Strengthened parental support for expectant parents – development, feasibility and preliminary outcomes

ANALYSIS PLAN

Background

The overarching goal for this project is to strengthen the parental support during pregnancy. During the first phase of the project (which started 2023 and is ongoing spring 2024), the intervention Mindfulness Based Childbirth and Parenting (MBCP) was adapted and modified to Swedish maternal healthcare services. Stakeholders – end-users (expectant parents), providers (midwifes) and representatives from the central maternal health unit in Region Stockholm – were engaged in an iterative intervention adaption process. A reference group of expectant parents and birthparents were involved during the development of materials. This resulted in the initial version of the adapted and modified intervention, which consists of four weekly group sessions, 2h 30 min long and is supported with a homepage containing short films, texts and audio-files. It was ensured that key aspects of the MBCP logic model were still captured. Additional elements were incorporated; such as Mindfetalness (an evidence-based method for pregnant women to bring awareness to fetal movements), breathing exercises (e.g. lengthening and slowing down the breath) and tapping/Do-In.

Data collection regarding acceptability and usability as well as ideas for modifications are carried out via focus groups and fieldnotes. The first acceptability and usability test led to minor adjustments and confirmed that expectant parents appreciate the group format, the reflective conversations and that the intervention leads to feeling emotionally and mentally strengthened.

Four midwifes have participated in the professional training and will lead one round of group meetings each. Additional adjustments may be done after final usability and acceptability tests with end-users as well as with providers, before moving to the next phase.

The intervention is called: *Parenting with Awareness and Compassion – Föräldraskap med medvetenhet och medkänsla (FMM)*

In the second phase of the project (which will start in August 2024) a pilot randomized controlled trial (RCT) with a hybrid design will be conducted. This analysis plan is for the pilot RCT. It serves as a roadmap to how data collected will be organized and analyzed. (https://learn.crenc.org/how-to-create-a-data-analysis-plan/). It includes the following:

- Objectives
- Hypothesis
- Dataset to be used
- Inclusion and exclusion criteria
- Research variables
- Statistical test hypotheses and the software for statistical analysis

Regarding study design: The initial plan was to pilot a cluster RCT, randomizing maternal care clinics to either intervention or control. However, during the project's first phase it was challenging to recruit maternal care clinics (due to financial loss if letting staff go to the professional training instead of seeing patients). The team therefore discussed changing the study design to randomize individuals instead of clusters/clinics. We have also applied for more funding to cover the financial losses for the clinics.

Objectives

1. Evaluate the feasibility of a full scale RCT, including a health economic evaluation.
2. Evaluate the scalability and feasibility of future implementation of the intervention.
3. Evaluate preliminary effects on parents' quality of life and mental health.
4. Explore how parents and midwifes experience PAC/FMM.

Hypothesis

For pilot RCT: Uncertainties regarding the feasibility of conducting a full scale RCT will be addressed and the trial design can be modified during the pilot to increase feasibility.

For full scale RCT: We hypothesize that FMM will promote mental wellbeing and prevent mental ill-health in expectant parents and build self-efficacy for childbirth and parenting. Through; 1) building skills in becoming more aware (of one's states of mind and body) and more compassionate (with self and others); 2) increasing parents' capacity to self-regulate to cope with stress, pain, fear and anxiety as well as savor more pleasurable moments; 3) providing communication skills for couples/co-parents; 4) giving access to peer-support and 5) providing useful information for labor, the needs of a newborn, the needs of a new mom/dad and breastfeeding.

Furthermore, we hypothesize that effects can influence labor and the child: Increases in maternal wellbeing and decreases in levels of stress can have a positive impact on gestational

age, weight at gestational age, onset of labor, mode of delivery and breastfeeding. We also hypothesis that the intervention can promote sensitive parenting and strengthen the couple/co-parent relationship.

Dataset

Objective 1 – data regarding feasibility of RCT

Recruitment procedures: Testing how to reach the expectant parents and how best inform about the study – by midwifes at participating clinics, with posters, folders and information letter. Informing at group-meetings, sending individual letters etc. Evaluate what strategies work best by monitoring the recruitment rate and strategies used at each site.

Recruitment rate: Percentage of enlisted pregnant women who consent to participate and are eligible. Plus, percentage of participating pregnant women who are joined by a co-parent also consenting to participate.

Retention rate: Percentage of sample who respond to T2 and T3 questionnaires. Monitor reasons for drop-out.

Time and resources needed for running study: Track time for research assistant tasks? Time to start up clinics, recruit, collect data…

Objective 2 – data regarding feasibility of implementation and scalability

*Fidelity: V*ideo-recording of the group-meetings in order to rate the leaders capacity to deliver the intervention using the Mindfulness Based Interventions: Teacher Assessment Criteria protocol (MBI:TAC) and also by filling out a checklist regarding to what extent they follow the manual. The first time the newly trained midwife will lead the group meetings it will be done under supervision. The videorecording will be done during the second round of them leading group meetings.

Costing analysis: Set-up and running costs will be calculated (training of staff, supervision, staff salaries, production loss, rent of room for group meetings, materials)

Objective 3 – data regarding preliminary outcomes

Data will be collected at three points-in-time: T1) at baseline around gestational week 20-25, T2) postintervention around gestational week 30-35 and T3) follow-up three months post-partum.

Sociodemographic data: In baseline questionnaire data regarding age, family status, country of origin, education, income, general health, history of mental health, PMS, adverse or

stressful events, history of abuse, social network of trusted persons, childhood and previous experience of meditation, mindfulness and yoga.

Data for parent's mental health, wellbeing, relationship, parental functioning and health economic evaluation:

- Self-Compassion Scale – Short form (SCS-SF) Primary outcome
- Fear of Birth
- Relationship between co-parents
- Assessment of Quality of Life 8-Dimension (AQoL-8D) Dimensions included: Independent Living, Happiness, Mental Health, Coping, Relationships, Self-Worth, Pain, Senses.
- Resource use questionnaire (regarding us of health care services).
- Edinburgh Postpartum Depression Scale (EPDS)
- General Anxiety Disorder (GAD)
- Prenatal Attachment inventor (PAI), T1 & T2, adjusted for non-birthing parent)
- Parental Reflective Function Questionnaire T3

Compliance: Monitor participation in group meetings (collect attendance-list from midwifes leading groups) and engagement in home practice; ask participants to respond to short questionnaire during meeting 2, 3 and 4 + ask about continued practice at T2 and T3 (for intention-to-treat as well as "completer-analysis" and any dose-response correlations).

Adverse events: logged by asking midwifes/group leaders to report such events and if participants drop out, contact them and ask for reasons for droping out. Also, at T2, ask parents if any of the practices elicited any unpleasant experiences.

Contamination: The postpartum questionnaire will include a question about whether parents have participated in other parent- or childbirth preparation classes.

Data from registry regarding obstetric outcomes and use of healthcare services: Onset of labor, induction, epidural analgesia, mode of delivery, gestational age and birth weight, Apgar scores, admission to neonatal unit etc.

Objective 4 – qualitative data regarding experiences

Individual interviews with providers/midwifes (about 10) and end-users/parents (about 15) regarding their experiences of delivering as well as receiving the intervention. The interviews will be semi-structured, audio-recorded and transcribed. The data will be analyzed using qualitative method such as thematic analysis with an inductive approach.

Inclusion and exclusion criteria

Inclusion criteria: Pregnant with first child and expectant fathers/non-birthing, at least 18-years of age and capable of giving informed consent. Swedish speaking.

(If only birthing parent want to participate in study but not the partner, the partner will still be welcome to take part of the intervention. An ethical consideration.)

Exclusion criteria: Previous or active psychosis, personality disorders perhaps add more criteria if things arise during the pilot.

Research variables

Feasibility of RCT variables:

Recruitment rates

Randomization issues

Retention rates

Compliance/adherence rates

Eligibility criteria (perhaps include only first-time mothers?)

Understanding questionnaires: any problems with answers (missing data, multiple answers, unanticipated answers).

Time and resources needed for running study

Willingness and capacity for maternal health clinics to collaborate

Important values forgotten that should be added

Variability in data (too much or too little?)

Trends in data (potential response to the intervention)

Adverse events/safety of intervention

Estimate of treatment effect and estimate of variance of the treatment effect

Feasibility of implementation and scalability variables:

MBI:TAC score

Fidelity checklists: Yes/No items (if practices were done according to the manual)

Costs: Set-up + running costs

Qualitative data from interviews with midwifes

Sociodemographics:

Age: in years.

family status: Singel, Co-habitig, Married, Living apart, Own children, Step children

country of origin: 4 groups – Nordic, European, outside of Europe

education, 4 groups – elementary, secondary, university no exam, university exam

Income: levels 0-10 000, 10 001-20 000, 20 000-30 000 (up to 100 000)

general health: 1-5 score

disease (mental or physical): Yes/No if yes: What? (Free text) Sick-leave Yes/No

history of mental health: Have you ever suffered from mental health problems (such as depression or anxiety)? Yes/No *Har du någon gång tidigare drabbats av psykisk ohälsa (som t ex depression eller ångest)*

PMS: Yes/No

adverse or stressful events: Free text list + 1-5 score

history of abuse, Yes, sexual/Yes, physical/No

social network of trusted persons: 1-5 score

childhood, 2 items 1-5 score

previous experience of meditation, mindfulness and yoga: Yes occasionally/Yes regularly during some period/No

Outcomes:

SCS-SF: 12 items 1-5 score

AQoL-8D: 35 items 1-5 score

EPDS: 10 items 1-4 score

GAD: 7 items

FOBS: 2 items 0-100

Relationship: 4 items, 1-5 score

PAI: 21 items (13 for non-birthing parent) 1-4 score

PBQ: 25 items 1-6 score

FÖS-test: 17 items, 1-7 score

Breastfeeding: Yes/No + free text regarding how much other food than breastmilk

Parental support: List of alternatives

Continues practice of meditation or yoga (for intervention only): frequency 4 levels and duration 6 levels.

Adverse events related to the practices during the intervention: 5 items, 1-3 score

Free text: Is there anything you would like to add?

Use of healthcare services and obstetric outcomes, data from registers listed below:

Variabellista Graviditetsregistret Include only simplex in register analysis. "Barn i börd = 1"

- Sysselsättning
- Graviditetslängd vid tillfället för inskrivning på mödrahälsovården, beräknad variabel för de som de med förlossning efter v.22+0
- Behandlats för psykisk ohälsa
- Barnmorskemottagning
- Inskrivningsdatum
- Först/Omföderska
- Antal levandefödda
- Antal dödfödda barn
- BMI vid inskrivning
- BP-datum
- Rökning vid tiden för inskrivning på mödrahälsovården.
- Användning av snus vid tiden för inskrivning på mödrahälsovården.
- Antal genomförda besök på mödrahälsovården
- Induktion
- Tidigare sectio
- Robsongrupp enligt Obstetrix
- Födelsedatum FV1
- Kvinnans ålder vid förlossningen
- Indikation till kejsarsnitt
- Spontan start
- Förlossningsslut FV1
- Förlossningsslut (Ej instrumentell)
- Förlossningsslut (VE)
- Förlossningsslut (Tång)
- Förlossningsslut (Kejsarsnitt)
- Förlossningsslut (Okänt)
- Bristning grad III-IV (med diagnoskoder)
- Moderns diagnoser: Datum för diagnos
- Diagnoskod enligt ICD-10
- Moderns åtgärd: Datum för åtgärd
- Åtgärdskod enligt klassifikation av vårdåtgärder (KVÅ)
- Graviditetslängd i antal veckor
- Graviditetslängd i antal dagar
- Prematur (v37+0 v+d)

- Överburen (>41+6 v+d)
- Födelseår
- Barnets födelsevikt (g)
- Vikt avvikelse (%) relaterad till förväntad födelsevikt
- AGA (Appropriate for Gestational Age), LGA (Large for Gestational Age), SGA (Small for Gestational Age).
- Barnets vikt kategoriserad till viktgrupper
- Kön
- Bedömning enligt Apgar efter 5 minuter
- Apgar <4 vid 5 min
- Smärtlindring epidural. Under förlossning (inte inför sectio)
- Amning
- Tillmatning
- Dödfött

Neonatalvårdsregistret

- Antal vårdtillfällen

VAL-databasen

- Alla vårdtillfällen inom öppen- och slutenvård samt ambulanstransport.

Test hypotheses

Pilot RCT

The main focus of the pilot is feasibility. A priori decision for go or no go – Feasible enough to proceed if the following is met:

- Recruitment rate: At least 10 pregnant first-time mothers per round recruited to the study. *(Instruction to BMMs, postpone the course if you have not received more than 8 who can be randomized 4/4. Actions after 1st round if recruitment is low: increase the range of gestational weeks, also include nulliparous women). During recruitment phase "accountabilibty check-in" with BM at each BMM*
- Loss to follow-up no more than 30% to T2 and no more than another 20% to T3
- Adherence to intervention is met if the majority of the expectant parents attend at least 3 out of 4 group meetings.
- Fidelity is regarded sufficient if course leaders receive an average rating of 3 in the MBI:TAC score
- What trends do we see in the data? (not do significance tests).
- Discuss if new power calculation should be done for full RCT.
- What does the qualitative data show regarding parents and midwifes experiences?

In the pilot RCT we will not carry out any interim analysis or significant tests, just report means and SD or confidence intervals. The goal is to include 50 pregnant women plus their partners/co-parents in each arm: intervention and control respectively. This may give a total

of slightly fewer than 200 participants given that some pregnant women are single. Running such large pilot is justified to shed light on the uncertainties of teacher fidelity, running groups in different sites etc.

For the future full scale RCT the following will be analyzed:

Primary outcomes:

- Change over time between groups from T1 to T2 (pre-post) in SCS-SF, and AQoL-8D.

Secondary outcomes:

- Change over time between groups from T1 to T2 (pre-post) in EPDS, FOBS, PAI.
- Are any improvements persistent to follow-up at T3 in SCS-SF, AQoL-8D and EPDS?
- At T3, is there a relation between PBQ and FÖS scores and SCS-SF, EPDS, AQoL-8D scores? Hypothesizing that the higher self-compassion and quality of life and lower depressive symptoms, the higher parental bonding and self-efficacy. A regression analysis.
- At one year postpartum use of healthcare services including obstetric variables will be assessed (register data) for a health economic evaluation.

The effect of intervention will be assessed using an intention-to-treat framework with participants analyzed according to the condition to which they were randomized, regardless of whether or not they received the intervention. Linear mixed models will be used to compare outcomes for the two conditions.

At this stage we may also want to have a sample large enough to do sub-group analysis, evaluating the intervention effect for parents with lower self-compassion and higher depressive symptoms or anxiety at baseline. Hypothesizing that effects will be larger in such sup-group since there is more room for improvement.

Sample size

A previous similar study that included 96 participants in the intervention group and 97 participants in the control group, provided sufficient power for the target group of pregnant women with an increased risk of mental illness in the EPDS outcome[1]. Based on this and taking into account that the planned study will evaluate the effect of the intervention on a universal target group (not aimed at those at increased risk), we expect a smaller effect size. Our power calculation (ANOVA: Repeated measures, within-between interaction, with f 0.1, alpha 0.05, power 0.95) gives a total sample of 260 participants (130 in each study group).

For the planned project, we want to analyze and report outcomes for pregnant women/birthing parent and for co-parents/non-birthing parents separately, which is why we

aim for a sufficiently large group also for co-parents randomized to intervention and control groups. To account for 15% lower inclusion in the co-parent group, we intend to include a larger sample of pregnant women. We also expect a 20% dropout to T2 and another 10% dropout to T3 (based on data from the above-mentioned study). This gives a sample of 208 pregnant women and about 180 co-parents in each study arm. A total of 416 pregnant women and about 360 co-parents.

Software R

1. Lönnberg G, Jonas W, Unternaehrer E, et al. Effects of a mindfulness based childbirth and parenting program on pregnant women's perceived stress and risk of perinatal depression–Results from a randomized controlled trial. *Journal of affective disorders* 2020; 262: 133-142. DOI: 10.1016/j.jad.2019.10.048.