL
Scientific
Universiteit van Tilburg

Postbus 905153
5000 LE Tilburg
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant woman:
-18 to 40 year old
-score higher then Pc 67 on standardised stress and anxiety questionnaires
-no substance abuse problems
-no severe psychiatric problems
-no pregnancy-related medical problems (e.g. diabetes, hypertension) or obstetrical problems;Babies
-their mothers score lower than Pc 50 on standardized stress and anxiety questionnaires, measuring concurrent stress and anxiety
- their mothers score lower than Pc 50 on standardized stress and anxiety questionnaires retrospectively measuring their experience of stress and anxiety during pregnancy;
- the babies were full term at birth and there were no pregnancy or birth complication, no neurological impairment, congenital malformation or disease for which extensive medical treatment was needed.

Exclusion criteria

Pregnant woman:
-other medical or obstetrical complications during this pregnancy
-18 to 45 year old
-score lower then Pc 67 on standardised stress and anxiety questionnaires
-substance abuse problems
-severe psychiatric problems
-pregnancy-related medical problems (e.g. diabetes, hypertension)
or obstetrical problems;Babies
- their mothers score higher than Pc 50 on standardized stress and anxiety questionnaires, measuring concurrent stress and anxiety
- their mothers score higher than Pc 50 on standardized stress and anxiety questionnaires retrospectively measuring their experience of stress and anxiety during pregnancy;
- the infants were preterm born and there were pregnancy or birth complications, neurological impairments, a congenital malformation or disease for which extensive medical treatment was needed.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	09-11-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL30051.008.09