

# Living life to the full: educational classes for older adults with low mood and depression

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The research team at the University of Glasgow is 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 (World Health Organization). Depression is a common problem in older adults (in 2004 the World Health Organization estimated that 2 to 15% in adults over 65 suffer from it).

There are a number of treatment options. Drug treatments are recommended in the NICE guidelines (2009). 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 (NHS Scotland website). The HEAT targets (a set of government objectives, targets and measures for the NHS) specify that it would be desirable to reduce anti-depressant prescribing generally but specifically in older adults, suggesting that psychological interventions are the preferred treatment options.

A recent study found that the use of anti-depressants was associated with many adverse outcomes in adults over 65 including falls, seizures and self-harm. Alternatively, there are various psychological therapies that can be effectively delivered 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?

During the study, life skills courses (called Living Life To The Full LLTFF) that consist of 8 weekly 1.5 hour course sessions will be held. 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. 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

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 classes at the next available opportunity. All participants will receive the same intervention.

Participants will be asked to complete questionnaire 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?

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, 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 LLTTF classes will take place in Glasgow and Edinburgh.

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

The study will start recruiting participants in November 2011 with the first classes starting in January 2012. The study is expected to run for a year and finish around the end of 2012.

Who is funding the study?

The study is carried out by researchers employed by the University of Glasgow (Chris Williams). Carrie-Anne McClay is employed as a Five Areas Researcher and is also a registered PhD student at the University of Glasgow. The other costs are low and will be met by a University of Glasgow funding source or through donation of time. The hope is that by doing such an initial study, funding for a future larger study may be secured.

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

Mental Health and Wellbeing

University of Glasgow

Administration Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow  
United Kingdom  
G12 OXH  
+44 (0)141 211 3912  
chris.williams@glasgow.ac.uk

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Living life to the full: educational classes for older adults with low mood and depression: a feasibility study

### **Study objectives**

1. Is a study of a community life skills course for older adults (65 years or over) with depression feasible?
2. Is it feasible to run these classes in this older adult age group?
3. Do participants consider the intervention acceptable, practical and effective?
4. Which community recruitment methods are most 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 feasible and acceptable?
7. Do the findings from this feasibility study support the need for a pilot or full randomised controlled trial (RCT) with older adults?

### **Ethics approval required**

Old ethics approval format

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

College of Medical, Veterinary and Life Sciences Ethics Committee, University of Glasgow, 17 October 2011, ref: FM08129

### **Study design**

Pre-post design interventional non randomised trial

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Depression, anxiety, stress.

**Interventions**

No control group or delayed access control group will be used in this preliminary study of this intervention.

The intervention: Living Life to the Full classes, 1.5 hour per class for 8 weeks, which cover:

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 that cannot be edited. Adherence to the use of the slides will be recorded by a research assistant sitting in at short notice on a randomised selection of 25% of classes.

Once accepted into the study, all participants will be allocated to a group and begin the classes as soon as possible. All participants will be asked to complete follow-up measures at 12 weeks and 6 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

To assess the feasibility of delivering and studying the community-based Living Life to the Full course in a sample of older adults with focus on take up, completion rates, drop out, recruitment, data collection. For the future RCT, the primary outcome measure will be the PHQ-9.

**Secondary outcome measures**

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 users levels of satisfaction in relation to the intervention and identify suggestions to better refine delivery of the course and the RCT
5. To assess the efficacy of the intervention in relation to scores on the PHQ-9, GAD-7, WASAS and HADS

**Overall study start date**

01/11/2011

**Completion date**

01/11/2012

## Eligibility

**Key inclusion criteria**

1. Individuals aged 65 or over who self-present to the classes
2. Must be able to understand and attend the classes for which normal polite behaviour is expected
3. A score of 5 or more on the Patient Health Questionnaire-9 (PHQ-9), indicating at least mild depressive symptoms and/or a score of 5 or more on the Generalised Anxiety Disorder (GAD-7) Assessment

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

We aim to recruit up to 45 participants (3 groups of 15)

**Key exclusion criteria**

1. Does not meet inclusion criteria
2. Participants who do not consent to abide by normal social etiquette within the classes

**Date of first enrolment**

01/11/2011

**Date of final enrolment**

01/11/2012

## Locations

**Countries of recruitment**

United Kingdom

**Study participating centre**  
**Mental Health and Wellbeing**  
Glasgow  
United Kingdom  
G12 OXH

## **Sponsor information**

### **Organisation**

University of Glasgow (UK)

### **Sponsor details**

c/o Ms Deirdre Kelliher  
Research and Enterprise  
10 The Square  
Glasgow  
Scotland  
United Kingdom  
G12 8QQ  
+44 (0)141 330 5005  
deirdre.kelliher@glasgow.ac.uk

### **Sponsor type**

University/education

### **Website**

<http://www.gla.ac.uk/>

### **ROR**

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

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

University of Glasgow (UK)

### **Alternative Name(s)**

### **Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

**Funder Name**

Five Areas Ltd (UK)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration