

Acceptance and use of Life To The Full online educational classes aimed at young adults: A pilot study

Submission date 03/10/2012	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/03/2013	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/01/2019	Condition category 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

For this initial study, an online cognitive behavioral therapy (CBT) life skills package based on the current Living Life To The Full online resource for stress and low mood will be evaluated. The information from this study will help to indicate whether guided self help online CBT based resources is an acceptable intervention (treatment) for low mood and stress in younger adults. By assessing the acceptance and use of the package and support we will be able to gain a key insight as to how online CBT based resources can be best delivered to young adults. It will also provide us with useful information about take-up, completion rates and an idea of the impact of the intervention on low mood and anxiety.

Who can participate?

Individuals aged 17 years and above, from the United Kingdom, who are experiencing mild to moderate symptoms of low mood with or without stress will be recruited directly from the community, predominantly through the Glasgow University Counselling and Psychology Service. It is hoped that this community based method of recruitment will help particularly to identify younger adults who are not currently receiving any specialist help for their symptoms.

What does the study involve?

Recruitment will be carried out via Google advertisements, email lists, social networking sites, student counselling services, posters and newspaper adverts; and we may approach a range of student websites including student counselling and Students Against Depression.

For this study, an online course (Living Life) consisting of online modules, online books and worksheets will be delivered with online support (email and online chat), and compared to a delayed access control who must wait 12 weeks before receiving access.

What are the possible benefits and risks of participating?

Participation within this study will allow younger adults who are experiencing mild to moderate symptoms of stress and low mood to take part in online CBT based educational life skills modules that are based on the cognitive behavioural therapy (CBT) approach. Previous studies suggests that CBT is effective in helping problems of low mood and stress as well as associated

issues such as reduced confidence. A potential risk to participants is that they may experience an increase in their feelings of stress or low mood during the study. If participants indicate that they need additional support at any time during the study they will have the opportunity to contact one of the researchers. Also built into the study is the safeguard of asking the participants to give the research team permission to contact their GP if there was a cause for concern in their symptoms of stress/low mood or if they disclose that they are suicidal. Research has shown that there is decreased risk of distress in those using such packages compared to those who are not using anything.

Where is the study run from?

Glasgow University Counselling and Psychology Service

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

The study started in December 2012 and will run until we have recruited at least 50 people.

Who is funding the study?

University of Glasgow

Who is the main contact?

Dr. David Osborne

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Contact information

Type(s)

Scientific

Contact name

Prof Christopher Williams

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

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Study objectives

This is a pilot study to establish:

1. Whether we can recruit young adults into a pilot randomised controlled trial (RCT) using email, poster and other community-based recruitment methods
2. To establish the use and experience of an online course addressing low and anxious mood
3. Identifying the take-up, use and drop out of young adults in responding to the research questionnaires
4. To obtain an estimate of clinical impact of the site on low mood, stress/anxiety in younger adults

This information could then be used to inform the future delivery of the approach as part of a larger substantive RCT.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Glasgow MVLS College Ethics Committee, 1st March 2010, ref: FM03409.
Amendment approved 27th September 2012.

Study design

Pilot randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Patient information can be found at <http://www.worrygym.com/wp-content/uploads/2012/10/Participant-Information-Sheet-PDF.pdf>

Health condition(s) or problem(s) studied

Depression and anxiety

Interventions

An online course (Living Life) compared to a delayed access control who must wait 12 weeks before receiving access.

The study will test the delivery of an educational life skills package (Living Life). This contains two components a series of little e-booklets 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

The course teaches these key life skills and is based on a CBT model with a strong educational focus.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

This is a pilot study. Our primary outcome is the ability to recruit, retain and collect evaluation data.

Secondary outcome measures

We will gain an estimate of site use, satisfaction and an estimate of clinical effect on low mood and anxiety

Overall study start date

22/10/2012

Completion date

30/06/2013

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Young adults aged 17 years and above
2. Living within the United Kingdom
3. Mild to moderate low mood or stress identified by a PHQ9 score of 5-19

Participant type(s)

Patient

Age group

Child

Lower age limit

17 Years

Sex

Both

Target number of participants

A minimum of 40

Key exclusion criteria

1. Age < 17 years
2. Not UK based
3. PHQ9 score < 5 or > 19; as this would indicate participants experiencing higher levels of low mood or no significant distress at all. Those scoring highly for low mood will be directed to other sources of support more suitable to their needs and their GP will be informed.

Date of first enrolment

22/10/2012

Date of final enrolment

30/06/2013

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

Academic Unit of Mental Health and Wellbeing

Glasgow

United Kingdom

G12 0XH

Sponsor information**Organisation**

University of Glasgow (UK)

Sponsor details

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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

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