Pregnancy And Infancy Reduced Stress study

Published: 19-03-2014
Last updated: 24-04-2024

Primary objective:To examine the effect of stress reduction through heart rate variability (HRV) biofeedback + psycho-education (condition 1) in pregnant women with at least moderate levels of stress, and their partners, as compared to psycho-...

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

Summary

ID

NL-OMON40370

Source
ToetsingOnline

Brief title
PAIRS study

Condition

- Other condition

Synonym
Stress, tension

Health condition

Verhoogd risico op stress en stressgerelateerde klachten

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Technologiestichting STW ,Nationaal Initiatief Hersenen & Cognitie (NIHC),Philips Research

Intervention

Keyword: HRV biofeedback, Pregnancy, Prenatal stress, Stress

Outcome measures

Primary outcome

Numbering corresponds to numbering *Primary Objective*

(a) Perceived stress and anxiety (pregnant women and their partners) assessed by means of self-report on validated questionnaires; stress physiology of parameters of the autonomic nervous system (e.g. heart rate, heart rate variability, pre-ejection period, respiratory sinus arrhythmia, skin conductance responses) as measured by basal functioning and by responses to a standardized stress task;

(b) Medical complications during pregnancy; birth outcomes for the mother and child with regard to: gestational age, birth weight, APGAR scores (1-5 minutes), method of delivery, complications;

(c) Infant behaviour and development: sleep patterns, feeding patterns, crying, infant temperament, motor and mental development.

Secondary outcome

Numbering corresponds to numbering *Secundary Objectives*

(1) HRV-biofeedback parameters (related to changes in total blood volume).

(2) Usability and validity of the DTI-2.

(3) Diverted attention, using an emotional interference task.

Study description

Background summary

There is accumulating evidence that prenatal maternal stress and anxiety may result in less optimal birth outcomes and has long-lasting adverse consequences on offspring*s development and behavior. Therefore, reducing maternal stress and anxiety during pregnancy is of major importance, because it will provide a fundament for a healthy child development.

A heart rate variability (HRV) biofeedback intervention has been proven to be effective in reducing stress and to increase adaptation to stressful situations in several populations, and is expected to be effective in stressed pregnant women as well. Recent research shows the importance of social support by their spouse and the major impact of the transition to parenthood for both women and men in their relationship. Therefore, we ask the spouses to participate in the intervention study as well.

Although several studies have shown that HRV-biofeedback can serve as a stress and anxiety reducing intervention, little is known about the mechanisms of this technique. One hypothesis is that blood volume is related to certain HRV-biofeedback parameters. In pregnant women, blood volume increases in a relatively short time, which makes this specific group an ideal population to study this relationship.
A possible mechanism that may contribute to the reduction of stress and anxiety via HRV-biofeedback is learning to focus and shift, i.e., regulate, your attention. To test this hypothesis, an emotional interference task is included in this study.

Study objective

Primary objective:
To examine the effect of stress reduction through heart rate variability (HRV) biofeedback + psycho-education (condition 1) in pregnant women with at least moderate levels of stress, and their partners, as compared to psycho-educational coaching only (reference condition), on: (a) physiological and subjective measures of stress, anxiety and well-being for pregnant women and their partners, (b) birth outcomes for mother and child, and (c) infant behaviour, development, and well-being (study 1).

Secundary objectives:
(1) To examine the changes in HRV-biofeedback parameters across pregnancy (due

to changes in total blood volume)(study 2).
(2) To test and validate a device for ambulatory monitoring of stress physiology against the well-validated and commonly used VU-AMS research device (study 1).
(3) To test the effects of HRV-biofeedback on diverted attention (study 2).

Study design

This study consists of two randomized controlled trails.

Study 1:
Pregnant women, together with their partners or a significant other, are randomized to either (1) HRV-biofeedback + psycho-educational training or (2) psycho-education training only (reference condition). Our study further includes repeated measures of determinants and outcomes during pregnancy and the first year of life of the infant. In short, repeated measures of outcomes during pregnancy (stress indices, medical complications, sleep quality; T1 and T2), at birth (T3: gestational age, birth weight, delivery and birth complications) and the first year of life at 1 (T4; parental adaptation and stress indices), 6 & 12 months (T5 & T6: infant behaviour, development, emotional well-being; parental adaptation and family functioning) will be conducted. Participation in the study will, therefore, take about 1.5 years.

Study 2:
Pregnant and non-pregnant women are randomized to either a Biofeedback-immediate group, or a Biofeedback-waitlist group (reference condition), resulting in four groups: (1) Biofeedback-immediate, pregnant; (2) Biofeedback-immediate, non-pregnant; (3) Biofeedback-waitlist, pregnant; and (4) Biofeedback-waitlist, non-pregnant. The study further includes repeated measures of stress indices, sleep quality and attention. In the Biofeedback-immediate condition these measurements take place before and after the training, and six weeks later (follow-up). In the Biofeedback-waitlist condition, the first two measurements take place before the training, with a six week period in between, and the third measurement takes place after the training.

Intervention

Study 1:
Two intervention conditions are part of the study: (1) HRV-biofeedback + psycho-education, and (2) psycho-education (reference condition). Each condition will consist of 9 weekly group sessions + 1 reunion session after birth of 2-2.5 hours, starting in mid-pregnancy. Groups consist of 6 pregnant women and their partners, led by a well-educated midwife-trainer. Both conditions will require daily homework practices (max. 40 min.) for participants.

Study 2:
The heart rate variability biofeedback intervention consists of 5 weekly group sessions of 60-90 minutes, with daily home practices (40 minutes). Groups consist of 6 participants.

Study burden and risks

Study 1:
There are no risks anticipated for women, partners, and their (unborn) child with the study. Burden for the pregnant women and their partners consists of participating in the intervention, filling out questionnaires, and physiological measurements. Burden for the child consists of mental and physical development measurements.

During the intervention, the pregnant women and their partners are asked to come to our research facility in Amsterdam for nine weekly group sessions of 2-2.5 hours each, with max. 40 min/day of home practice and diary reports during these weeks.
Both the pregnant women and their partners are asked to fill out questionnaires twice during pregnancy (approx. 60 minutes per set of questionnaires) and three times during the first year following birth (approx. 30-40 minutes per set of questionnaires). Questionnaires can be filled out at home.

For the physiological measurements during pregnancy, the pregnant women and their partners are asked to visit our research facility in Amsterdam twice. It will take about 60-90 minutes to complete these measurements.

The child born from this pregnancy is tested two times on mental and physical development during the first year (at 6 months and 1 year; 45-60 minutes for each measurement). For these measurements, at least one of the parents is asked to visit our research facility in Amsterdam with the child.

Study 2:
There are no risks anticipated for the participants. Burden for the participants consists of participating in the intervention, filling out questionnaires, and physiological measurements.

During the intervention, participants are asked to come to our research facility in Amsterdam for five weekly group sessions of 60-90 minutes each, with 30-40 min/day of home practice and diary reports during these weeks. Participants will be asked to fill out questionnaires three times (approx. 25-40 minutes for each set of questionnaires). This can be done at home. For the measurements of the HRV parameters, the participants are asked to visit our research facility in Amsterdam. It will take about 30-40 minutes to complete these measurements. Furthermore, an emotional interference tasks is applied three times, when participants are at our research facility. In this task, participants are presented with pictures from the widely used International

Affective Picture System (IAPS), and some of the pictures contain an image that can be experienced as unpleasant (e.g., accidents). This task will take about 15 minutes to complete.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 1
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 1
Amsterdam 1081BT
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

Study 1:
In order to be eligible to participate in this study, a subject must meet all of the following criteria: The pregnant women should be >18 years of age, and <22 weeks pregnant. They should have at least moderate levels of prenatal stress, determined by a score of 22 or higher on the PSS, or a score of 21 or higher on the PRAQ-R.;Study 2:
In order to be eligible to participate in this study, a subject must meet all of the following

criteria: For pregnant women see *Study 1* above. The non-pregnant women need to have comparable ages, relevant for matching purposes, and should have at least moderate levels of stress, determined by a score of 22 or higher on the PSS.

Exclusion criteria

Study 1
A potential subject (pregnant woman) who meets any of the following criteria will be excluded from participation in this study: (1) chronic medical conditions such as Diabetes, (2) use of medication which is known to affect cardiovascular stress reactivity measures (e.g., * blockers), (3) substance abuse, (4) insufficient command of the Dutch language required to fill out questionnaires, (5) a score of 16 or higher on the depression scale of the HADS (cut-off score for severe depression), and (6) presence of a history of other severe mental disorders, such as Bipolar disorder or Schizophrenia.;If the partner of the pregnant woman meets any of the following criteria, the couple will be excluded from participation in this study: (1) presence of a history of other severe mental disorders, such as Bipolar disorder or Schizophrenia, (2) substance abuse, (3) insufficient command of the Dutch language required to fill out questionnaires.;Study 2
See exclusion criteria women of study 1.

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:	Recruitment stopped
Start date (anticipated):	19-05-2014
Enrollment:	560
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL46065.029.13