

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

<b>Submission date</b> 18/06/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/02/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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 woman's 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 baby's 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

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

## Protocol serial number

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

## Study type(s)

Treatment

## 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(s)**

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).

### **Key secondary outcome(s)**

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).

### **Completion date**

01/04/2014

## **Eligibility**

### **Key inclusion criteria**

Participants may take part in the program 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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **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

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## **Sponsor information**

**Organisation**

University of Regina (Canada)

**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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, 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 | Saskatchewan Health Research Foundation | Canada, SaskHealthResearch, SHRF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Canada

# 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?
<a href="#">Results article</a>	results	01/03/2016		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes