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Testing an internet intervention for preventing and reducing perinatal depressive symptoms and promoting subjective well-being

Submission date
02/06/2021

Recruitment status
No longer recruiting

Registration date
04/06/2021

Overall study status
Completed

Last Edited
14/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Every year 60,000 women give birth in Norway, of whom about 10-15% develop moderate to severe depressive symptoms during pregnancy and/or after birth, called perinatal depression (PND). Although not all women with perinatal depression meet the DSM-IV criteria for depression, the negative consequences of PND can be quite severe for the woman, her child, and her partner. A very low proportion of depressed women are identified and offered help. Despite the high prevalence, perinatal depression is often undetected and untreated. Interactive internet-based interventions can provide a rich, stimulating, engaging and actively supportive environment, and they have been found to be effective in treating depression, anxiety, phobias and diabetes. Mamma Mia is a universal preventive internet-based program for perinatal depression and a recent study demonstrated its effectiveness. Interviews with users showed that women wanted Mamma Mia to be integrated into ordinary care. Moreover, internet-based programs, guided by persons with lived experience or health personnel, have shown promising results for depression, with effects equivalent to those of face-to-face treatment. Consequently, clinical and implementation guidelines were designed for a blended care model (Mamma Mia with guidance) that includes up to five contact points with practitioners in well-baby clinics. Hence, the overall aim of this study is to test the effectiveness, cost-effectiveness, and implementation of Mamma Mia with guidance compared to unguided Mamma Mia in a primary care setting, on perinatal depressive symptoms.

Who can participate?
All pregnant women aged over 18 years old who are not beyond gestational week 26

What does the study involve?
All municipalities will be randomly assigned to either blended care or unguided Mamma Mia. Participants allocated to the blended-care intervention will receive Mamma Mia in combination with face-to-face guidance from midwives and public health nurses. Participants allocated to the unguided-intervention group will receive Mamma Mia in addition to care as usual. Mamma Mia begins in gestational week 21-26 and lasts up to 6 months after childbirth with varying intensity and frequency during the intervention period. All participants will answer internet-based surveys

at the start and during gestational week 37 prenatally, and 1 ½, 3, 6, and 12 months after giving birth.

What are the potential benefits and risks of participating?
It is expected that pregnant/postpartum women in both groups will benefit from participating in the study. The effectiveness of unguided Mamma Mia has already been demonstrated, and guided internet interventions typically have greater effects compared to face-to-face treatment. Women in both groups should experience lower depressive symptoms, increased subjective well-being and an increased sense of available social support compared with regular follow-up. Expected benefits for midwives and public health nurses include the knowledge and competence to implement an evidence-based internet intervention to prevent perinatal depression, as well as expertise in guiding pregnant and postpartum women in how to use Mamma Mia.
As midwives will inform and recruit pregnant women to participate in the study, there is an increased risk that the women may experience pressure to participate in the study, and therefore the researchers have emphasized volunteering in the information letter, and made it easy for a participant to withdraw consent if she changes her mind. A possible disadvantage is the time it will take to fill out questionnaires and possibly the time it will take to take part in an interview. On the basis of previously completed and published studies, no other significant risks or disadvantages are expected for the participants in the study.

Where is the study run from?
Regional center for child and adolescent mental health, eastern and southern Norway (Norway)

When is the study starting and how long is it expected to run for?
October 2018 to March 2026

Who is funding the study?
Research Council of Norway (Norway)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
RCN Project Number: 295944

Study information

Scientific Title
Mamma Mia - an internet intervention for preventing and reducing perinatal depressive symptoms: a multi-site cluster-randomized trial

Acronym
MaMi

Study objectives
Current study objectives as of 28/10/2025:

The main study hypotheses:
1.1. Participants in the blended-care intervention group will obtain lower scores on measures of depressive symptoms compared to participants in the unguided intervention group over time.
1.2. Prevalence of participants in the blended-care intervention group with a probable minor depression will be lower as compared to the unguided intervention group at each point of measurement.
2. Participants in the blended care intervention group will obtain higher levels of subjective well-being, as indicated by higher life satisfaction and positive affect, and lower negative affect compared to the participants in the unguided intervention over time.
3. Participants in the blended-care intervention group will obtain lower scores on measures of anxiety symptoms compared to participants in the unguided intervention group over time.
4. Participants in the Mamma Mia-with-guidance-group (blended intervention) will obtain a

higher health-related quality of life score and an associated Quality Adjusted Life Years gain compared to the unguided intervention group.
5. The Mamma Mia blended intervention cost is higher per participant than in the unguided intervention group.
6. The Mamma Mia blended intervention is cost-effective compared to the unguided intervention; that is, the incremental cost-effectiveness ratio (ICER) is below the threshold for willingness to pay for an extra QALY within a Norwegian context.
7.1. Participants in the blended intervention will have increased program uptake and use compared to participants in the unguided intervention.
7.2. Program uptake and use in the blended intervention group will be independent of predictors, such as education and depressive symptoms, compared to the unguided intervention.
8.1. Women in the blended intervention will have higher (more positive) scores on implementation outcomes, such as working alliance, acceptability, and relative advantage, compared to women in the unguided intervention.
8.2. Health personnel in the blended intervention will have higher (more positive) scores on implementation outcomes, such as acceptability, feasibility, and relative advantage, compared to the unguided intervention.

Additional study aims:
9. To explore whether the effects of the two groups are (a) moderated by contextual variables such as baseline symptomatology, parity, education, and child temperament, and (b) mediated by variables such as social support, working alliance, and program use.
10. To explore whether uptake, use, adherence, and implementation outcomes are a) moderated by contextual factors such as organizational culture and health personnel's attitudes to evidence-based practice, and b) mediated by variables such as leadership engagement, available resources, and implementation climate.

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Previous study objectives:

The main study hypotheses:
1.1. Participants in the blended-care intervention group will obtain lower scores on measures of depressive symptoms compared to participants in the unguided intervention group over time.
1.2. Prevalence of participants in the blended-care intervention group with a probable minor depression will be lower as compared to the unguided intervention group at each point of measurement.
2. Participants in the blended care intervention group will obtain higher levels of subjective well-being, as indicated by higher life satisfaction and positive affect, and lower negative affect compared to the participants in the unguided intervention over time.
3. Participants in the blended-care intervention group will obtain lower scores on measures of anxiety symptoms compared to participants in the unguided intervention group over time.
4. Participants in the Mamma Mia-with-guidance-group (blended intervention) will obtain a higher health-related quality of life score and an associated Quality Adjusted Life Years gain compared to the unguided intervention group.
5. The Mamma Mia blended intervention cost is higher per participant than in the unguided intervention group.
6. The Mamma Mia blended intervention is cost-effective compared to the unguided intervention; that is the incremental cost-effectiveness ratio (ICER) is below the threshold for willingness to pay for an extra QALY within a Norwegian context.
7.1. Participants in the blended intervention will have increased program uptake, use and adherence compared to participants in the unguided intervention.

7.2. Uptake, use and adherence in the blended intervention group will be independent of predictors, such as education and depressive symptoms, compared to the unguided intervention.
8.1. Women in the blended intervention will have higher (more positive) scores on implementation outcomes, such as working alliance, acceptability, and relative advantage, compared to women in the unguided intervention.
8.2. Health personnel in the blended intervention will have higher (more positive) scores on implementation outcomes, such as acceptability, feasibility, relative advantage, compared to the unguided intervention.

Additional study aims:
9. To explore whether the effects of the two groups are (a) moderated by contextual variables such as baseline symptomatology, parity, education, and child temperament and (b) mediated by variables such as emotion regulation, breastfeeding self-efficacy and social support.
10. To explore whether uptake, use, adherence, and implementation outcomes are a) moderated by contextual factors such as organizational culture and health personnel's attitudes to evidence-based practice, and b) mediated by variables such as leadership engagement, available resources, and implementation climate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2020, Regional Committees for Medical and Health Research Ethics south and east C (Gullhaugveien 1-3, 0484 Oslo, Norway, +47 (0)22 84 55 11; rek-sorost@medisin.uio.no), ref: 112830

Primary study design
Interventional

Study design
Multi-site two-armed cluster-randomized hybrid trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Perinatal depressive symptoms and subjective well-being

Interventions
Current interventions as of 14/11/2025:

The overall aim of the current project is to test the effectiveness, cost-effectiveness, and implementation of Mamma Mia with guidance compared to unguided Mamma Mia and usual care. As the effectiveness of unguided Mamma Mia compared to usual care has already been evaluated in an existing trial, the study will be a two-armed cluster-randomized hybrid trial.

On January 1st, 2020, several Norwegian municipalities were merged as part of a nationwide reform aimed at enhancing administrative efficiency and public services. As a result, 119 municipalities were merged to 47, several of which were included in our study. This restructuring also led to the consolidation of various municipal services, including well-baby clinics. Fortunately, randomization had not yet commenced when the reform was announced. To

preserve the integrity of the study design, we changed the randomization unit from clinic to municipality. Had we proceeded with clinic-level randomization as originally planned, there was a risk that clinics in the control group could be merged with those in the intervention group.

In the original power estimation, we discovered other errors, which are corrected in the in the following text:
Using Optimal Design v3.01, 24 municipalities will be randomized to either Mamma Mia or Mamma Mia with guidance. It is based on a cluster size of 24 women per municipality which gives ≥80% probability to detect a standardized effect size of 0.50. The prerequisites are based on an intra-cluster correlation coefficient of 0.01, as observed in previous cluster studies on pregnancy and postpartum depression, five measurements (from baseline to 6 months), an alpha level of 5% and 24 municipalities at the outset. The estimated number of women will therefore be 576. Adjusted for a dropout rate of 37% as observed in the first Mamma Mia study, the total sample size is 913 participants with a 1: 1 distribution of participants between the groups.

Methods and procedures:
Municipalities will be randomly allocated to the two treatment groups. Pregnant women will be recruited prior to gestational week (GW) 26 during routine, using an online registration form. Surveys will be completed electronically at baseline; GW 21-26, GW 37, 1.5, 3, 6 and 12 months postpartum. Automatically generated log data will also be collected throughout the Mamma Mia program to assess program use and drop-out. Information on health care service utilization will be collected through electronic registers. Midwives and public health nurses in well-baby clinics will deliver Mamma Mia in combination with f-2-f guidance (i.e., the blended model). A heterogenous sample of women will be interviewed to explore their experiences with Mamma Mia with guidance from well-baby clinics and unguided Mamma Mia. Interviews will be audio-recorded and transcribed for subsequent analyses. The researchers will also collect organizational data for each well-baby clinic to assess the implementation (e.g., number of annual births, man-hours, participants recruited for Mamma Mia). Furthermore, from health personnel within each clinic, demographics, individual/organizational readiness, barriers, and facilitators will also be collected. Adherence checklists based on the clinical guidelines will be used to assess fidelity. An in-depth understanding of the implementation process in well-baby clinics will be explored in focus group interviews before and after the implementation of Mamma Mia.

Mixed models and/or structural equation modelling will be applied, as appropriate, to test the effects of Mamma Mia on primary and secondary aims. Qualitative data, both on maternal experiences with Mamma Mia (both unguided and the blended care model) and on the delivery of Mamma Mia among clinical staff, will be coded and analyzed using thematic or related analytic approaches (e.g., template analysis), as appropriate. A comparative method will be used for before-and-after focus group interviews with clinical staff to understand behaviors and meanings that clinical staff give to their experiences of the implementation process and delivery of Mamma Mia to women. An economic evaluation will be based on a comparison of costs and effects as measured by the main outcome measures, EQ-5D-5L in particular. Costs include direct costs associated with Mamma Mia blended (intervention costs), as well as costs related to hospital as well as secondary care services. Data on service utilization will be obtained from questionnaires, alternatively hospital and municipal registers, respectively. Intervention costs (Mamma Mia with and without guidance) will be calculated in detail.

Municipalities will be randomly allocated (1:1) to the two treatment groups: unguided or blended care model of Mamma Mia.

The treatment groups
1. Unguided Mamma Mia: participants in this group will use Mamma Mia (which is an app) without any form of guidance. Mamma Mia consists of 44 sessions over a period of 10 1/2 months, starting mid-pregnancy until the baby is 6 months old. Users of the Mamma Mia program progress through the intervention in a predetermined sequence of modules. The intervention schedule varies over the intervention period. However, in the prenatal phase, Mamma Mia has mostly one session per week. In the postnatal phase, the frequency and intensity of the intervention increase to three sessions per week before declining to one session per week in the follow-up phase. The main components in the "Mamma Mia" intervention include (a) assessment of depressive symptoms, (b) meta-cognitive therapy, (c) positive psychology, (d) relationship satisfaction, and (e) useful information for the parents (e.g. breastfeeding, baby's sleeping patterns, infant development, etc).
2. Blended care model: participants in this group will receive Mamma Mia (as described above) in combination with face-to-face guidance from midwives and public health nurses. Guidance will be offered as part of the regular consultations (2-3 times during pregnancy, and 2 times postpartum). Midwives and public health nurses will follow guidelines for the clinical work and for the implementation of Mamma Mia. The guidelines are based on the efficiency model of support, including techniques from motivational interviewing, Cognitive Behavioral Therapy (specifically, the ABC-model) and solution-focused therapy.

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Previous interventions as of 28/10/2025:

The overall aim of the current project is to test the effectiveness, cost-effectiveness, and implementation of Mamma Mia with guidance compared to unguided Mamma Mia and usual care. As the effectiveness of unguided Mamma Mia compared to usual care has already been evaluated in an existing trial, the study will be a two-armed cluster-randomized hybrid trial.

Using Optimal Design v3.01, min. 14 and max. 24 well-baby clinics will be randomized to either Mamma Mia or Mamma Mia with guidance. To ensure implementation, the researchers calculate a min/max 3/5 midwives/public health nurses per child health clinic. It is based on a cluster size of 15 women per health center. It gives ≥80% probability to detect a standardized effect size of 0.50 which corresponds to an average group difference divided by the standard deviation for the outcome measure. The prerequisites are based on an intra-cluster correlation coefficient of 0.01, as observed in previous cluster studies on pregnancy and postpartum depression, six measurements, an alpha level of 5% (p-value <0.05) and a minimum of 14 health stations. The estimated number of women will therefore be min. 210 and max. 360. Adjusted for a dropout rate of 37% as observed in the first Mamma Mia study, the total sample size is between 334 and 572 participants with a 1: 1 distribution of participants between the groups.

Methods and procedures
Well-baby clinics will be randomly allocated to the two treatment groups. Pregnant women will be recruited prior to gestational week (GW) 26 during routine consultations using an online registration form. Surveys will be completed electronically at baseline; GW 21-26, GW 37, 1.5, 3, 6 and 12 months postpartum. Automatically generated log data will also be collected throughout the Mamma Mia program to assess program use and drop-out. Information on health care service utilization will be collected through electronic registers. Midwives and public health nurses in well-baby clinics will deliver Mamma Mia in combination with f-2-f guidance (i.e., the blended model). A heterogenous sample of women will be interviewed to explore their experiences with Mamma Mia with guidance from well-baby clinics and unguided Mamma Mia. Interviews will be audio-recorded and transcribed for subsequent analyses. The researchers will

also collect organizational data for each well-baby clinic to assess the implementation (e.g., number of annual births, man-hours, participants recruited for Mamma Mia). Furthermore, from health personnel within each clinic, demographics, individual/organizational readiness, barriers, and facilitators will also be collected. Adherence checklists based on the clinical guidelines will be used to assess fidelity. An in-depth understanding of the implementation process in well-baby clinics will be explored in focus group interviews before and after the implementation of Mamma Mia.

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Well-baby clinics will be randomly allocated (1:1) to the two treatment groups: unguided or blended care model of Mamma Mia.

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2. Blended care model: participants in this group will receive Mamma Mia (as described above) in combination with face-to-face guidance from midwives and public health nurses. Guidance will be offered as part of the regular consultations (2-3 times during pregnancy, and 2 times postpartum). Midwives and public health nurses will follow guidelines for the clinical work and for the implementation of Mamma Mia. The guidelines are based on the efficiency model of support, including techniques from motivational interviewing and solution-focused therapy.

Previous interventions:

The overall aim of the current project is to test the effectiveness, cost-effectiveness and implementation of Mamma Mia with guidance compared to unguided Mamma Mia and usual care. As the effectiveness of unguided Mamma Mia compared to usual care has already been evaluated in an existing trial, the study will be a two-armed cluster-randomized hybrid trial.

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Mixed models and/or structural equation modelling will be applied, as appropriate, to test the effects of Mamma Mia on primary and secondary aims. Qualitative data, both on maternal experiences with Mamma Mia (both unguided and the blended care model) and on the delivery of Mamma Mia among clinical staff, will be coded and analysed using thematic or related analytic approaches (e.g., template analysis), as appropriate. A comparative method will be used for before-and-after focus group interviews with clinical staff to understand behaviors and meanings that clinical staff give to their experiences of the implementation process and delivery of Mamma Mia to women. An economic evaluation will be based on a comparison of costs and effects as measured by the main outcome measures, EQ-5D-5L in particular. Costs include direct costs associated with Mamma Mia blended (intervention costs), as well as costs related to hospital as well as secondary care services. Data on service utilization will be obtained from questionnaires, alternatively hospital and municipal registers, respectively. Intervention costs (Mamma Mia with and without “blending”) will be calculated in detail.

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2. Blended care model: participants in this group will receive Mamma Mia (as described above) in combination with face-to-face guidance from midwives and public health nurses. Guidance will be offered as part of the regular consultations (2-3 times during pregnancy, and 2 times postpartum). Midwives and public health nurses will follow guidelines for the clinical work and for the implementation of Mamma Mia. The guidelines are based on the efficiency model of support, including techniques from motivational interviewing and solution-focused therapy.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 28/10/2025:

1. Depression measured using the Edinburgh Postnatal Depression Scale (EPDS) at baseline (approx. gestational week 25), gestational week 37, 1.5, 3, 6, and 12 months postpartum
2. Subjective well-being measured using the Satisfaction with Life Scale and the Positive and Negative Affect Scale at baseline (approx. gestational week 25), gestational week 37, and 1.5, 3, 6, and 12 months postpartum
3. Anxiety measured by the (a) anxiety sub-scale of the EPDS (i.e., EPDS-3A) and (b) the Acute anxiety and adjustment subscale of the Perinatal Anxiety Screening Scale at baseline (approx. gestational week 25), gestational week 37, and 1.5, 3, 6, and 12 months postpartum

Implementation primary outcomes:
1. Acceptability, appropriateness and feasibility respectively measured using the Acceptability of Intervention Measure, the Intervention Appropriateness Measure and the Feasibility of Intervention Measure at approx. 3 and 15 months after training and initial instructional meetings
2. Systems and capacity changes measured using the Systems and Capacity Changes –Section D at approx. 3 and 15 months after training and initial instructional meetings
3. Working alliance measured using Working Alliance Inventory–Short Revised at approx. 3 and 15 months after training and initial instructional meetings
4. Implementation outcomes measured using the Implementation Components Questionnaire–Implementation Outcomes at approx. 3 and 15 months after training and initial instructional meetings

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Previous primary outcome measures:

1. Depression measured using the Edinburgh Postnatal Depression Scale at baseline (approx. gestational week 25) at gestational week 37 and 1.5, 3, 6, and 12 months postpartum
2. Subjective well-being measured using the Satisfaction with Life Scale and the Positive and Negative Affect Scale at baseline (approx. gestational week 25), gestational week 37, and 1.5, 3, 6, and 12 months postpartum

3. Anxiety measured by the acute anxiety and adjustment subscale of the perinatal anxiety screening scale at baseline (approx. gestational week 25), gestational week 37, and 1.5, 3, 6, and 12 months postpartum

Implementation primary outcomes:
1. Acceptability, appropriateness and feasibility respectively measured using the Acceptability of Intervention Measure, the Intervention Appropriateness Measure and the Feasibility of Intervention Measure at approx. 3 and 15 months after training and initial instructional meetings
2. Systems and capacity changes measured using the Systems and Capacity Changes –Section D at approx. 3 and 15 months after training and initial instructional meetings
3. Working alliance measured using Working Alliance Inventory–Short Revised at approx. 3 and 15 months after training and initial instructional meetings
4. Implementation outcomes measured using the Implementation Components Questionnaire–Implementation Outcomes at approx. 3 and 15 months after training and initial instructional meetings

Key secondary outcome(s)

1. Health-related quality of life score measured by 5-Level EuroQoL-5D at baseline (approx. gestational week 25), gestational week 37, and 1.5, 3, 6, and 12 months postpartum
2. Relationship satisfaction measured using Relationship Satisfaction (RS) at baseline, 6 weeks postpartum, and 6 and 12 months postpartum
3. Self-efficacy measured using Coping Self-Efficacy (SE) at baseline
4. Attachment measured using Prenatal Attachment Inventory at baseline and gestational week 37
5. Stress measured using Perceived Stress Scale at baseline, 1.5, 6, and 12 months postpartum
6. Breastfeeding self-efficacy measured using the Breastfeeding Self-Efficacy Scale at 1.5, 3, 6, and 12 months postpartum
7. Social support measured using Berlin Social Support Scales at baseline, gestational week 37, and 1.5, 3, 6, and 12 months postpartum
8. Emotion regulation measured using the Emotion Regulation Questionnaire at baseline, 1.5, 6, and 12 months postpartum
9. Sleep measured using the Brief Infant Sleep Questionnaire at 1.5, 3, 6, and 12 months postpartum
10. Infant socio-emotional development measured using Ages & Stages Questionnaire: Socio-Emotional at 1.5, 3, 6, and 12 months postpartum

Implementation secondary outcome measures:
1. Adherence to the guidelines for the implementation and the clinical work in the blended intervention group, measured using an Adherence checklist that will be completed by health personnel after all consultations for all the postpartum women who receive guidance in using Mamma Mia
2. Log data recorded continuously throughout the Mamma Mia program
3. The implementation process will be explored at focus groups completed with health personnel at one timepoint during the project period
4. The plan for implementation will be completed by health personnel in the blended intervention following training and before recruitment of pregnant women
5. SWOT interview (strength, weaknesses, opportunities, threats) completed with perinatal women (approx. after when they have completed the Mamma Mia program) at one timepoint during the project period

Completion date

30/03/2026

Eligibility

Key inclusion criteria
1. Pregnant women aged 18 years and over
2. Up until 26 gestational weeks
3. Provide a valid email address
4. Read and understand Norwegian at a high-school level

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
812

Key exclusion criteria
1. Pregnant women who are beyond gestational week 26
2. Aged less than 18 years
3. Do not provide a valid email address

Added 14/11/2025:
4. Acute and ongoing personal crisis

Date of first enrolment
06/10/2021

Date of final enrolment
10/04/2024

Locations

Countries of recruitment
Norway

Study participating centre
Regional centre of child and adolescent mental health (RBUP), eastern and southern Norway
Postboks 4623, Nydalen
Oslo
Norway
0405

Sponsor information

Organisation
The Research Council of Norway

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Silje Marie Haga (smh@r-bup.no) and Filip Drozd (filip.drozd@r-bup.no) after the project is completed and for 5 years after the project is terminated. Data will be made available for researchers who wish to perform systematic reviews and meta-analyses. The Identification and Enrollment Log will not be shared. Participants are informed of all of these issues in the consent form.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes