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Using online-cognitive behaviour therapy (Online-CBT) to treat maternal depression

Submission date
18/06/2013

Recruitment status
No longer recruiting

Registration date
25/02/2014

Overall study status
Completed

Last Edited
02/03/2016

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Postpartum depression (PPD) is a disorder that affects about 8 to 15% of Canadian women after childbirth. This affects a womans overall quality of life and her ability to care for and connect with her baby. PPD is also related to short- and long-term effects on the babys development. Research suggests that psychological treatment is highly effective for this disorder. Many women suffering from PPD do not receive treatment for reasons including a shortage of qualified professionals, child caring duties and limited mobility. Internet and computer-based methods are a new way to improve access to psychological treatment. Research has suggested that online-cognitive behaviour therapy (Online-CBT) is particularly effective for the treatment of a variety of psychological disorders. This study examined whether Online-CBT works for the treatment of PPD.

Who can participate?
This study is available to women living in Saskatchewan aged over 18, who have given birth in the past year and experience depressive symptoms.

What does the study involve?
All interested individuals will participate in a telephone interview to determine if Online-CBT matches their needs. The interview takes about 30-45 minutes and will ask questions about your depression symptoms and other difficulties. Following the interview, you will be randomly allocated to either receive Online-CBT immediately or after waiting 10 weeks. The Online-CBT program consists of 7 treatment modules containing CBT materials that are accessed online, as well as activities that are to be completed offline. The modules include information about maternal depression, how to become more active, relaxation techniques, how to monitor thoughts and challenge them, problem solving skills, and other coping strategies. The program takes about 7 to 10 weeks to complete. All participants are asked to complete questionnaires after being allocated and again 10 weeks later. The questionnaires will help us understand whether Online-CBT is more efficacious immediately than with a 10-week waiting. Those who receive Online-CBT will also be contacted one month following treatment and asked about their symptoms. This will allow us to find out how effective the treatment is over the longer term.

What are the possible benefits and risks of participating?
This research may help women to address their postpartum depression. For participants assigned to the waitlist, there are no anticipated risks associated with completing the telephone interview or the online questionnaires. The only cost will be your time required to complete the interview and questionnaires. For participants assigned to receive Online-CBT and for those waitlist participants who decide to receive Online-CBT after the waiting period, the potential benefits include no appointment or travel required, no availability constraints, no concerns about stigma, therapy taken at your own pace, access the online material from the location of your choice at your convenience for up to four weeks after the end of therapy. If you would like to continue referencing materials after four weeks, you can print off the pages, you can e-mail your therapist at any time through our secure website, you may feel more comfortable disclosing personal information online than in person and this service is provided free of charge. The potential risks or challenges include assessment and diagnosis may be more difficult without seeing the person, online-CBT may require more self-motivation than other forms of therapy, greater potential for misinterpretation of e-mail messages between you and your therapist, risk for breaches of confidentiality, potential for technology failures that may result in messages not being received by either you or your therapist, Online CBT is not meant to be a long- term form of therapy and Online-CBT is not meant for use in the event of an emergency.

Where is the study run from?
University of Regina (Canada)

When is the study starting and how long is it expected to run for?
Recruitment for this study began in the summer of 2012 and is expected to be completed in the winter of 2014.

Who is funding the study?
The Canadian Institutes of Health Research (CIHR) (Canada) and the Saskatchewan Health Research Foundation (SHRF) (Canada).

Who is the main contact?
1. Ms. Nicole E. Pugh, pugh200n@uregina.ca, Tel: (306) 585-5369
2. Dr Heather D. Hadjistavropoulos, hadjista@uregina.ca

Study website
https://www.onlinetherapyuser.ca/intro/mdo/

Contact information

Type(s)
Scientific

Contact name
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S4S0A2

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled trial of a Therapist-Assisted Internet Cognitive Behaviour Therapy (TAICBT) program for women with postpartum depression

Study objectives
1. It is hypothesized that women who receive Online-CBT will demonstrate greater symptom improvement from pre- to post-treatment than participants who receive a waitlist condition on all primary and secondary outcome measures.
2. It is predicted that all expected symptom improvements will be maintained 4-weeks following the conclusion of treatment.
3. It is predicted that the participants will report satisfaction with the Online-CBT program. Specifically, it is hypothesized that participants will report an acceptable level of satisfaction with the treatment program, with approximately 80% reporting being either very satisfied or mostly satisfied.
4. It is hypothesized that significant associations (medium effect size) will be revealed between post-treatment therapeutic alliance ratings and change score from pre- to post-treatment on primary and secondary outcome measures (i.e., the more positive participants experience the therapeutic relationship, the greater the change in scores from pre-post treatment). Finally, for TAICBT participants, treatment expectancy and treatment satisfaction will be moderately correlated with change scores on the primary and secondary outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study has joint research ethics board approvals from:
1. The University of Regina (File #44S1112)
2. University of Saskatchewan (BEH# 12-64)
3. The Regina QuAppelle Health Region (REB-12-19)

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Maternal depression (i.e., postpartum depression)

Interventions
Single-centre randomized controlled trial that compares an active treatment (therapist-assisted Online-CBT) to a non-active wait-list group using a between-subjects design

The intervention consists of a therapist-assisted Online Cognitive Behaviour Therapy program. The program is titled Maternal Depression Online and consists of 7 cognitive behavioural modules. The program is interactive and includes text, graphics, animation, audio, video, and online activities. The modules focus on the following areas:
1. Psycho-education on maternal depression
2. Behavioural activation
3. Relaxation strategies
4. Monitoring unhelpful thoughts
5. Cognitive restructuring
6. Problem solving
7. Relapse prevention

At the beginning of each module, women complete check-in questions and mood ratings, which are submitted to their assigned therapist. The therapist emails or calls the client on a set day during the week to provide support and encouragement and to answer any questions. Following each module, offline activities are downloaded from the program and completed by the clients to apply the learned materials into the clients' daily life.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measure is the Edinburgh Postnatal Depression Scale. Measured pre-treatment (time 1), at 7-10 weeks (time 2, post-treatment for TAICBT participants), and at 14 weeks (time three, 4 weeks post-treatment for TAICBT participants).

Secondary outcome measures
1. Depression Anxiety Stress Scale
2. Parental Stress Index- Short Form
3. WHO-Quality of Life-BREF
4. Credibility/Expectancy Questionnaire
5. Therapeutic Alliance Questionnaire
6. Treatment Satisfaction Questionnaire-Modified
Measured pre-treatment (time 1), at 7-10 weeks (time 2, post-treatment for TAICBT participants), and at 14 weeks (time three, 4 weeks post-treatment for TAICBT participants).

Overall study start date
01/07/2012

Completion date
01/04/2014

Eligibility

Key inclusion criteria
Partipipants may take part in the prgoram if she:
1. Is a Saskatchewan resident and over 18 years of age
2. Reports symptoms of minor or major depression (Edinburgh Postnatal Depression Scale greater than 10)
3. Has a child aged less than 1 year
4. Has access to a computer
5. Have basic experience with using the internet and email
6. Has a family physician or medical clinic to contact in the case of an emergency

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
The goal is to randomize at least 50 participants.

Key exclusion criteria
1. More than minimal risk of self-harm or suicidality
2. Reporting psychotic or manic symptoms
3. Reporting a primary substance abuse problem
4. Symptoms are too minimal (less than 10 on Edinburgh Postnatal Depression Scale)

Date of first enrolment

01/07/2012

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
Canada

Study participating centre
University of Regina
Regina
Canada
S4S0A2

Sponsor information

Organisation
University of Regina (Canada)

Sponsor details
c/o Dr Heather Hadjistavropoulos
Department of Psychology
3737 Wascana Parkway
Regina, SK
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S4S0A2

Sponsor type
University/education

ROR
https://ror.org/03dzc0485

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Saskatchewan Health Research Foundation (SHRF) (Canada)

Alternative Name(s)
SHRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No