Effectiveness of a prenatally implemented parenting support intervention on preventing postpartum parental distress and enhancing infant well-being.

Published: 07-09-2016
Last updated: 19-03-2025

The primary objective is to assess the effect of the parenting support intervention on parental stress. Secondary objectives are the effect of theintervention on other parental outcomes (anxiety and depression, satisfaction with the parental role,...

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

Summary

ID

NL-OMON43052

Source
ToetsingOnline

Brief title
A parenting support intervention on preventing parental distress.

Condition

- Family issues

Synonym
Parenting stress - Stress related to the parenting role

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO Talentbeurs

Intervention

Keyword: Attachment, Infant well-being, Parenting distress, Parenting support intervention

Outcome measures

Primary outcome

The primary outcome of the study will be parenting stress.

Secondary outcome

Secondary outcomes will be parent's well-being (indicated by anxiety and depression, satisfaction with the parenting role and self-efficacy in caring for the infant); caregiving (attachment, breastfeeding duration, and co-sleeping); and the infant's well-being (sleeping, crying and feeding problems and health).

Study description

Background summary

The first months after birth can be challenging for parents and affect well-being. This might lead to high parental stress and to other negative outcomes for the parents (e.g. to postpartum depressive symptoms). Parents with high levels of parental stress are also less able to respond adequately and sensitively to their infant. This might lead to less secure attachment bonds and to less than optimal infant (brain) development. Effective interventions to reduce parental stress are available but until now only used for high-risk groups. Furthermore, those interventions focus exclusively on the mother. The proposed study focuses on a parenting support intervention consisting of psycho-education and practical tools. This intervention is aimed at reducing parental stress for both parents.

Study objective

The primary objective is to assess the effect of the parenting support intervention on parental stress. Secondary objectives are the effect of the intervention on other parental outcomes (anxiety and depression, satisfaction with the parental role, self-efficacy in caring for their infant), caregiving outcomes (bonding, duration of breastfeeding and co-sleeping) and on infant well-being (indicated by their patterns of crying and sleeping behaviour and the infant*s health).

Study design

The proposed study is a randomized controlled intervention study. Random allocation will take place at the individual level on a 1:1 ratio to either the intervention or a wait-list control group. Participants are randomized using random sequence block randomization (blocks of 2, 4 or 6), stratified by birth order of their child (first or second) and participation of the father (participate/not participate). Patients will receive the outcome of randomization by mail. Due to the nature and design of the study, blinding of the researchers or participants is not possible.

Intervention

The parenting support intervention is based on the work of Hiscock et al (2014) about infant sleeping and crying patterns which has proven to be effective on parents* and infants* health. We add information about how to respond to signals of distress which is essential for the bonding process. The intervention will be introduced prenatally, between the 34th and the 36th week of pregnancy. Parents will receive a booklet and access to an online video which will be accessible with individual credentials. During a subsequent prenatal home visit, parents will receive further explanation about the materials and how to implement the tools provided. Also, they are given the opportunity to ask questions. Parents will receive a phone call 4 weeks after birth, to ask how they are doing and to further support them with implementing the intervention.

Study burden and risks

Participation in the proposed study contributes to a better understanding of how parents can be supported prenatally in preparing for parenthood and the first months with a newborn infant. The main burden for parents will be to keep the infant behavior diary, and to fill in the questionnaires pre- and postnatally. In the experimental group, parents also need to read the booklet and watch the online video before the child is born.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 1
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 1
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Women expecting their first or second child
* Uncomplicated pregnancy
* Sufficient Dutch language proficiency (to understand the information in the booklet and on the website)
* Access to a computer and the internet

Exclusion criteria

* Current psychopathology (defined as current treatment for psychopathology or treatment in the 6 months before inclusion)

* Insufficient Dutch language proficiency

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):	02-11-2016
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2016
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

ID: 24862
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58528.028.16
OMON	NL-OMON24862