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A web-based program for depressive symptoms and life satisfaction during pregnancy and after childbirth

Submission date
15/11/2013

Recruitment status
No longer recruiting

Registration date
09/12/2013

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Every year 60,000 women give birth in Norway, of whom approximately 10-15% (more than 6000) develop moderate to severe depressive symptoms called postpartum depression (PPD). Although not all women with postpartum depression meet DSM-IV criteria for depression, the negative consequences of PPD can be quite severe for the woman, her child, and her partner. A very low proportion of depressed women are identified and offered help. Recent studies have shown that interactive internet-based interventions can provide a rich, stimulating, engaging and actively supportive environment, and they have been found effective in treating depression, anxiety, phobias, diabetes, etc. At present, no systematic efforts aimed at preventing PPD exist. A web-based intervention program (Mamma Mia) has recently been developed in Norway with the aim to prevent postpartum depression. The aim of this study is to test how well this program works.

Who can participate?
All pregnant women and their partners aged over 18 years old that are not beyond gestational week
25. All participants must read and understand Norwegian at a high-school level and provide a valid e-mail address to participate.
Participants will be recruited via midwifes during the womans regular ultrasound (i.e. gestational week1820) at the hospitals and during the 1st regular follow-up in well-baby clinics (i.e. gestational week 2325). The midwives will hand out an information folder that describes the program. Potentially interested participants are referred to a website containing further study information and informed consent. Participants who wish to participate must confirm that they have read the information and submit the informed consent. In case this procedure fails to recruit the numbers needed, we will start recruiting participants by other means as well (e.g. media campaigns, social media, referrals, etc.).

What does the study involve?
All eligible participants are randomly allocated to either an intervention or control group. Participants allocated to the intervention group will receive the fully automated internet-based

intervention Mamma Mia, in addition to care as usual. The control group will only receive care as usual. Mamma Mia begins in gestational week 21-25 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 baseline and during gestational week 37 prenatally, and 1 ½, 3, 6, and 12 months postnatally.

When does the study take place?
From January 2013 to June 2018.

Where does the study take place?
The study will take place at various hospitals and well-baby clinics across Norway.

What are the possible benefits and risks of participating?
There are no known risks to study participation.

Who is funding the project?
The Research Council of Norway and the Norwegian Public Association for Womens Health

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
213737

Study information

Scientific Title
A randomized controlled trial of a web-based program for reducing perinatal depressive symptoms and enhancing life satisfaction during pregnancy and after birth

Study objectives
1. Women in the web-based intervention group will obtain lower scores on measures of depressive symptoms postpartum than the women in the control group.
2. Women in the web-based intervention group will obtain higher levels of life satisfaction, as indicated by lower parental stress and greater relationship satisfaction than the women in the control group.
3. Women in the web-based intervention group will score higher on breastfeeding self-efficacy and maternal self-efficacy than the women in the control group.
4. Women in the web-based intervention group will score lower on attachment dysfunction than the women in the control group.
5. Children of women in the web-based intervention group will score higher on communication skills as compared to children of women in the control group.

Details in Norwegian can be found in https://www.cristin.no/as/WebObjects/cristin.woa/wa/presentasjonVis?pres=413655&type=PROSJEKT and https://www.cristin.no/as/WebObjects/cristin.woa/wa/presentasjonVis?pres=416722&type=PROSJEKT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committees for Medical and Health Research Ethics, case number 2012/1716)

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Perinatal depressive symptoms

Interventions
Participants are randomized to either an intervention or control group.
1. Intervention group: "Mamma Mia" is a fully automated internet-based intervention available for PC/Mac, tablets, and smartphones. In total, it consists of 44 session over a period of 10 1/2 months. 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 increases to three session 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) metacognitive therapy, (c) positive psychology, (d) couple relationship, and (e) useful information for the parents (e.g. breast-feeding, baby's sleeping patterns, infant development, etc.)
2. Control group: Receives care as usual

For a demonstration, please see: http://smarturl.it/current-trials. For a more thorough description of the intervention, please see the cited article below.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Edinburgh postnatal depression scale (EPDS; Cox, Holden & Sagovsky, 1987)
2. Subjective well-being is measured by using the Satisfaction with Life Scale (SWLS; Diener, Emmons, Larson & Griffin, 1985) and the Positive and Negative Affect Scale (PANAS; Watson, Clark & Tellegen, 1988)
3. Anxiety is assessed by using the anxiety subscale of the EPDS (items 3;4;5)

All primary outcomes will be assessed at baseline (approx. gestational week 21), gestational week 37, and 1.5, 3, 6, and 12 months postpartum (i.e. on all time-points).

Key secondary outcome(s))
1. Parental Stress Scale (PSS; Berry & Jones, 1995)
2. Relationship satisfaction using Relationship Satisfaction Scale (RS; Røysamb, E, Vittersø, J, Tambs, K, 2012) will be at baseline (approx. gestational week 21), gestational week 37, and 1.5, 3, 6, and 12 months postpartum
3. Breast-feeding self-efficacy using Breastfeeding Self-Efficacy Scale (BSES-SF; Dennis 2003) will be assessed at baseline (approx. gestational week 21), gestational week 37, and 1.5, 3, 6, and 12 months postpartum
4. Prenatal Attachment Inventory (PAI; Muller & Mercer, 1993)
5. Oslo 3-Item Social Support Scale (Dalgard, Dowrick, Lehtinen, et al., 2006)
6. Postpartum Attachment / Parenting Stress Index (PSI; Abidin, 1983)
7. Efficacy Subscale of the Parenting Sense of Competence Scale (PSOC), developed by Gibaud-Wallson and Wandersman (1978, cited in Johnston & Mash, 1989)
8. Emotional reactivity (child temperament) is assessed by means of nine items from the Infant Characteristic Questionnaire (ICQ), fussy/difficult subscale (Bates, 1979)
9. Childs sleeping pattern (2 questions)
10. Ages and stages questionnaire-Communication subscale will be measured at 6 and 12 months postpartum

All remaining secondary outcomes will be measured at 1.5, 3, 6, and 12 months postpartum.

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Pregnant women and their partners aged +18 years and below 25 gestational weeks who provide a valid e-mail address. Implicit inclusion criteria include reading and understanding Norwegian at a high-school level.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1342

Key exclusion criteria
Pregnant women that are in gestational week 25 or beyond, aged less than 18 years and do not provide a valid e-mail address.

Date of first enrolment
01/01/2013

Date of final enrolment
03/06/2018

Locations

Countries of recruitment
Norway

Study participating centre
National Institute of Infant Mental Health
Oslo
Norway
0484

Sponsor information

Organisation
The Research Council of Norway (Norway)

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

Funder Name
Norges Forskningsråd (Norway) (reference number: 213737)

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

Funder Name
Norwegian Public Association for Women's Health (Norway) (project number: H3/2013).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2019	21/06/2019	Yes	No
Protocol article	Protocol	12/08/2013		Yes	No