

Randomized controlled study of internet-based cognitive behavioural therapy for women having post-traumatic stress after childbirth

Submission date 28/04/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 12/01/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/11/2022	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Childbirth can be associated with both positive and negative psychological wellbeing. About 20-50% of women report symptoms that indicate some aspect of their childbirth as negative. Overall, up to 7% develop post-traumatic stress disorder after childbirth. Among many consequences, post-traumatic stress symptoms due to childbirth may affect the bonding between mother and child, cause depression for the mother, and cause fear of having more children. The aim of this study is to assess the effect of psychological treatment via the internet for women who had a negative birth experience (this includes women with emergency caesarian and major bleeding after childbirth). If this internet treatment is effective, it offers a great opportunity for other women with the same experiences, potentially at a low cost.

Who can participate?

Women aged 18 or over who are giving birth

What does the study involve?

Participants answer questionnaires on the internet after which they are randomly allocated to receive either internet treatment (cognitive behavior therapy) or treatment as usual. The internet treatment group receive a 6-week treatment that involves education about symptoms and psychological techniques that are aimed at coping and reducing their symptoms. The treatment is delivered via recorded sessions (movie clips) and participants can also read these sessions via the internet. Participants are also assigned homework every week. Women who have full PTSD at the end of these 6 weeks of treatment are offered a more individualized internet CBT program. This treatment phase consists of 8 weeks of treatment. All participants are asked to complete questionnaires after 6 weeks, 14 weeks and then annually up to 4 years.

What are the possible benefits and risks of participating?

Participants who receive the CBT treatment hopefully experience reduced anxiety and depression, higher quality of life and a quicker recuperation after the negative child birth experience. The assessment phase might increase participant's reflections about the childbirth experience and their current situation. All women have full access to standard care throughout

the study. A PTSD treatment may increase anxiety during the treatment and this is expected. Participants are in contact with a research assistant and a psychologist during treatment and are advised or/and referred to further care if needed.

Where is the study run from?

1. Linköpings University Hospital (Sweden)
2. Örebro University Hospital (Sweden)
3. Falu Lasarett (Sweden)
4. Uppsala Akademiska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2012 to December 2022

Who is funding the study?
Regional Research Council (Sweden)

Who is the main contact?
Prof. Agneta Skoog Svanberg
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
version 1

Study information

Scientific Title
A longitudinal multi-center, randomized, superiority, controlled trial of Internet-based cognitive behavioural therapy (iCBT) versus treatment-as-usual (TAU) for negative experiences and posttraumatic stress following childbirth: the JUNO study protocol

Acronym

JUNO

Study objectives

iCBT is better than treatment as usual (TAU) regarding post traumatic stress symptoms and depression

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethics Review Board in Uppsala, Sweden, 20/03/2013, dnr 2012-495

Study design

Interventional longitudinal multicenter superiority randomized controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post traumatic stress

Interventions

Women with negative experiences from childbirth are included and randomized to either iCBT or TAU. The iCBT presents in two steps. iCBT step 1 is presented in six modules and includes minimal therapeutic support. The partners of the included women are invited to take part in the iCBT step 1 intervention. The partner receives identical content and a 'partner instruction' with specific tasks to perform that aims at supporting the mother (support and make room for practice; reflective listening; talk about the birth experience and present symptoms etc.). iCBT step 2 consists of eight modules with extended therapeutic support offered to the participants who after step 1 have symptoms of PTSD. Assessments are made at baseline and post and follow-up assessments are taken at 1, 2, 3 and 4 years after baseline.

Intervention Type

Behavioural

Primary outcome(s)

Assessed at baseline, 6 weeks, 14 weeks, 1 year, 2 year, 3 years and 4 years:

1. Post-traumatic stress symptoms related to childbirth, measured using the Traumatic Event Scale (TES)
2. Symptoms of depression, measured using the Edinburgh Postnatal Depression Scale (EPDS)

Key secondary outcome(s)

Assessed at baseline, 6 weeks, 14 weeks, 1 year, 2 year, 3 years and 4 years:

1. Quality of life and well-being, measured using the Satisfaction with Life Scale (SWLS)
2. Functional health and well-being, measured using the Short Form Health Survey – 36 (SF-36)
3. Thoughts and actions individuals use to cope with a stressful event, measured using the Ways of Coping Questionnaire (WCQ)
4. Feelings and attitudes towards communication in the relationship, measured using the

communication subscale from the Evaluation and Nurturing Relationship Issues, Communication and Happiness (ENRICH)

5. Relationship quality, measured using the Revised Dyadic Adjustment Scale (RDAS)

6. Parent–infant bonding disorders, measured using the Postpartum Bonding Questionnaire (PBQ)

7. Health outcome, measured using the EuroQol 5D (EQ-5D)

The partner also answers WCQ, PBQ, SWLS, R-DAS, the communication subscale from ENRICH, EQ5D, SF-36 and the Hospital Anxiety and Depression Scale at the same time points as above

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Women aged 18 or over who are giving birth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

266

Key exclusion criteria

1. Severe mental illness

2. Ongoing CBT treatment

3. Intrauterine fetal deaths

4. Stillbirths

5. Neonatal deaths

6. Difficulties understanding Swedish

7. Unable to use internet

Date of first enrolment

01/09/2013

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

Sweden

Study participating centre

Linköpings University Hospital

Sweden

58750

Study participating centre

Örebro University Hospital

Sweden

70362

Study participating centre

Falu Lasarett

Sweden

79137

Study participating centre

Uppsala Akademiska University Hospital

Department of Women's and Children's Health

Akademiska Hospital

Uppsala

Sweden

75185

Sponsor information

Organisation

Uppsala Universitet

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

Research council

Funder Name

Regional Research Council (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Agneta Skoog Svanberg (agneta.skoog_svanberg@kbh.uu.se).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/11/2022	14/11/2022	Yes	No
Results article	Predictors of dropout results	28/11/2022	29/11/2022	Yes	No
Protocol article	protocol	01/10/2018	12/02/2021	Yes	No