ISRCTN14694502 https://doi.org/10.1186/ISRCTN14694502

Professional support with soft tissue massage during pregnancy

Submission date
02/05/2024

Recruitment status
Recruiting

Registration date
12/05/2024

Overall study status
Ongoing

Last Edited
31/12/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Massage during pregnancy and labor has long been demonstrated to be beneficial to women. From the massage, feelings of depression, anxiety and stress decrease. Further, massage during pregnancy could reduce women's pain or, more specifically, back and leg pain, as well as women' s cortisol levels and risk of premature birth. Massage that is included in the professional support seems to be meaningful to women's feelings of being able to handle the challenges that come with pregnancy and birth. The overarching aim of the prospective study is to explore professional support in the form of soft tissue massage to facilitate parents' health and well-being during pregnancy, labour, and postpartum. The secondary aims address multiple aspects of soft tissue massage interventions for parents during and after childbirth. The first part focuses on understanding parents' expectations of educational interventions in soft tissue massage and their experiences with professional support post-birth. Part two explores the significance of soft tissue massage for parents throughout pregnancy, labor, birth, and the postpartum period, exploring their usage patterns. Part three examines parents' use of soft tissue massage during labor and birthing. Finally, part four investigates the correlation between parents' Sense of Coherence (SOC) and their well-being during pregnancy and six months post-birth concerning educational interventions with professional support in soft tissue massage.

Who can participate?
Expectant mother with their partner or support person/doula, aged 18 years and over following a normal pregnancy and planned vaginal birth at the county hospital

What does the study involve?
Parents are offered to participate in the study and receive the educational intervention of professional support with soft tissue massage from gestational week 37+0.

What are the possible benefits and risks of participating?
Verbal and written consent is obtained before the educational intervention and data collection begins. Participants will be able to indicate on the consent form which substudies they choose to participate in.

Research projects are a complement to the existing care offered today to the future. Parents, where the partner is made more involved during pregnancy, childbirth and the time afterwards. The pregnant women who participate will receive the usual basic program during pregnancy at the midwifery clinic and usual care during childbirth.

The educational intervention can strengthen the expectant parents as a couple. They will spend time in contact with each other during training, give each other massages, prepare for the baby's arrival and get extra professional support during the research project.

The risks associated with participation in the project are considered to be small compared with the benefits that the research will bring. To minimize the risks in the research project, researchers and resource persons are used with the required knowledge and competence. The project's trained touch therapists have long experience in training people and giving soft massage to both healthy and sick people. Soft tissue massages are always given on the participants' terms and participants will be instructed to always ask each other for permission to give one partner a soft massage. Participants' privacy is thus respected. The touch therapists will not provide soft tissue massage to the participants. Previous research on professional support from a salutogenic perspective has shown positive results and effects on parents' health and well-being. To minimize risk for participants, exclusion criteria have been designed

Where is the study run from?
The study is being conducted in a southwest county of Sweden. The areas are both rural and suburban hence representative of the ordinary Swedish population. There are 15 antenatal clinics in the setting and the labor ward at the county´s only hospital has about 2700 childbirths annually, and one ultrasound clinic.

When is the study starting and how long is it expected to run for?
September 2023 to December 2026

Who is funding the study?
1. Region Västra Götaland, Hospital Skövde, Department of FoUUI, [Skövde], Sweden
2. Region Västra Götaland, Skaraborgs Hospital Skövde, Sweden
3. Region Västra Götaland, FoU-counsil Skaraborg, Regional Health, Sweden
4. Skaraborgsinstitutet (the Skaraborg Institute for Research and Development), Skövde, Sweden

Who is the main contact?
PhD student Amanda Claesson Karhunen, amanda.claesson@vgregion.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Amanda Claesson Karhunen

ORCID ID
https://orcid.org/0000-0001-7098-7398

Contact details

(PhD Student) Lövängsvägen
Skövde
Sweden
54949
+46 765802632
amanda.claesson@vgregion.se

Additional identifiers

Protocol serial number
281 728

Study information

Scientific Title
Professional support in the form of soft tissue massage for first-time parents during pregnancy and parental transition for parents' health and well-being

Study objectives
The overall aim of the prospective study is to explore professional support in the form of soft tissue massage to facilitate parents' health and well-being during pregnancy, labor and birth, and postpartum. The secondary aims are to explore the following:
1. Parents' expectations of educational intervention in soft tissue massage and their experiences with professional support in the form of soft tissue massage after birth
2. The meaning of soft massage and parents' use of soft tissue massage during pregnancy, labor and birth, and postpartum
3. Parents' use of soft tissue massage during labor and birth
4. Parents' Sense of coherence (SOC) and well-being during pregnancy and six months after birth to the educational intervention with professional support in soft tissue massage

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 03/04/2024, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 0104750800; registrator@etikprovning.se), ref: 2024-01280-01

2. Approved 22/11/2024, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: 2024-06990-02

3. Approved 28/09/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: 2025-06015-02

Primary study design
Interventional

Study design
Prospective longitudinal non-randomized study using both quantitative and qualitative methods

Study type(s)
Other

Health condition(s) or problem(s) studied
Professional support with soft tissue massage, an educational intervention for parents during pregnancy

Interventions
Participants in the study will receive an educational intervention of professional support with soft tissue massage from full-term pregnancy, gestational week 37+0.

The educational intervention will be introduced at full term (gestational week 37) to couples expecting their first child. A total of 25-30 parental couples will be included and divided into groups of five couples/group and training session. The groups will involve participants in approximately the same gestational week who will be followed in the four training sessions offered. A midwife and touch therapist with certifications in soft tissue massage with extended experience of professional support to couples during pregnancy will be responsible for the educational intervention together with a registered nurse, associated professor, and touch therapist with certifications in soft tissue massage.

The first session, in gestational week 37, begins with the two touch therapists (midwife and specialist nurse) providing background information about the research project and previous research studies on soft tissue massage. Information is also provided on how participants will be trained in soft tissue massage techniques for use during pregnancy, childbirth, and the postpartum period. Following the theoretical overview, a practical demonstration of back /lumbar massage is conducted, where participants within the parental couple are introduced to giving each other soft tissue massages under the guidance and support of the touch therapists. The touch therapists will not be massaging the participants themselves but rather supporting and guiding them on the techniques. After the first session, participants are encouraged to continue practicing giving each other back/lumbar massages for a minimum of 15-20 minutes per day until the second training session.

The second session is conducted in gestational week 38 and begins with a reflection group session (five parental couples), led by touch therapists ECand. The touch therapists support the participants in conversation and reflection on their experiences of using soft tissue massage at home. This is followed by a practical overview of the goals for the second session, focusing on hand and foot massage techniques to be introduced and practiced. This session will also include a practical demonstration of soft tissue massage during labor and birth. The parental couples will be encouraged to provide soft tissue massage at home when labor contractions begin, with a particular focus on supporting the partner in providing soft tissue massage to the pregnant woman during the onset of labor contractions. The touch therapists will strive to empower each parental couple, supporting them to feel that soft tissue massage can serve as a tool to support the woman before, during, and after the impending birth.

The third session is conducted via a digital meeting (approximately 1 hour) around one week after the second session. If any of the five parental couples in the same group have given birth, they will be divided into Group 1 - participants who have given birth, and Group 2 - participants who have not given birth. This grouping is done to prevent the influence of those who have given birth on those who have not during the third session. This session begins with the touch

therapists encouraging participants to share their experiences and reflections on using soft tissue massage. Furthermore, the touch therapists will motivate and support participants to continue using soft tissue massage before, during and after labor and birth.

Before the fourth and final digital sessions, participants will be asked to watch a recorded informational video created by the touch therapists. The informational video covers “What happens in the body after childbirth?” and “How can parenting couples utilize soft tissue massage after childbirth?”.

The fourth session will be conducted via a digital meeting and is planned to last approximately 1-2 hours. The purpose of this session is to support participants and provide guidance on continuing to use soft tissue massage. This is the final occasion when participants and touch therapists meet in person during the educational intervention. Participants are encouraged to continue practicing back/lumbar, hand, and foot massages for at least 15-20 minutes per day until birth.

Data collection will be conducted through semi-structured interviews, written individual narratives, non-participatory observations, and repeated surveys.

Intervention Type
Behavioural

Primary outcome(s)
Parents’ health and well-being will be measured using data collection from semi-structured interviews before the first session, and within two weeks after birth; written individual narratives from gestational week 37 until four weeks after birth; non-participatory observations during labor and birth, and repeated surveys (including Swedish versions of the World Health Organisation- Five Well-Being Index [WHO-5]) at gestational week 25 (baseline), within two weeks and six months after birth.

Key secondary outcome(s)
The following secondary outcome measures will be measured using data collection from semi-structured interviews before the first session, and within two weeks after birth; written individual narratives from gestational week 37 until four weeks after birth; non-participatory observations during labor and birth, and repeated surveys at gestational week 25 (baseline), within two weeks and six months after birth:
1. Parents’ expectations of educational intervention in soft tissue massage and their experiences with professional support in the form of soft tissue massage after birth
2. The meaning of soft massage and parents’ use of soft tissue massage during pregnancy, labor and birth, and postpartum
3. Parents’ use of soft tissue massage during labor and birth
4. Parents’ Sense of coherence (SOC) and well-being measured using the Swedish versions of the Sense Of Coherence Scale-13 (SOC-13) during pregnancy and six months after birth

Completion date
31/12/2028

Eligibility

Key inclusion criteria

Current inclusion criteria as of 31/12/2025:
1. Age ≥ 18 years
2. Expectant mother with partner or support person/doula
3. Normal pregnancy and planned vaginal birth at the county hospital
4. Swedish- or English speaking

Previous inclusion criteria:
1. Age ≥ 18 years
2. Expectant first-time mother with partner
3. Normal pregnancy and planned vaginal birth at the county hospital
4. Swedish- or English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 31/12/2025:
1. Severe infection or skin conditions and diseases that make it inappropriate to touch the skin
2. Research subjects whose judgement is compromised due to illness, mental health issues such as psychosis or similar conditions, or debilitated health conditions
3. Situations where informed consent cannot be obtained

Previous exclusion criteria:
1. Multiple pregnancy
2. Severe infection or skin conditions and diseases that make it inappropriate to touch the skin
3. Research subjects whose judgement is compromised due to illness, mental health issues such as psychosis or similar conditions, or debilitated health conditions
4. Situations where informed consent cannot be obtained

Date of first enrolment
20/05/2024

Date of final enrolment

31/12/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Västra Götalandsregionen (VGR), Skaraborgs Hospital Skövde (SkaS)
Lövängsvägen
Skövde
Sweden
54949

Sponsor information

Organisation
Region Västra Götaland

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Government

Funder Name
Västra Götalandsregionen

Alternative Name(s)
Region Västra Götaland, Västra Götaland Regional Council, Västra Götaland region, Västra Götalandsregiona, VGR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Skaraborg Institute

Alternative Name(s)
Skaraborgsinstitutet

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available