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Online cognitive behavioural therapy (CBT) for individuals with Christian beliefs

Submission date
25/02/2014

Recruitment status
No longer recruiting

Registration date
18/03/2014

Overall study status
Completed

Last Edited
02/03/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Mental health problems such as depression and anxiety are widespread. However, evidence-based psychological interventions are often difficult to access. Access can be improved with online self-help incorporating Cognitive behavioural therapy (CBT) techniques. Around 10% of the population attends church regularly. There can be stigma in such settings around attending mental health services. As such, an intervention for mental health problems targeted at this population may reach individuals who would otherwise miss out on evidence-based interventions. This study aims to test an online CBT intervention modified for use by Christians who want an intervention that explicitly incorporates and respects their faith. The content is modified from an existing online intervention: Living Life to the Full (LLTTF). This study aims to find out how effective this course is in improving mood and reducing levels of anxiety and to describe the sample demographics of interested participants.

Who can participate?
Individuals with Christian beliefs experiencing mild to moderate symptoms of depression or anxiety.

What does the study involve?
Consenting participants will complete questionnaires assessing mood, anxiety, social functioning, religiosity and beliefs about mental health. Participants will be randomly allocated to either use the course immediately or after a wait. Participants in the immediate treatment group will be given access to the intervention website. Remaining participants will be offered access after 8 weeks. At 8 weeks, participants will complete repeat measures of mood, anxiety and functioning. Participants who have had access to the course will be asked questions about its acceptability. At this point, remaining participants will be given access to the LLTTF website. After a further 4 weeks, the immediate treatment group will complete follow-up questionnaires again. Questionnaires will be offered online and by post. Data will be stored securely online through the survey hosting website, and then downloaded to a password-protected secure computer. Data will be anonymised before data analysis.

What are the possible benefits and risks of participating?
By taking part in the study, participants may learn new skills to help with symptoms of low

mood, anxiety or depression. In addition, their opinions about the resource will help us modify the approach so it is more suitable for other Christians who are experiencing symptoms of low mood, anxiety or depression. The purpose of resources such as this is to provide the most effective help for individuals with these psychological problems, and therefore future course users may benefit from participation. The intervention if found to be effective, it may reach a group of individuals who may not have previously had access to an evidence-based intervention. It may also be possible to enhance the intervention based on feedback regarding acceptability from participants. The risks could be that the questionnaires participants will be asked to complete before and after the study ask about symptoms of low mood, anxiety or depression. Whilst most people do not mind answering these questions, it may be upsetting for some people. 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.

Where is the study run from?
Participants will be recruited through advertisements in churches and university Christian Unions, Christian and secular mental health media, and an advertisement in the Metro newspaper, and is open to any interested parties. Design involves online recruitment, so although based at the University of Glasgow, recruitment will extend nationally.

When is the study starting and how long is it expected to run for?
February 2014 to July 2014

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

Who is the main contact?
Professor Chris Williams, University of Glasgow

Study website
http://www.moodhelp4churches.com

Contact information

Type(s)
Scientific

Contact name
Prof Chris Williams

Contact details
Institute of Health and Wellbeing
Administration Building
Gartnavel Royal Hospital
Glasgow
United Kingdom
G12 0XH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Online CBT for individuals with Christian beliefs: a pilot randomised controlled trial

Study objectives
The primary hypothesis of the study to be tested is that there will be a greater improvement in mood, anxiety levels and quality of life in participants completing an online, cognitive behavioural therapy course modified to specifically incorporate Christian beliefs than those in waiting list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of College of Medical Veterinary and Life Sciences at the University of Glasgow, 03/10/2013, ref: 200130015

Study design
Randomised waiting list controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://www.moodhelp4churches.com/4.html

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

Interventions

The intervention is a low intensity, online CBT resource aimed at individuals with Christian beliefs experiencing mild to moderate depression or anxiety, called 'Living Life To The Full With God'. The resource incorporates videos, presentations, e-books and worksheets and is modified from an existing widely used resource (Living Life to the Full). Participants will be randomised between this intervention and a waiting list control. The initial duration of the treatment will be 8 weeks, where both groups will complete follow up questionnaires. Further questionnaires will be completed by the treatment group after a further 4 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The following assessments will be completed at baseline and 8 week follow up, as well as 12 week follow up for the intervention group:
1. The Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001)
2. The General Anxiety Disorder-7 (GAD-7; Spitzer et al., 2007)
3. The Work and Social Adjustment Scale (WSAS; Mundt et al., 2002)

Secondary outcome measures
The Duke University Religiosity Index (Koenig & Bössing, 2010) will be completed at baseline, as well as demographic information, and novel questions relating to views on the relationship between religion and mental health.

Overall study start date
26/02/2014

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. The intervention is targeted at individuals experiencing mild to moderate symptoms of depression or anxiety who have Christian beliefs that they wish to be incorporated into a psychological intervention
2. Participants will be those who respond to advertisements for a course to help people experiencing these symptoms who may want their faith recognised in the intervention they receive

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
80

Key exclusion criteria
1. Active suicidal ideation
2. Current psychological therapy

Date of first enrolment
26/02/2014

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Gartnavel Royal Hospital
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
University of Glasgow (UK)

Sponsor details
Gartnavel Royal Hospital
Administration Building, 1st floor
1055 Great Western Road
Glasgow
Scotland
United Kingdom
G12 0XH

Sponsor type
University/education

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
Plan to submit to peer reviewed journal with planned publication Autumn 2017

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ben Wiffen (b.wiffen@nhs.net)

IPD sharing plan summary
Available on request