

Evaluation and treatment of low and anxious mood in Chinese speaking international students studying in Scotland

Submission date 30/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/06/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The research team at the University of Glasgow are carrying out a research project looking at low mood and stress in Chinese speaking international students. Low mood is a common mental health problem affecting up to 121 million people worldwide (World Health Organisation) and is common in students. Although approaches based on cognitive behavioural therapy (CBT) are known to be successful in a one-to-one setting, this can be expensive. We want to know if computerised CBT could be used as an alternative. We aim to find out whether it is possible to investigate an online CBT resource for Chinese speaking students at the University of Glasgow experiencing low mood and anxiety.

Who can participate?

International students who speak Chinese (Mandarin or Cantonese), aged 18 yrs or older, registered as students (undergraduate or postgraduate) at the University of Glasgow who will be living in the UK for the next two months and currently experiencing symptoms of mild to moderate symptoms of low mood and/or anxiety.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 start to use a self-help CBT website straight away. Those in group 2 start to use the website after a 3 month delay. This study helps the researchers to compare the groups at 3 and 6 months after they start the trial and see how many join the programme and then stick to it, whether the approach is acceptable to them and whether those who have used the resource have greater improvements in mood than those who have not yet used the website. During the study, participants are able to access online modules with video and audio that addresses various aspects of low mood and anxiety. They are informal and friendly sessions that aim to teach skills that may help to reduce feelings of stress and improve low mood. Participants are assigned a support worker to help them progress through the sessions and apply what they have learned.

What are the possible benefits and risks of participating?

By using the package it is hoped that participants may learn new skills to help with symptoms of

low mood, anxiety or depression. In addition participants' opinions about the package will help us modify the approach so it is more suitable for Chinese speaking international students who are experiencing symptoms of low mood, anxiety or depression. 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?

The study is being run by researchers at the University of Glasgow. Participants will use the self-help website at home.

When is the study starting and how long is it expected to run for
August 2014 to June 2015.

Who is funding the study?

The Provincial government in Zhejiang (China)

Who is the main contact?

Mengyi Zheng

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Study website

<http://help4lowmood.com/>

Contact information

Type(s)

Scientific

Contact name

Mr Chris Williams

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Evaluation and treatment of low and anxious mood in Chinese speaking international students studying in Scotland: a pilot randomised controlled trial

Study objectives

This is pilot study to test the recruitment, retention, data gathering and trial delivery of a RCT before-after design.

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, University of Glasgow, 07/07/2014, ref. 200120022.

Study design

A pilot study, pre-post design randomised controlled design with a delayed access control group.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

<http://help4lowmood.com/>

Health condition(s) or problem(s) studied

Low mood, depression and anxiety

Interventions

The student life skills training intervention: The study will test the delivery of an educational life skills package (Living Life Chinese version). The course teaches key life skills and is based on an existing CBT model with a strong educational focus. It contains a series of little e-books - 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

Each is accompanied by colourful worksheets. Simple/traditional Chinese versions of the materials are available and these will be presented as well as English language version. In addition some audio/text support modules will be available as Mandarin and Cantonese options as well as English language. Participants will receive automated weekly support emails that are automated. In the feasibility study we will explore the added support needs requested by users (phone, face to face or online support, English or Mandarin or Cantonese language support).

Control group: Students will receive access to the intervention after a 3-month delay. During these three months, participants in this group are advised to continue with their treatment as usual, whatever that may be, ex. antidepressant medication. We will not provide a usual care package while they wait.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

In this pilot study the primary outcome will be the take-up, drop-out and completion rates of the online course, and the collection rates for data.

Secondary outcome measures

Secondary outcomes will be mood ratings at 3 months. We will use changes in PHQ9 score to provide an impact of effect of the intervention on mood. This will give an indication of efficacy and will be used to obtain a power calculation for the future substantive RCT.

Overall study start date

01/08/2014

Completion date

01/06/2015

Eligibility

Key inclusion criteria

International students who speak Chinese (mandarin or Cantonese), participating in this study, more than 18 years of age, and are registered as students (undergraduate or postgraduate) at the University of Glasgow who will be living in the UK for the next two months. Currently experiencing symptoms of mild to moderate symptoms of low mood with the score 5 or more on the English language version of the PHQ9 depression questionnaire and/or a score of 5 or more on the English language version of the GAD7 anxiety score. These students need to have broadband web access, and also be willing and able to use the online course.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

We will randomise 50 students in total so that 25 have immediate access to the site and 25 are offered access after the end of the study (3 months).

Key exclusion criteria

Not fulfilling inclusion criteria, currently receiving specialist mental health treatment, or current psychotherapy/ counselling. Students who are on antidepressants are not excluded but we will record the tablet, dose and length of time on the prescription.

Date of first enrolment

01/08/2014

Date of final enrolment

01/06/2015

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

University of Glasgow

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

Government

Funder Name

Zhejiang Province Government (China)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No