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A community based group guided self-help intervention for low mood and stress

Submission date
13/09/2012

Recruitment status
No longer recruiting

Registration date
02/11/2012

Overall study status
Completed

Last Edited
03/10/2018

Condition category
Mental and Behavioural Disorders

[_] 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 is carrying out a research project looking at low mood and stress in adults aged 16 and over. This study will potentially provide a great amount of information about these problems and how they can be effectively managed.
Low mood is a common mental health problem affecting up to 121 million people worldwide (World Health Organisation). During 2004/05, the total cost of antidepressant medication prescribed in Scotland was over £58 million, an increase of 300% in the last 10 years. Various psychological therapies can also be used to aid depression and can be effectively delivered to reduce depressive symptoms. Although approaches based on the talking therapy, cognitive behavioural therapy (CBT) are known to be effective when delivered one to one by an expert practitioner, it is unclear whether group-delivered CBT is as effective. The aim of this study is to determine whether community based life skills classes that use the CBT approach can help improve feelings of low mood, depression and anxiety. The study aims to recruit people in the community, so as to improve access to help to a wide range of people rather than those who are attending health care treatment alone.

Who can participate?
Individuals aged 16 and over with symptoms of low mood can enter the study. Participants must be able read, speak and understand English, travel to the classes, and agree to abide by normal social etiquette within the classes. We are not including those who are already receiving a current course of psychotherapy or counselling.

What does the study involve?
Individuals who are suitable for the study will be randomly allocated to begin the classes immediately (within 1 month) or after a 6 month delay. All participants will receive the same intervention. This study will help the researchers to compare the groups at 6 months and determine whether those who have received access to the classes have greater improvements in mood than those who have not yet attended the classes.
During the study, life skills courses that consist of 8 weekly 1.5 hour course sessions will be held. These classes are delivered by Action on Depression (AOD) and use a cognitive behavioural therapy (CBT) group guided self-help approach. They are informal and friendly classes that aim to teach skills that may help to reduce feelings of stress and improve low mood. The final

session is a revision and reunion session 6 weeks after the last class.
During these classes topic covered include:
Why do I feel so bad?
Why does everything always go wrong?
I'm not good enough: (low confidence)
10 things you can do to help you feel happier straight away
Participants will be asked to complete questionnaires about their mood and treatments they have received/are currently receiving for their low mood when they enter the study and 6 and 12 months after entering the study.

What are the possible benefits and risks of participating?
Participating in the study means participants will have access to a new life skills course which aims to give an informal, friendly and fun way of teaching the skills we all need to improve and maintain wellbeing. Attending these classes may result in an improvement in mood, levels of stress and quality of life. Also, the community based classes may bridge the gap between the onset of low mood and receiving specialist treatment. Another main benefit of taking part is that participants will be contributing to a large research study that will help researchers, the health service and charities such as Action On Depression better understand how helpful community based classes are for depression.
There are not expected to be significant side effects, however if participants experience any they will be advised to consult their GP.

Where is the study run from?
The study is being run by researchers at the University of Glasgow. The classes will take place in Glasgow and Edinburgh and are run by the Scottish charity Action on Depression staff or volunteers.

When is the study starting and how long is it expected to run for?
The study will start recruiting participants in September with the first participants joining the study in October 2012. The first classes will start in October 2012. The study is expected to end in January 2014.

Who is funding the study?
The study is funded by the Chief Scientist Office (CSO)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CZH/3/738

Study information

Scientific Title
A randomised controlled trial of a community based group guided self-help intervention for low mood and stress

Study objectives
1. The Living Life to the Full (LLTTF) classes will result in an improvement in symptoms of depression and anxiety, at 6 months for those will a PHQ-9 score of 10+ and 5+, compared to delayed access control group, as measured by the PHQ-9 and GAD-7
2. The LLTTF classes will result in an improvement in social function at 6 months compared to delayed access (DAC) as measured by the WSAS
3. The LLTTF classes will be more cost effective than DAC
4. The LLTTF classes will be more satisfactory to participants than DAC

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medical, Veterinary & Life Sciences Ethics Committee for Non Clinical Research Involving Human Subjects, 09/07/2012, ref: 2012065

Study design
Pre-post design randomised controlled trial with delayed access control

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression, low mood

Interventions

Individuals who are suitable for the study will be randomly allocated to begin the classes immediately (within 1 month) or after a 6 month delay.

Living Life to the Full (LLTTF) guided CBT self-help classes - 1.5 hour per class for 8 weeks, plus a 6 week follow-up support session, which covers:

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
9. Revision and Reunion session (6 weeks after final class)

Sessions are scripted to give a clear idea of content and are structured/presented using standardised slides. Once accepted into the study, participants will be allocated to either the immediate access (IA) group (beginning the course within a month) or the delayed access (DAC) group (beginning the course after a 6 month delay) group. All participants can continue with treatment as usual during the study, this will be recorded at the various time points. All participants will be asked to complete outcome measures at baseline, 6 months and 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary analysis will use analysis of co-variance, testing the difference between groups in PHQ-9 scores in all participants at 6 months.

Key secondary outcome(s))
Planned secondary analysis will be carried out for those will PHQ-9 scores of 10 or more, and those with scores of less than 10, at baseline, and test whether the intervention effect interacts with baseline PHQ-9 score i.e. is the intervention more or less effective dependent upon baseline PHQ-9 depression scores. We will also assess improvements in anxiety and work and social functioning at 6 months, comparing the immediate and delayed access control groups. Cost effectiveness of the intervention will also be calculated. Finally, satisfaction with the classes will be investigated.

Completion date
07/01/2014

Eligibility

Key inclusion criteria
Individuals aged 16 or over with at least mild depressive symptoms defined as a score of 5 or more on the PHQ-9

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Aged < 16
2. Does not meet inclusion criteria
3. Cannot read, speak and understand English
4. Cannot travel to the classes
5. Do not consent to abide by normal social etiquette within the classes
6. Individuals currently receiving psychotherapy or counselling at the eligibility stage

Date of first enrolment
01/10/2012

Date of final enrolment
07/01/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
University of Glasgow (UK)

ROR

https://ror.org/00vtgdb53

Funder(s)

Funder type
Research organisation

Funder Name
Chief Scientist Office (UK) ref: CZH/3/738 (UK)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

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	01/02/2018		Yes	No
Protocol article	protocol	19/11/2013		Yes	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