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An online CBT life skills programme for low mood and anxiety.

Submission date
22/06/2015

Recruitment status
No longer recruiting

Registration date
28/07/2015

Overall study status
Completed

Last Edited
18/02/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The research team at the University of Glasgow are carrying out a research project looking at low mood and stress in the community. Low mood is a common mental health problem affecting up to 121 million people worldwide (World Health Organisation) and people often do not receive the help they need. Although approaches based on cognitive behavioural therapy (CBT) are known to be successful in a one-to-one setting, this can be expensive and there are often long waiting lists. We want to know if computerised CBT could be used as an alternative. We aim to find out whether it is possible to investigate an online CBT resource, recruiting from the general population.

Who can participate?
Patients aged 18 or over, living in the UK and with the ability to understand the written and spoken English language. They must also have regular access to a computer with audio and broadband connection and score of 10 or more on PHQ-9 (a depression diagnostic measure).

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 start to use a self-help CBT website straight away. Those in group 2 start to use the website after a 3 month delay. This study design help researchers to compare the groups 3 months after they start the trial and see how many join the programme and then stick to it, whether the approach is acceptable to them and whether those who have used the resource have greater improvements in mood than those who have not yet used the website. During the study, participants are able to access online modules with video and audio that addresses various aspects of low mood and anxiety. They are informal and friendly sessions that aim to teach skills that may help to reduce feelings of stress and improve low mood. Participants are assigned a support worker to help them progress through the sessions and apply what they have learned.

What are the possible benefits and risks of participating?
By using the package it is hoped that participants may learn new skills to help with symptoms of low mood, anxiety or depression. 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. The support workers will be trained to signpost participants to additional help if needed.

Where is the study run from?
University of Glasgow. Participants will use the self-help website at home.

When is the study starting and how long is it expected to run for?
August 2015 to August 2016.

Who is funding the study?
NHS Greater Glasgow and Clyde (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A pilot randomised controlled trial of an online CBT life skills programme for low mood and anxiety.

Study objectives
This is a pilot study that aims to address the following questions:
1. Is the study design feasible- is it possible to recruit from the community, remotely randomise participants, deliver the online intervention with telephone/email support and collect data at baseline and 3 months post randomisation?
Secondary questions:

2. To what extent will participants adhere to the online intervention?
3. Is the Living Life package acceptable to participants?
4. How many participants will be needed for a sufficiently powered future RCT?

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medical, Veterinary and Life Sciences Ethics Committee for Non Clinical Research Involving Human Subjects, University of Glasgow, ref. 200140159.

Study design
Parallel two-arm pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low mood./depression

Interventions
The study will test the delivery of an online educational life skills package (LLTTF4). The course teaches key life skills and is based on an existing CBT model with a strong educational focus. It contains a series of e-books - together with linked online modules that focus on the following topics:
1. Why do I feel so bad?
2. I can't be bothered doing anything
3. Why does everything always go wrong?
4. I'm not good enough: (low confidence)
5. How to fix almost everything
6. The things you do that mess you up
7. Are you strong enough to keep your temper?
8. 10 things you can do to help you feel happier straight away
Each is accompanied by colourful worksheets. Participants will work through the LLTTF4 online sessions at their own pace (1 session per week is recommended). All participants will be allocated a support worker (trained in delivering support for the online intervention) who will deliver 6 weeks of support via email or telephone. The support will be offered by Action on Depression (support workers, who have delivered similar content before online or in classes.

Control group: Students will receive access to the intervention after a 3-month delay. During these three months, participants in this group are advised to continue with their treatment as usual, whatever that may be, ex. antidepressant medication. We will not provide a usual care package while they wait.

Intervention Type
Other

Primary outcome(s)

In this pilot study, the main aim will be to investigate take-up, drop-out and completion rates of the online course, and the completion rates for data collection.

Key secondary outcome(s))
Secondary outcomes will be mood ratings at 3 months. We will use changes in the Patient Health Questionnaire 9 (PHQ-9) score to provide data relating to the effect of the intervention on depression levels. This will give an indication of efficacy, and together with the drop-out /retention rate, will be used to provide a power calculation for the future substantive RCT; providing evidence that a change in depression levels between the intervention and control groups can be observed. Anxiety, social adjustment and satisfaction with the intervention will also be assessed.

Completion date
01/08/2016

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Living in the UK
3. Ability to understand the written and spoken English language
4. Regular access to a computer with sound card and broadband connection
5. Score of 10 or more on PHQ9

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. High rating of suicidality (i.e. scoring 2 or 3 on PHQ-9 item 9)
2. Currently receiving any psychological intervention such as counselling or psychotherapy
3. No new or altered dose of antidepressant in the last month
4. Taking part in other research

Date of first enrolment
01/08/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Glasgow
Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
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Sponsor information

Organisation
University of Glasgow

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Greater Glasgow and Clyde

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/02/2022	18/02/2022	Yes	No
Protocol article	protocol	27/04/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes