"I have changed my mind"

No registrations found.

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

Summary

ID

NL-OMON24715

Source
NTR

Brief title
N/A

Health condition

stress, anxiety, pain, childbirth, parenting, mindfulness

Dutch: stress, angst baringspijn, geboorte, ouderschap, mindfulness

Sponsors and support

Primary sponsor: The Research Institute of Child Development and Education at the University of Amsterdam
Source(s) of monetary or material Support: The Research Institute of Child Development and Education at the University of Amsterdam

Intervention

Outcome measures

Primary outcome

- stress, anxiety and depression will be assessed by the Depression Anxiety & Stress Scales (DASS-
21; Lovibond & Lovibond, 1995),

- stressful situations in one’s life will be assessed by the Perceived Stress Scale (PSS; Cohen, 1988)
- prenatal stress will be assessed by the Pregnancy Experience Scale (PES; DiPietro et al., 2008)

- anxiety trait will be assessed by the subscale T-anxiety derived from the State-Trait Anxiety Index (STAI; Spielberger et al., 1983),

- anxieties related to pregnancy will be assessed by the Pregnancy Related Anxieties Questionnaire - Revised (PRAQ-R; Huizink et al., 2004),

- childbirth fear-eliciting beliefs will be assessed by participant’s pre-defined beliefs about childbirth- related events that cause them fear (max. 3 beliefs) and assessing the probability of those events occurring during childbirth on the Visual Analogue Scale (VAS), (0-100%), (Voncken & Bögels, 2006)

- current depression symptom levels will be assessed by the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987),

- the anxiety disorders as well as additional commonly co-occurring disorders such as depression will be assessed by the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-DSM IV), (Boden & Melick, 2002), a non self-report instrument.

Secondary outcome

- sleep quality during the previous months will be assessed by the Pittsburgh Sleep Quality Index
(PSQI; Buysse et al., 1989),

- preferences for obstetrical interventions will be assessed by the Willingness to Accept Obstetrical
Interventions measure (WAOI; Green, 2007),

- negative thoughts about the possible catastrophic consequences of labour pain will be assessed by the Catstrophizing Labour Pain (CLP) subscale derived from the Labour Pain Coping and Cognition List
(Veringa et al., 2011),

- anticipated acceptance of pain during labour will be assessed by the Labour Pain Acceptance Questionnaire (LPAQ) an adaptation of the Chronic Pain Acceptance Questionnaire (CPAQ ; McCracken et al., 2004),

- elements of mindfulness: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience will be assessed by the Five Facet Mindfulness
Questionnaire (FFMQ; Baer et al.2006; Dutch validation de Bruin et al., 2012),
- extending compassion to one’s self will be assessed by the Self-Compassion Scale-Sort

Form (SCS-SF; Raes et al., 2011),

- general quality of life/health status (required for economic evaluation) will be assessed by the Five-
Dimensional EuroQol instrument (EQ-5D; (EuroQol group, 1990),

- healthcare costs from a societal perspective will be assessed by the Cost Evaluation in Perinatal Care
Questionnaire (CEPCQ; Steensels & Veringa 2013) based on healthcare consumption by Bodden
(2008), a non self-report instrument,

- breastfeeding intention and status quo will be assessed by two questions: 'Are you intending to
breastfeed?' and 'Do you breastfeed your baby?',

- model of childbirth, setting, obstetrical complications in pregnancy and birth, child-birth weight,
Apgar score, a non self-report instrument.

Other study parameters

Background information will be gathered such as age, place of birth, ethnicity, education level, employment, civil status, duration of relation, family composition, smoking behavior, alcohol use, and medication, psychopathology, prior experience with meditation or yoga, and perceived expectation regarding the training. Information from midwifery file will be collected by the researcher investigator.

Study description

Background summary

Although the effects of mindfulness-based interventions in stressed adults are well established, research on the effects of these intervnetions in a population of stressed pregnant women is a new domain. The MBCP program is an innovative application of mindfulness for expectant couples designed to ameliorate the impact of stress related to pregnancy, childbirth and early parenting. MBCP seems to be potentially effective in reducing stress, anxiety and negative mood and increasing adaptation to pregnancy, childbirth, early parenting, and overall psychological well-being in new parents as evaluated in two small pilot studies.
The objective of our study is threefold: (a) to investigate whether the MBCP program decreases stress, anxiety and childbirth fear-eliciting beliefs and increases overall

psychological well-being, and mindfulness during pregnancy, (b) to test whether these changes mediate perinatal outcome, and (c) to evaluate the cost effectiveness of MBCP.
Study design: A RCT with two study arms: MBCP and SB program: a standardized psycho-education program for couples.
Expectant couples (n = 160) from whom pregnant women have at least moderate levels of stress and/or anxiety at the end of the second trimester of pregnancy.
The MBCP program consists of: a 9-week course with 3 hours per class and a 7 hour silent Retreat Day during end of the second and the third trimester and a Reunion Class after birth.
A series of self-report questionnaires will be used to measure the following outcomes: mental health of both partners (including stress, anxiety, childbirth fear-eliciting beliefs), attitude toward medical interventions in childbirth, experience of pain, perinatal outcomes, breastfeeding, early parenting stress and quality of life. Measurements will be collected at pre and post intervention, about two weeks and three months following childbirth.
Dysfunctional childbirth beliefs and mindfulness will be assessed as potential mediators. An economic evaluation will be conducted to assess the cost-effectiveness of MBCP.
This will be one of the first studies to investigate the efficacy of the MBCP program using an active control group. MBCP has a potential to be an effective, non-invasive, and non-medical intervention for pregnant women and their partners, and may become popular from a client's perspective.

Study objective

The Mindfulness Based Childbirth and Parenting (MBCP) program is an innovative application of mindfulness for expectant couples designed to ameliorate the impact of stress related to pregnancy, childbirth and early parenting. MBCP seems to be potentially effective in reducing stress, anxiety and negative mood and increasing adaptation to pregnancy, childbirth and early parenting, and psychological well-being in new parents. Since stress, anxiety and depression influence pregnancy, the childbirth process and childbirth outcomes negatively, and general childbirth education seems to be inefficient in preparing expectant mothers for the challenges of childbirth, we propose to examine effects and costs of the MBCP program in a population of stressed pregnant women with their partners.

Study design

Data will be collected several time points during the study: at baseline 20-24 weeks pregnancy (T=0), pre intervention at 26-28 weeks pregnancy (T=1), post intervention at 36-38 weeks pregnancy (T=2), following birth at 10-14 day (T=3), and following birth at 12-14 week (T=4).

Intervention

The American MBCP program is an adaptation of the Mindfulness-Based Stress Reduction (MBSR) program. The MBCP program includes 9-weekly 3 hours sessions and a one day of silent retreat. Different mindfulness meditation instructions are given and practiced in each class and participants are expected to practice mindfulness at home every day during the intervention. The teaching of mindfulness is fully integrated with the knowledge of the

psychobiological processes in pregnancy, birth and early, postpartum adjustment and psychobiological needs of the baby.

Control group: The Dutch SamenBevallen (SB) is an official pregnancy course for expectant couples (www.samenbevallen.nl). This program includes 9-weekly classes of about 3 hours each. In the sessions information is provided on life-style issues including eating, physical activity, sleeping patterns, relaxation, pleasurable activities, and unhealthy habits, explicit information on stress and anxiety during pregnancy, the normal course of and health and psychological aspects related to pregnancy, birth and early parenting.

Contacts

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Eligibility criteria

Inclusion criteria

Pregnant women in the second trimester of gestation with at least moderate levels of stress and/or anxiety.

Exclusion criteria

Pregnant women with (a) no mastery of the Dutch language, (b) high-risk obstetrical complications during the current pregnancy including, being admitted to the obstetrical unit, (c) an acute psychosis/psychotic disorder, suicidal risks, substance abuse and dependency, or borderline personality disorder, (d) receiving a mindfulness-based intervention on regular

basis during last year.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-01-2014
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-12-2013
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	NL4151
NTR-old	NTR4302
Other	Medical Ethical Committee of the University of Amsterdam, Academic Medical Center : ABR 44033
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A