Pregnancy And Infancy Reduced Stress (PAIRS) study.

No registrations found.

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

Summary

ID

NL-OMON21785

Source
NTR

Brief title
PAIRS study

Health condition

Participants have at least moderate levels of stress and/or pregnancy related anxiety

Stress; pregnancy related anxiety
Stress; zwangerschapsgerelateerde angst

Sponsors and support

Primary sponsor: Faculty of Psychology & Education,
Dept. of Developmental Psychology,
VU University, Van der Boechorststraat 1, 1081
BT Amsterdam
Source(s) of monetary or material Support: STW – Technology Foundation, National Initiative Brain & Cognition (NIHC), and Philips Research

Intervention

Outcome measures

Primary outcome

Study 1:

(a) Perceived stress, anxiety and well-being (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

Study 2:

HRV biofeedback parameters (e.g. heart rate, heart rate variability, RSA); perceived stress, anxiety and well-being assessed by means of self-report on validated questionnaires; diverted attention

Study description

Study objective

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 various populations, and is expected to be also effective in stressed pregnant women. 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.

Primary Objective: To assess whether HRV-biofeedback can provide an additional stress reducing effect to psycho-educational coaching in pregnant women with at least moderate levels of stress, and their partners, that influences the development of the child as shown by: (a) physiological and subjective measures of stress and anxiety during pregnancy for pregnant women and their partners, (b) birth outcomes for mother and child, and (c) physical, cognitive, and social-emotional development of the infant (Study 1).

Secondary Objectives: (1) To examine the changes in HRV-biofeedback parameters across pregnancy (due to changes in total blood volume); (2) To test the effects of HRV-biofeedback on diverted attention (Study 2).

Study design

Study 1:

T1: 16 wks pregnant

T2: 26 wks pregnant

T3: 1 wk after birth

T4: infant 1 month old

T5: infant is 6 mos old

T6: infant is 12 mos old

Everyday Problem List (Daily hassles; T1 & T2); Pregnancy Related Anxieties Questionnaire-Revised (T1 & T2); Pregnancy Experience Scale (T1 & T2); Dyadic Coping Inventory (Marital satisfaction; T1 & T2); Partnership Questionnaire (T1 & T2); Penn State Worry Questionnaire (T1 & T2); Perceived Stress Scale (T1&T2, T4-T6); Depression, Anxiety, Stress Scale (T1&T2,

T4-T6); Pittsburgh Sleep Quality Index (T1&T2, T4-T6); Utrecht Coping List (T1 & T2); Attentional Control Scale (T1&T2, T4-T6); Scales of Psychological Well-being (T1&T2, T4-T6); Self-Efficacy in the Nurturing Role Questionnaire (parental self-efficacy; T1&T2, T4-T6); Pregnancy complications and obstetric information (T3); Birth measures including gestational age at birth, birth weight, APGAR scores, method of delivery (spontaneously, forceps, primary/secondary caesarean section), complications at delivery (fetal distress, oxygen supply, infection, neonatal intensive care needed, time spent in incubator) (T3); Infant health including duration of feeding, infant height and weight, illnesses, and medication use (T3-T6); Infant Behavior including measures of infant crying, development of sleep/wake cycles (T4-T6); Infant Behavior Questionnaire - Revised (temperament; T5 & T6); Infant Developmental Inventory (T4-T6); Bayley Scales of Infant and Toddler Development - Third Edition (T5 & T6); General Functioning subscale of the Family Assessment Device (T6); Comprehensive Parenting Behavior Questionnaire (parenting style; T4-T6)

Study 2:

All questionnaires are filled out at three time points with six weeks intervals: pre-intervention, post-intervention and follow-up (Biofeedback-immediate condition); or two times before the intervention and ones after the intervention (Biofeedback-waitlist condition)

Perceived Stress Scale; Depression, Anxiety, Stress Scale; Everyday Problem List (Daily hassles); Pregnancy Related Anxieties Questionnaire-Revised (pregnant women only); Pittsburgh Sleep Quality Index; Utrecht Coping List; Attentional Control Scale; Scales of Psychological Well-being; Rosenberg Self Esteem Scale; Mastery Scale

Intervention

Study 1:

Two intervention conditions are part of the study: (1) HRV-biofeedback + psycho-education, and (2) psycho-education (reference condition). The psycho-education consists of an extensive pregnancy course for couples, called 'Samen Bevallen'. Each condition consists 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 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

There are two types of control in study 2: (1) a group of non-pregnant women serves as a control for the pregnant women; (2) half of the participants of both groups are randomized into a wait-list control group.

Contacts

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Eligibility criteria

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 (mean score derived from Cohen & Janicki-Deverts, 2012), or a score of 21 or higher on the PRAQ-R (mean score derived from unpublished data from the Generations2 study of VU university).

Partners should be >18 years of age.

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 (mean score derived from Cohen & Janicki-Deverts, 2012)

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., betablockers), (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.

Study2:

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2014
Enrollment:	480
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-05-2014
Application type:	First submission

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
NTR-new	NL4402
NTR-old	NTR4599
Other	STW – Technology Foundation / Medical Ethical Committee VUmc : 12001 / NL46065.029.13

Study results