ISRCTN90927910 https://doi.org/10.1186/ISRCTN90927910

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

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
06/11/2015

Overall study status
Completed

Last Edited
06/10/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Contact information

Type(s)
Public

Contact name
Miss Claire Adey

Contact details
University of Glasgow
Institute of Mental Health and Wellbeing
Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Type(s)
Scientific

Contact name
Miss Claire Adey

Contact details
University of Glasgow
Institute of Mental Health and Wellbeing
Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow

United Kingdom
G12 0XH

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
United Kingdom

Scotland

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
G12 0XH

Sponsor information

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

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

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?
Basic results		05/10/2016	06/10/2016	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes