

# Enjoy your baby, life skills for mums with new babies: a pilot randomised control trial

<b>Submission date</b> 05/11/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/10/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Around 13% of new mothers experience significant and sustained depression soon after giving birth, this is referred to as postnatal depression (PND). PND has been described as a global public health problem not just because of the effect this has on mothers, but also on the mothers' partners and their babies. Untreated PND can affect the developing relationship and attachment between mother and baby and this can have long term consequences for the children e.g. being at higher risk of developing depression themselves. Cognitive behavioural therapy (CBT) has been shown to be effective in treating PND. This study aims to test a CBT-based online treatment for mothers with low mood. It is hoped that the online nature of the treatment will make it easier for new mothers to access than traditional, clinic based face-to-face therapy.

### Who can participate?

Women over the age of 18 with a baby less than 18 months old that are experiencing mild to moderate symptoms of low mood, stress and anxiety.

### What does the study involve?

Potential participants are asked to complete short questionnaires which ask about their mood as well as personal information such as age, school history and work status. This information is used to select suitable participants. Selected participants are randomly allocated to one of two groups. Those in group 1 (immediate access group) are given access to the online course. Those in group 2 (delayed access group) are told that they will be given access to the online course later. The course has been developed to help Mums learn a number of practical life skills, such as problem solving, overcoming low confidence, boosting mood with the aim of improving mild to moderate feelings of low mood and stress. The course runs for a period of 8 weeks. All participants (from both groups) are asked to complete questionnaires before they begin the study and again after the 8 week study period.

### What are the possible benefits and risks of participating?

It is hoped that the mothers will learn a series of life skills which they can use to reduce stress, improve their mood and build closeness to their baby. Participants will be given a £5 Amazon voucher as a thank you for their time. The set of questionnaires that mothers are asked to

complete before and after the study ask about symptoms of low mood, anxiety and depression. Most people do not mind answering these questions, but some people may feel upset. It is important that these questions are asked to find out if the online package is effective. Sometimes when people find out more about low mood and stress they can feel worse to start with. However, this is usually just for a short time and most people feel better again quite quickly as they work through online courses like this one.

Where is the study run from?

The study will take place online and mothers can complete this wherever and whenever is most convenient for them.

When is the study starting and how long is it expected to run for?

July 2015 to July 2016

Who is funding the study?

University of Glasgow (UK)

Who is the main contact?

Miss Claire Adey

**Study website**

<http://www.lifeskills4mums.com/>

## Contact information

**Type(s)**

Public

**Contact name**

Miss Claire Adey

**Contact details**

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**Type(s)**

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Enjoy your baby, online CBT for mothers with new babies: a pilot randomised control trial

### **Study objectives**

1. It is possible to recruit up to 60 participants into the study and gather baseline and follow up data.
2. More than 50% of participants will complete the four core course modules with at least 65% data available at follow-up.
3. A reduction in the scores on the depression and anxiety measures of participants in the immediate access group will be seen when compared with the delayed access group at eight week follow-up.
4. There will be minimal or no change to participants' scores on the depression and anxiety measures between baseline and gaining access at week eight, in the delayed access group.
5. Higher scores of satisfaction will be observed in the immediate access versus the delayed access arm.
6. There will be a higher reduction in scores on depression, anxiety and social function in the immediate access arm than in the delayed access arm.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

MVLS College Ethics Committee, 27/10/2015, ref: 200150010

### **Study design**

Waiting list randomised control design

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Treatment

**Participant information sheet**

<https://dl.dropboxusercontent.com/u/9042231/Participant%20info%20sheet%201.1%20Life%20Skills%204%20Mums.pdf>

**Health condition(s) or problem(s) studied**

Low mood/ postnatal depression

**Interventions**

CBT based life skills online intervention.

The course focuses on helping mums learn a number of practical life skills (including problem solving, tackling low confidence and boosting mood) that they can use in their daily lives. It is hoped that these skills will help to relieve mild to moderate symptoms of low mood and stress. It begins with a welcome module, the first topic looks at understanding why you might feel like you do, the next how to make positive changes, the third building closeness with your baby, and finally how to look at things differently. Extra modules include topics like irritability, how to plan for the future and poor sleep.

**Intervention Type**

Behavioural

**Primary outcome measure**

Assess the ability to recruit participants, deliver the online course and to gather evaluations.

Recruitment and engagement will be monitored from the study opening and throughout. Descriptive statistics will be used to describe the sample demographic details. An intention to treat protocol will be used when analysing the data obtained on the outcome measures. Descriptive statistics will be used to show how participants evaluate the intervention. A power calculation for future studies will be conducted at the end of the study and be informed by the take-up, follow-up and retention rates in the study, coupled with estimates of treatment effect gathered during the pilot phase.

**Secondary outcome measures**

1. PHQ-9, a self-report measure of depressive symptoms
2. Generalized Anxiety Disorder-7 (GAD-7) a self-report measure of generalized anxiety
3. Edinburgh Postnatal Depression Scale (EPDS) a 10 question self-report measure designed for use with mothers of young babies

Timepoints as of 31/03/2016:

These will be administered at baseline and at eight week follow-up

Initial timepoints:

These will be administered at baseline, eight week follow-up and 12 week follow-up

**Overall study start date**

17/07/2015

**Completion date**

29/07/2016

## **Eligibility**

**Key inclusion criteria**

1. Women over the age of 18 with a child under 18 months (amended from: a child under one year old as of 31/03/2016)
2. Not currently accessing formal mental health services e.g. a psychologist/counselor
3. Score of 5 or more on the PHQ-9 (amended from: score of 10 or more on 31/03/2016)
4. Ability to read and understand English
5. Access to the internet and able to listen to audio recordings

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

60 participants in total required, 30 in both the immediate access and delayed access arms.

**Key exclusion criteria**

1. Women under 18 years old without a child under the age of 18 months (amended from: child under the age of 1 on 31/03/2016)
2. Already engaged with formal mental health supports e.g. attending a CMHT
3. Cannot read or understand English
4. Does not have web access as the intervention is via the internet
5. Not presenting with symptoms of low mood- assessed by a score of less than 5 on the PHQ-9 (amended from: score of less than 10 as of 31/03/2016)
6. Women who report active suicidal ideation, identified by their response to question nine on the PHQ-9 ("Thoughts that you would be better off dead or of hurting yourself in some way" either "more than half the days" or "nearly every day") will be excluded and redirected to their GP to seek immediate access to mental health services.

**Date of first enrolment**

09/11/2015

**Date of final enrolment**

18/04/2016

# Locations

## Countries of recruitment

Scotland

United Kingdom

## Study participating centre

### University of Glasgow

Institute of Mental Health and Wellbeing

1st floor, Administration Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

United Kingdom

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# Sponsor information

## Organisation

University of Glasgow, College of Medical, Veterinary and Life Sciences

## Sponsor details

Institute of Mental Health and Wellbeing

Administration Building

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1055 Great Western Road

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## Sponsor type

University/education

## ROR

<https://ror.org/00vtgdb53>

# Funder(s)

## Funder type

University/education

**Funder Name**

University of Glasgow

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

The trial report and submissions of the research will be written up but participants will not be identifiable. These will be written up in a PhD thesis and submitted to the University of Glasgow in accordance with the Doctorate in Clinical Psychology course requirements and also submitted to a scientific journal. We also hope to present these at scientific conferences.

**Intention to publish date**

31/12/2016

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		05/10/2016	06/10/2016	No	No