ISRCTN11445342 https://doi.org/10.1186/ISRCTN11445342

Strengthened parental support for expectant parents – a pilot to assess trial feasibility and preliminary outcomes

Submission date
05/12/2024

Recruitment status
No longer recruiting

Registration date
06/12/2024

Overall study status
Ongoing

Last Edited
16/05/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The support expectant parents receive is an important protective factor for their children. It is extra important to offer support that reduces the risk of stress, depression and anxiety already during pregnancy. These conditions not only cause suffering for the pregnant woman but also pose risks for the foetus and the future mental health of the child. For expectant parents there is both an increased risk for mental ill-health and a unique opportunity to promote mental wellbeing for the whole family. The overarching goal for this project is therefore to strengthen parental support during pregnancy. The specific aim is to do a pilot study to see if it can be scaled up to a larger study. Doing a pilot means that we want to test things like recruiting and keeping participants in the study, collecting the data and also looking at preliminary results about how the support works. If running the study is smooth, the researchers can continue with a larger study to test how well the support works.

Who can participate?
Expectant parents who speak Swedish and are at least 18 years old

What does the study involve?
We have adapted mindfulness-based parental support to Swedish maternal health services. This new parental support is called 'Parenting with Awareness and Compassion'. It includes four group meetings and material on a homepage. During the group meetings mindfulness and yoga practises are mixed with information about childbirth, breastfeeding, the needs of a newborn and new parents, as well as couple communication. Half of the participants will receive this new support and the other half (the control group) will receive the standard support given in maternal healthcare. The participants will fill out questionnaires about their quality of life, mental health and how it feels to be a parent. They will fill out the questionnaires three times: Around the middle of the pregnancy (gestational weeks 20-25), toward the end of the pregnancy (gestational weeks 32-34) and 3 months after their baby is born.

What are the possible benefits and risks of participating?
The participants who will receive the new support may feel more prepared and strengthened for

childbirth and parenting. The risk of side effects, like anxiety or emotional sensitivity, from such support is low. All participants will receive gifts for the baby, a blanket and a baby book as thanks for their time filling out questionnaires.

Where is the study run from?
Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
April 2022 to October 2026

Who is funding the study?
The Kamprad Family Foundation (Sweden)

Who is the main contact?
Dr Gunilla Lönnberg, gunilla.lonnberg@uu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
20223263

Study information

Scientific Title

A pilot to assess the feasibility of a randomized controlled trial evaluating a strengthened parental support program vs standard support for expectant parents

Acronym
PACT

Study objectives
The rationale is to address uncertainties regarding the feasibility of conducting a full scale randomized controlled trial and if appropriate modify the study design.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/09/2023, The Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2023-05031-01

Study design
Multicenter interventional single-blinded pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Other, Prevention, Quality of life

Health condition(s) or problem(s) studied
Mental health of expectant parents

Interventions
The intervention Parenting with Awareness and Compassion consists of four group meetings, led by a midwife and is supported by a homepage with short informative texts and videos as well as audio files with practices. It includes the traditional elements of parental support from maternal healthcare such as preparation for childbirth, parenting, breastfeeding and alternative feeding, infant care and the couple relationship. These elements are woven together with mindfulness-based practices that strengthen emotional self-regulation, interoceptive awareness, meta-cognition, relational responsiveness, and compassion. Simply put, the practices, including peer support and reflective conversations give parents tools to decrease stress, anxiety and negative moods and increase their ability to reevaluate and see wider perspectives as well as become more sensitive and kind with themselves, each other and their child.

Randomisation lists are made for each site using 'sealed envelope', with random blocks of 2-4. An administrator external to this project has the lists. Half of the participants will receive the new support and the other half (the control group) will receive the standard support given in maternal healthcare. The participants will fill out questionnaires about their quality of life, mental health and how it feels to be a parent. They will fill out the questionnaires three times: Around the middle of the pregnancy (gestational week 20-25), toward the end of the pregnancy (gestational week 32-34) and 3 months after their baby is born.

Intervention Type
Behavioural

Primary outcome(s)
1. Self-compassion is measured using the Self-Compassion Scale Short Form at baseline, 2 months (around gestational week 34) and 5 months (around 3 months postpartum)
2. Quality of life is measured using Assessment of Quality of Life 8-Dimension at baseline, 2 months (around gestational week 34) and 5 months (around 3 months postpartum)

Key secondary outcome(s))
1. Fear of birth is measured using the visual analogue score fear of birth at baseline and 2 months (around gestational week 34).
2. Depressive symptoms are measured using the Edinburgh Postpartum Depression Scale at baseline, 2 months (around gestational week 34) and 5 months (around 3 months postpartum)
3. Anxiety is measured using the General Anxiety Disorder form at baseline, 2 months (around gestational week 34) and 5 months (around 3 months postpartum)
4. Prenatal attachment is measured using the Prenatal Attachment Inventory at baseline and 2 months (around gestational week 34)
5. Postpartum bonding is measured using the Postpartum Bonding Questionnaire at 5 months (around 3 months postpartum)

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Expectant primiparous mother or partner of expectant primiparous mother
2. In pregnancy weeks 18 to 30
3. Patient enlisted in one of seven participating maternal health clinics
4. Swedish speaking
5. 18 years of age or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
159

Key exclusion criteria
1. Previous or active psychosis, personality disorders

Date of first enrolment
09/12/2014

Date of final enrolment
08/05/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Tiohundra Norrtälje Barnmorskemottagning
Drottning Kristinas väg 70A
Norrtälje
Sweden
761 32

Study participating centre
Mamma Mia Täby Barnmorskemottagning
Östra Galleriagången 2013
Täby
Sweden
183 34

Study participating centre
Liljeholmens Barnmorskemottagning
Liljeholmstorget 7
Stockholm
Sweden
117 94

Study participating centre
Haninge Barnmorskemottagning
Rudsjöterassen 3
Stockholm
Sweden
136 40

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
Familjen Kamprads Stiftelse

Alternative Name(s)
Kamprad Family Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical reasons and the handling of personal sensitive information.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	Study website	18/09/2024	16/05/2025	No	No

Study website	11/11/2025	11/11/2025	No	Yes