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Community use of living life to the full educational classes

Submission date	Recruitment status
09/05/2011	No longer recruiting
Registration date	**Overall study status**
03/11/2011	Completed
Last Edited	**Condition category**
29/10/2015	Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
We are carrying out a study looking at low mood and stress in older adults aged 65 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. Depression is a common problem in older adults with prevalence rates estimated at between 2 – 15% in adults over 65. Although the prevalence of low mood is high and trends seem to suggest it will continue to rise, there are a number of treatment options. Drug treatments are recommended in the NICE guidelines. However, 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. A recent study found that the use of anti-depressant was associated with many adverse outcomes in adults over 65 including falls, seizures and self-harm. Therefore, it would be desirable to reduce anti-depressant prescribing generally but specifically in older adults, and instead use psychological therapies to reduce depressive symptoms. The aim of this study is to determine whether community-based life skills classes can help improve feelings of low mood, depression and anxiety in older adults.

Who can participate?
Individuals aged 65 and over with symptoms of low mood can enter the study. Participants must be able to travel to the local classes and be free to attend at least 6 out of the 8 classes of the course.

What does the study involve?
Up to 45 participants will take part in the study. Classes will be run in Glasgow and/or Edinburgh. All individuals who are suitable for the study will be invited to begin attending the life skills classes at the next available opportunity. The courses consist of 8 weekly 1.5 hour sessions. These classes are informal and friendly and 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. Participants will be asked to complete questionnaires about their mood, their everyday life and their opinions of treatments they have received when they enter the study and 3 and 6 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, if participants currently on a waiting list. There are no expected side effects, and 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.

When is the study starting and how long is it expected to run for?
The study will start recruiting participants in November with the first classes starting in January. The study is expected to run for a year so will finish around the end of 2012.

Who is funding the study?
University of Glasgow (UK).

Who is the main contact?
Carrie-Anne McClay
c.mcclay.1@research.gla.ac.uk or c.mcclay@hotmail.co.uk

Contact information

Type(s)
Scientific

Contact name
Prof Chris Williams

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

Additional identifiers

Study information

Scientific Title
Community use of living life to the full educational classes: a pilot study

Study objectives

1. Is a randomised controlled trial (RCT) of a community life skills course for depression feasible?
2. Is a randomised controlled trial with a delayed treatment control (DTC) arm acceptable for participants?
3. Which community recruitment methods are most effective?
4. Do participants consider the intervention acceptable, practical and effective?
5. What sample size is required to find a difference in outcome of various magnitude on the PHQ-9?
6. Is the suggested method of collecting data for economic analysis feasible and acceptable?
7. Do the findings from this pilot study support the need for a large RCT?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Faculty Ethics Committee, University of Glasgow, 25/01/2011, Project No. FM01910

Study design
Multicentre randomised controlled trial with a delayed access control arm

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1. The intervention is a community based life skills course called 'Living Life To The Full' which applies to the principles of cognitive behavioural therapy
2. The weekly sessions last 1.5 hours and cover:
2.1. Why do I feel so bad?
2.2. I can't be bothered doing anything
2.3. Why does everything always go wrong?
2.4. I'm not good enough: (low confidence)
2.5. How to fix almost everything
2.6. The things you do that mess you up
2.7. Are you strong enough to keep your temper?
2.8. 10 things you can do to help you feel happier straight away
2.9. Revision and Reunion session (6 weeks after final class)
3. Sessions are scripted to give a clear idea of content and are structured/presented using uneditable slides
4. Adherence to the script will be recorded by a research assistant/volunteer sitting in at short notice on a randomised selection of 30% of classes and ticking key points in the slides/scripts to establish adherence
5. Once accepted into the study, participants will be randomly allocated to the Immediate Access (IA) or Delayed Access Control (DAC) arm
6. The IA group begins their course 2 weeks following baseline measures and the DAC group gains access to the intervention 14 weeks following the collection of baseline measures. All participants will be asked to complete follow-up measures at 12 weeks and 6 months.

Intervention Type
Behavioural

Primary outcome(s)
To assess the feasibility of completing a randomised controlled study of the Living Life to the Full course using a delayed treatment control approach in Scotland and Northern Ireland.

Key secondary outcome(s))
1. To test the feasibility of recruiting participants into the RCT using multiple community recruitment strategies
2. To assess the feasibility of collecting data at baseline and at follow-up points by letter, telephone and email
3. To gain information regarding the attendance, completion and drop out rates in the classes
4. To record user's levels of satisfaction in relation to the intervention and identify suggestions to better refine delivery of the course and the RCT
5. To test the feasibility of completing an economic analysis of NHS and social care costs prior to and following the intervention

Completion date
07/11/2011

Eligibility

Key inclusion criteria
1. Individuals aged 16 or over, either sex
2. Must be able to read, speak and understand the English Language
3. Must be able to travel to attend the classes
4. A score of 5 or more on the Patient Health Questionnaire (PHQ-9), indicating at least mild depressive symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age <16
2. Cannot read speak and understand English
3. If participants do not consent to abide by normal social etiquette within the classes
4. If their score on the PHQ-9 is below 5
As the study is a pilot study we feel that we should not exclude individuals based on changes in antidepressant medication or participation in psychotherapeutic intervention, therefore these variables will not be included in the exclusion criteria.

Date of first enrolment
25/01/2011

Date of final enrolment
07/11/2011

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
University/education

Funder Name
University of Glasgow (UK) (Research Project Ref 48261)

Alternative Name(s)
The University of Glasgow

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 provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/02/2015		Yes	No