



## A group intervention for pregnant multiparas with fear of childbirth: A protocol of a feasibility study of the MOTIVE trial

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### ABSTRACT

**Background:** Although research interest in fear of childbirth has increased, interventions targeting especially multiparas with fear of childbirth have been overlooked, although untreated fear can cause serious adverse effects on the mother and the whole family. Thus MOTIVE (Multiparas overcoming Childbirth Fear Through Intervention and Empowerment), an intervention for pregnant multiparas with fear of childbirth, was designed. **Methods:** This is a protocol of a single-arm non-randomized feasibility study of the MOTIVE trial with a mixed-methods design. The primary aim of the intervention is to assist pregnant multiparas with fear of childbirth, with the desired outcome to alleviate fear. MOTIVE consists of four group sessions (2 h each); three during pregnancy and one after giving birth and in addition of a phone call after birth. The intervention is provided by a midwife and a psychiatric nurse at the maternity hospital. Quantitative data will be gathered via self-report questionnaires at three time points, at baseline, at 4 weeks post-baseline and post-intervention. Qualitative data will be gathered by diaries, open-ended questions from post-intervention questionnaires, and individual interviews. The target is to assemble four groups of four multiparas over a 12-month period. **Discussion:** The findings will provide insights into the feasibility and acceptability of the intervention and will inform revisions to it. The results will guide the development of a definitive, larger-scale trial evaluation to further examine the efficacy of the refined intervention.

### Introduction

Childbirth is a transformative and significant event in a woman's life. While it is often anticipated with joy and excitement, for some, it can evoke feelings of fear and anxiety. Fear of childbirth (FOC) ranges from minor worries and anxieties to an intense and irrational fear of the birthing process, also known as tokophobia [1].

FOC is not uncommon, with prevalence rates in Scandinavia ranging from 8.4% to 31.1% and appearing to have increased in recent years [2,3]. FOC can have profound effects on the woman's overall well-being and may significantly impact her birth experience [4]. It may lead to decision-making dilemmas regarding the mode of delivery and increased requests for medical interventions [4]. Furthermore, FOC has been associated with negative psychological outcomes such as increased

rates of postpartum depression and impaired mother-infant bonding [5].

To effectively address and support women with FOC, it is crucial to understand the underlying factors contributing to this fear. Research suggests that FOC can stem from a variety of sources, including previous traumatic birth experiences, negative perceptions of childbirth, lack of knowledge about the process, inadequate social support, and negative experiences of healthcare [4,6]. Additionally, individual psychological factors, such as anxiety and depression, may also contribute to the development and persistence of childbirth related fear [4].

Recognizing the multifaceted nature of FOC, interventions aimed at addressing this issue have gained attention, where psychoeducation, cognitive behavioural therapy, and childbirth education classes have emerged as promising approaches for addressing the specific needs of women with FOC without any known harms [1,7–9]. Also, social

**Abbreviations:** MOTIVE, Multiparas overcoming Childbirth Fear Through Intervention and Empowerment; FOC, Fear of childbirth; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; TIDieR, Template for Intervention Description and Replication; RCT, Randomized Controlled Trial; PI, Principal Investigator; FOBS, Fear of Childbirth Scale; PRAQ-R2, Pregnancy Related Anxiety Questionnaire Revised; HADS-A, Hospital Anxiety and Depression Scale, the anxiety subscale; EPDS, Edinburgh Postnatal Depression Scale; CPS, Childbirth Perception Scale; VAS, Visual Analog Scale.

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support and relaxation techniques have showed to possibly play an important role in the efficacy of interventions [10]. Although, interventions aimed at treating fear have been developed, these have focused on addressing fear of nulliparas or women with mixed parity [1,7–9]. While nulliparous women are generally afraid of the unknown, multiparous women's fears usually stem from previous birth experiences [4]. Thus, more studies are needed to explore the treatment tailored solely for the needs of multiparas due to the different nature of their fears.

In response to this need MOTIVE (Multiparas Overcoming Childbirth Fear Through Intervention and Empowerment) was developed to offer a high-quality intervention for pregnant multiparas with FOC. This current paper describes the protocol for a single-armed non-randomized feasibility trial targeting to treat FOC in pregnant multiparas with MOTIVE. Outcomes of the feasibility trial will inform the refinement of the intervention design and the development of a powered randomized controlled trial to determine the efficacy of MOTIVE. The protocol is described in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [11,12]. The intervention is described in accordance with the Template for Intervention Description and Replication (TIDieR) guidelines [13].

### Aim

The overall aim is to evaluate and explore the feasibility and acceptability of the MOTIVE trial for multiparas with FOC.

### Design

This will be a single-arm non-randomized feasibility study. A mixed-methods approach to exploring intervention feasibility, acceptability, and initial efficacy was chosen to assure comprehensive exploration of outcomes that include the participants' perspectives. The target is to recruit 16 participants, with the sessions beginning at approximately week 32 of pregnancy and ending at 8 weeks after birth. To assess changes in fear, anxiety, and depression a repeated measures design will be conducted; at baseline, at 4 weeks post-baseline and post-intervention. In addition, interviews will be conducted post-intervention to gain insight into the experiences and opinions of the participants and interventionists regarding the intervention, for further improvement.

## Methods

### Participants and recruitment

The study will recruit pregnant women from a single maternity outpatient clinic in Finland. Eligible women will be identified by midwives providing routine ultrasound scans at weeks 20 of pregnancy. Potential participants will be assessed against the inclusion and exclusion criteria (Table 1). The planned method of birth is irrelevant, meaning women with both vaginal and caesarean section birth plans are invited to participate.

**Table 1**  
Participant inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Multiparous	Openly psychotic
Under 35 weeks of pregnancy at beginning of intervention	At risk of self-harm
18 years or older	Serious substance abuse problem
Understands Finnish	
Personal experience of fear towards the upcoming birth	
Capable of giving informed consent	

Eligible women will be informed about the ongoing study and invited to participate by the midwives. Those women who fulfil the inclusion criteria and show interest in participating in the study will receive an information leaflet describing the study in detail with contact information of the Principal Investigator (PI), an informed consent paper to fill out and a prepaid envelope. Women who are willing to participate will be advised to send the signed consent form in two weeks' time to the PI. She will then contact the participant and inform her of the group's meeting times. Women will also be informed of the study by trial posters in the maternity outpatient clinic and on social media. Thus, women may also self-identify by asking a midwife or by contacting the PI. The study will be conducted over 12 months.

### Sample size

All studies should have a sample size justification. However, not all studies need to have a sample size calculation [14]. The primary aim for this study is not to prove the efficacy of the intervention but to explore whether the study is feasible and acceptable. Hence, the sample size for this study was calculated pragmatically given the feasibility nature of the study.

The maternity outpatient clinic receives an average of 30 multiparous women coming in for their 20-week ultrasound scan each month, this is equivalent to 360 multiparas over the proposed 12-month recruitment period. It is anticipated that ~15 % of these multiparous women will fulfil the inclusion criteria, meaning that 54 women will be eligible for this study. A previous recruitment of a similar type of intervention for women with FOC suggests that around 30 % of women will volunteer [15], calculating a sample size of  $n = 16$ . This sample size was discussed with a statistician to be satisfactory.

### The MOTIVE intervention

The overall approach of the entire study from design to the trial phases is guided by the United Kingdom Medical Research Council framework for developing and evaluating complex interventions [16]. MOTIVE is theoretically based on socio-constructivism, which posits that knowledge is constructed through interaction with others via reflective thinking, problem-solving, collaborative learning, and discussion [17,18]. The contents of the intervention's sessions were designed based on previous research [1,7,8] and on qualitative enquiry where pregnant multiparous women were asked about their experiences of treatment for FOC [19] and in turn what kind of care and support they would have wished for from professionals for their FOC [20]. The intervention was developed primarily by the PI, who is a midwife, but also by consulting experienced researchers and midwives in the field of maternity care.

Study interventionists are two licensed clinicians (a midwife and a psychiatrist nurse). The midwife works at a maternity hospital in a birthing unit. In addition, she offers counselling for FOC at an outpatient clinic. The psychiatrist nurse works with pregnant and postpartum women and has additional training in the spectrum of traumatization during pregnancy and infancy. She has also completed Theraplay-training, which is an application of attachment theory to clinical work. Both interventionists have previous experience of delivering interventions for nulliparas with FOC. The interventionists participated in a 4-hour foundational training held by the PI where the contents and methods of the intervention were discussed.

The intervention consists of four group sessions each lasting two hours. The intervention is held in a birthing hospital. Four to eight participants are taken into each group. The first group session is held at pregnancy week 32 (+3 weeks), the second and third with an interval of two weeks and the last session is four to eight weeks after giving birth. Each session contains certain core contents, but the informative content is structured according to the needs of the group. Mindfulness exercises are incorporated into each session. Participants are treated as active

learners through individual and group work during session, as well as incorporating homework between sessions (Table 2).

### Outcomes

Primary outcome measures address feasibility and acceptability of the intervention.

1. Recruitment will be deemed feasible if the target of 16 eligible women is met within the study period.
2. Adherence will be assessed by determining the number and percentage of participants who complete all the 4 sessions and all three questionnaires, and in addition participate in the interviews. A retention of 80 % of the sample (at least 13 participants) will be considered acceptable.
3. Acceptability of the design, intervention contents and delivery will be assessed through the post-intervention questionnaire and interviews with participants and interventionists.
4. Fidelity of the intervention sessions will be assessed through the diaries held by the interventionists.

Secondary outcome measures include assessing initial efficacy of the intervention. Individual scores on the secondary data measures (fear of childbirth, anxiety, and depression) will be plotted graphically, and visual analysis will be used to assess change across timepoints. Clinical outcomes in this study will only provide preliminary supporting data (Table 3).

### Data collection

Given the challenges associated with evaluating this type of intervention and effectively measuring these complex clinical outcomes, a mixed-methods approach is used. Both quantitative and qualitative data are gathered with questionnaires, records, diaries, and interviews.

### Questionnaires

The questionnaires were developed by the research team by going through previous research questionnaires related to interventions, pregnancy, childbirth and FOC. To assess the clinical outcomes, several possible scales were evaluated based on validity in the population at hand, length of the scale, and whether the scale had been previously translated into Finnish language. Finally, the scales were chosen which were appraised to be most appropriate for this study. The questionnaires

**Table 2**

Overview of the intervention sessions in the MOTIVE intervention for FOC.

Timepoint	Goals	Content	Homework
T1 at 32 weeks of pregnancy	Grouping, understanding, and accepting FOC, strengthening the bond with the baby, learning active means to cope with FOC.	Psychoeducation concerning pregnancy, fear, anxiety, and depression in general and FOC especially, attachment to baby, awareness exercise.	Exercises and reflection to deepen attachment to baby. Thinking about own needs with partner for the next session.
T2 at 34 weeks of pregnancy	Learning about the physiology of birth, different adverse events, ways to cope with pain (both non-medical and medical) and creating a confidence for own individual birth in hospital by familiarizing with hospital premises and practices.	Birthing class with interactive components (e.g., trying different pain relief strategies, birthing positions for first and second stages of labour). Support person or partner welcomed to participate. Relaxation exercise. Second half of the session is held in the birthing room with a participatory approach.	Breathing exercises and picking own birth mantras. Writing own wishes for birth (a letter to the midwife).
T3 at 36 weeks of pregnancy	Learning new and reinforcing what has already been learnt, orientation towards time after birth, strengthening confidence for upcoming birth.	Role of relaxation and breathing during birth, hormones, control, and postpartum period, imagery exercise of upcoming birth.	Continuing with breathing and relaxation exercises.
After Birth	Enabling the participant to go through the birth experience and feelings after birth with a familiar professional.	Psychiatric nurse calls the participant to talk about her birth. Some guiding questions are provided for the professional, but the call is woman centred.	
T4 at 4–8 weeks after birth	Peer support, getting practical guidance to cope with everyday life, detection of adverse symptoms (trauma, postpartum depression).	Psychoeducation about subjective birth experience, discussing own means to recover physically and mentally from childbirth, and ways of strengthening own coping in everyday life (exercise, own time, diet, sleep).	

**Table 3**  
Study outcome measures.

Outcome measures	
Recruitment outcomes	Proportion of women meeting eligibility criteria Proportion of eligible women consenting to participate in the study
Adherence outcomes	Proportion of participants taking part in all four intervention sessions and answering call after birth Proportion of participants not contributing to data due to premature delivery or drop-out
Acceptability	Acceptance of the design, intervention contents and delivery
Fidelity	Fidelity of the intervention sessions' contents
Clinical outcomes	Changes in fear, anxiety, and depression Childbirth experience

were pilot tested on four women (data not included in the analysis). Small revisions were made based on the feedback from the women.

Data are collected using questionnaires at three measurement points: at baseline (T1), at 4 weeks post-baseline (T3), and post-intervention (T4) (Table 4). The questionnaires are self-administered 20–30-minute hard copy questionnaires. They are handed out during the intervention sessions for participants to fill in. The questionnaires contain questions on sociodemographic characteristics, medical information (concerning mental health, pregnancy, and birth), contents of FOC, previous experiences of health care, and clinical outcomes.

The clinical outcomes are measured with well-validated self-report measures (reliability in parentheses): The Fear of Birth Scale (FOBS) [21] measures fear of childbirth (Cronbach's  $\alpha$  0.91), The Pregnancy Related Anxiety Questionnaire Revised (PRAQ-R2) [22] measures birth-related and childhood outcomes independent of general anxiety (Cronbach's  $\alpha$  0.85), Hospital Anxiety and Depression Scale with only anxiety subscale used (HADS-A) [23] measures anxiety (Cronbach's  $\alpha$  0.89–0.93), Edinburgh Postnatal Depression Scale (EPDS) [24] measures pre- and postnatal depression (Cronbach's  $\alpha$  0.87), The Childbirth Perception Scale (CPS) [25] (Cronbach's  $\alpha$  0.82) and Visual Analog Scale (VAS) [26,27] measure childbirth experience.

Acceptance concerning the intervention will be asked in the post-intervention questionnaire with Likert-scales and open-ended questions. Questions concerning acceptance include participants' experiences of various components (e.g., contents of sessions, materials, activities, interventionist, location, mode of delivery, duration, and number of sessions).

**Table 4**  
Data collection points and outcomes.

	Screening (T0)	Baseline at intervention session 1 (T1)	Intervention session 2 (T2)	Intervention session 3 (T3)	After intervention session 4 (T4)	8–12 weeks after birth (T5)
Recruitment rates	x					
Informed consent	x					
Adherence		x	x	x	x	x
Sociodemographic variables		x				
Medical information		x		x	x	
Clinical outcomes: FOBS		x		x	x	
PRAQ-R2		x		x		
HADS-A		x		x	x	
EPDS		x		x	x	
CPS				x	x	
VAS					x	
Acceptance					x	x
Fidelity		x	x	x	x	

**FOBS** = Fear of Childbirth Scale; **PRAQ-R2** = Pregnancy Related Anxiety Questionnaire Revised; **HADS-A** = Hospital Anxiety and Depression Scale, the anxiety subscale; **EPDS** = Edinburgh Postnatal Depression Scale; **CPS** = Childbirth Perception Scale; **VAS** = Visual Analog Scale.

### Records and diaries

Recruitment rates will be monitored using the number of women told about MOTIVE, those eligible to receive the intervention, and those who are subsequently recruited. Midwives recruiting women at the ultrasound scans will keep records which will be used to evaluate recruitment outcomes. The PI will also keep records of women who self-recruit through posters at the outpatient clinic or social media advertisements.

Adherence to the MOTIVE intervention will be monitored by diaries filled out by the interventionists. The number of participants taking part for each session will be recorded by the interventionists. In addition, the post-intervention questionnaire contains questions regarding adherence to the sessions and the phone call.

Intervention fidelity is assessed from the diaries that the interventionists fill out after each group session. They are asked to write down their observations about the group dynamic, if something surprising happened and did everything go as planned, and if not, why.

### Interviews

In addition to the questionnaires, qualitative research methodology was chosen to allow sensitive topics and participants and interventionists' perceptions to be explored in depth without the constraints of predetermined or closed questioning. Interviews will be used to assess acceptability and identify areas for modification and improvement for MOTIVE together with the data from the post-intervention questionnaire.

Semi-structured interviews are conducted 8–12 weeks after birth with the participants and with the interventionists after the completion of the trial. All interviews are conducted by the PI to allow for consistency in the style and technique of the interviews. Interviews are audio-recorded. The interview targets domains of acceptance, satisfaction, and feasibility of the intervention as a whole. Participants and interventionists will be asked to talk about their views and experiences of MOTIVE according to the TiDieR template including satisfaction with content, mode of delivery, location, duration, possible suggestions for modifications, and facilitators and barriers to acceptability and implementation.

### Data analysis

Primary outcomes are related to feasibility and acceptability metrics, which will involve descriptive data on the proportion of women meeting eligibility criteria, participating in the study, participating in all four sessions, answering call after birth, and proportion of women not contributing to data, as well as a qualitative review of participants' and

interventionists' reports of acceptance and satisfaction with the intervention as a whole and with specific components.

The demographic and medical data collected will describe some of the characteristics of this sample of participants. This data will be analysed using the descriptive and frequency functions in IBM SPSS software.

Secondary analysis will involve data pertaining to clinical outcomes. Individual scores on the secondary data measures will be plotted graphically, and visual analysis will be used to assess change across the three timepoints (baseline, 4 weeks post-baseline and post-intervention). Because of the feasibility nature of this study, it will not be powered to accurately interpret results from statistical modelling, thus relying on visual analysis and simple descriptive statistics to inform decisions regarding signals of efficacy to support a larger-scale trial.

Audiotape recordings for each interview will be transcribed verbatim and double-checked to ensure the accuracy of transcription. To explore and interpret the data from the semi-structured interviews in addition to the open-ended questions from the post-intervention questionnaire concerning acceptability, satisfaction and feasibility, thematic analysis will be used [28,29]. Transcripts will be sorted, coded, and categorized accordingly to facilitate thematic analysis, aligning codes, subthemes, and themes against the TiDieR guidelines to help ensure completeness of inquiry and understanding of the relevant factors of the intervention. The qualitative data and the quantitative data concerning acceptance will be analysed with a mixed methods approach in a meta-matrix [30].

### Discussion

Fear of childbirth has increased during the recent decades, but interventions for treating fear have concentrated on nulliparous women's fear. Hence, MOTIVE was designed to meet the needs of multiparous women suffering from FOC. MOTIVE is a group intervention tailored for pregnant multiparas with FOC. This intervention brings together multiparas who share similar concerns and provides a safe and nurturing environment for sharing experiences, receiving information, and developing coping strategies to alleviate fear and enhance their sense of control and confidence during childbirth.

This is a feasibility study, which will likely be used to inform revisions to the current intervention and a larger-scale evaluation to further examine the efficacy of MOTIVE. If the results of this feasibility study are favourable, a larger-scale Randomised Control Trial (RCT) should be conducted to determine the efficacy of the revised intervention.

### Ethical considerations

The purpose of this study and the expected level of involvement will be explained to prospective eligible study participants. Potential participants will be reminded by the recruiting midwives that their participation in the study is voluntary, that participation will not affect their normal care pathways, and that they can discontinue with MOTIVE at any time. All personal information about enrolled participants will be handled confidentially by the research team. A data management plan has been written to ensure safe collection and maintenance of data during and after the trial.

Written consent will be sought from individuals who agree to participate in the study. Each participant will retain a signed copy of the consent form containing the PI's contact details if they have further queries.

Ethical approval was granted on 14 of February 2023 by Pirha Regional Research Ethics Committee and study approval was gained by Kanta-Häme Central Hospital. The study is registered on [clinicaltrials.gov](https://clinicaltrials.gov) (NCT05766202).

**Trial and Protocol Registration:** [Clinicaltrials.gov](https://clinicaltrials.gov): NCT05766202.

### Ethical approval

Pirkanmaan hyvinvointialueen alueellinen lääketieteellinen tutkimuseettinen toimikunta, R22124H/14.2.2023.

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### Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used ChatGPT to improve readability of the background section. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

### CRediT authorship contribution statement

**Laura Sandström:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Marja Kaunonen:** Conceptualization, Funding acquisition, Methodology, Resources, Software, Supervision, Validation, Writing – review & editing. **Anna Liisa Aho:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Software, Supervision, Validation, Writing – review & editing.

### Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: This work was supported by a PhD studentship provided by Tampere University, and grants from the Finnish Federation of Midwives and the Finnish Cultural Foundation.

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