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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

Registration date
12/01/2017

Overall study status
Completed

Last Edited
29/11/2022

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
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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
04/01/2012

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Women aged 18 or over who are giving birth

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

N=130 patients with negative experiences

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 Childrens Health

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75185

Sponsor information

Organisation
Uppsala Universitet

Sponsor details
Women and Children's Health
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Sponsor type
University/education

Website
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ROR
https://ror.org/048a87296

Funder(s)

Funder type
Research council

Funder Name
Regional Research Council (Sweden)

Results and Publications

Publication and dissemination plan
The results of iCBT +TAU versus TAU will be published on two occasions; first at 1 year follow up and second at 4 years follow up. Ancillary publications to be confirmed at a later date.

Intention to publish date
31/12/2019

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?
Protocol article	protocol	01/10/2018	12/02/2021	Yes	No
Results article	Predictors of dropout results	12/11/2022	14/11/2022	Yes	No
Results article		28/11/2022	29/11/2022	Yes	No