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Comparing psychological interventions in order to find out what treatments are effective in helping students cope and manage with challenges to their mental health

Submission date
30/08/2018

Recruitment status
No longer recruiting

Registration date
07/09/2018

Overall study status
Completed

Last Edited
10/09/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Over the past 10 years there has been a significant increase in the number of university students who disclose a mental health condition. The most common mental health problem reported by university students is depression; one research study found that 30.6% of students report suffering from depression. In addition to depression, symptoms of stress and anxiety are also reported to have increased amongst university students.
With an increasing number of students struggling with their mental health, it is important that universities offer students the opportunity to attend services that are inexpensive and are proven to help. The current study hopes to further contribute to the evidence base on the wellbeing of university students and provide evidence about what therapies are/are not effective.

Who can participate?
Students at Cardiff University

What does the study involve?
Participants will be invited to take part in a study that offers the opportunity to attend a course of therapy. Participants who enrol onto the study will be randomly allocated to 1 of 3 conditions. In two of the conditions participants will receive a therapy which is 4 weeks long, 2 hours per week, and the third condition will comprise of a waitlist control group. The therapies that are being delivered are Acceptance and Commitment Therapy (ACT) and Cognitive Behavioural Therapy (CBT); These are psychological interventions that propose to help individuals with challenges to their mental health. Participants in the waitlist control group will be offered either ACT or CBT after the other two conditions and once the post intervention data has been collected. In order to for the researchers to be able to evaluate the effectiveness of the interventions (ACT and CBT), participants in each of the conditions will be asked to complete questionnaires and a series of eye tracking tasks at varying times intervals (Participants in all 3 conditions will be asked to complete questionnaires before, during and after the interventions

are delivered ; The eye tracking tasks will only be completed before and after the inventions are delivered).

What are the possible benefits and risks of participating?
It is hoped participants will learn psychological skills that will help them cope better with the stressors associated with university/everyday life. It is possible that participants may feel low in mood whilst completing questionnaires or attending the interventions and therefore the researchers involved in the study have the contact details of different mental health support services, including the student counselling service, which they will be able to give to students if they feel they need further support.

Where is the study run from?
Psychology Tower Building at Cardiff University (UK)

When is the study starting and how long is it expected to run for?
July 2018 to July 2019

Who is funding the study?
Cardiff University (UK)

Who is the main contact?
1. Dr. Cerith Waters (watersCS@cardiff.ac.uk)
2. Benjamin Annear (annearB2@cardiff.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Mr Benjamin Annear

ORCID ID
http://orcid.org/0000-0003-3557-1092

Contact details
School of Psychology
Cardiff University
Tower Building
70 Park Place
Cardiff
United Kingdom
CF10 3AT
0000
annearb2@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr Cerith Waters

Contact details
School of Psychology
Cardiff University
Tower Building
70 Park Place
Cardiff
United Kingdom
CF10 3AT
029 208 70709
WatersCS@cardiff.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
None

Study information

Scientific Title
Acceptance and commitment therapy and cognitive behavioural therapy for stress, anxiety and depression among university students: efficacy and mechanisms of action

Study objectives
The current study will use a randomised controlled trial (RCT) design comparing two group-delivered active treatment conditions, Acceptance and Commitment Therapy (ACT) and Cognitive Behavioural Therapy (CBT) with a wait-list control condition. There are no known studies that evaluate and compare the effectiveness of 4 week long ACT and CBT interventions among a University students presenting with stress, anxiety and depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cardiff University, School of Psychology Research Ethics Committee, 24/04/2018, EC. 18.03.13.5261R

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Stress, anxiety and depression

Interventions
Participants will be randomised using a web-based random number generator to the three conditions. Participants will receive either cognitive behavioural therapy (CBT), acceptance and commitment therapy (ACT) or will be allocated to a waitlist.
Those in the CBT group will receive a 4 week CBT psychoeducational intervention, based on the Living Life to the Full (LLFT) programme routinely delivered in Student Wellbeing and NHS primary care mental health services in Cardiff and the Bristol area. Each session is 2 hours in duration and is delivered by trained presenters (Assistant Psychologists trained in the NHS) under the supervision of a Chartered Clinical Psychologist.The CBT intervention teaches psychological coping skills in line with the cognitive behavioural therapy model. Participants are also requested to engage in weekly skills practice outside of the 2 hour session.
Those in the ACT group will receive the ACTivate your life (AYL) psychoeducation course. AYL is a group delivered psychoeducation course delivered over 4 consecutive weeks. Each session is 2 hours in duration and is delivered by trained presenters (Assistant Psychologists trained in the NHS) under the supervision of a Chartered Clinical Psychologist). AYL draws on fundamental ideas and therapeutic strategies from Acceptance and Commitment Therapy (ACT) and the course is designed to be engaging, clear and accessible, with many everyday examples used to illustrate core concepts. A series of psychological coping skills are taught each week. Course participants are requested to engage in weekly skills practice outside of the 2 hour session.
Participants randomly allocated to the waitlist control group will be on a ‘waiting list for therapy’. They will be asked to complete questionnaire measures at the same time intervals as the participants in the other conditions as this will enable comparisons between groups to be made. Once all of the data has been collected participants in the waitlist control group will then be invited to attend either ACT or CBT therapy.
Participants in each of the above conditions will be asked to complete the same questionnaires at the same time intervals. Participants will be asked to complete pre-intervention questionnaires within a 2 week period before starting therapy, the process measures each week during therapy and post intervention questionnaires 1, 5 and 12 weeks post therapy.
Participants will also be invited to complete eye-tracking tasks 1 month before therapy and within a 2 week period post therapy.

Intervention Type
Other

Primary outcome measure

The following will be assessed 1 week prior to the intervention, immediately prior to each intervention session and at 1, 5 and 12 weeks after the intervention:
1. Psychological distress, assessed using the General Health Questionnaire 12 (GHQ-12)
2. Symptoms of depression, assessed using the Patient Health Questionnaire (PHQ-8)
3. Levels of anxiety, assessed using the Generalised Anxiety Disorder Assessment (GAD-7)

Following the delivery of the 4 week ACT or CBT intervention participants will be invited to participate in a 30 minute telephone interview about the aspects of the intervention that they found helpful or unhelpful.

Secondary outcome measures
Measures 1-10 will be assessed 1 week prior to the intervention, immediately prior to each intervention session and at 1, 5 and 12 weeks after the intervention:
1. Capacity to be mindful, assessed using the 15 item Five Facet Mindfulness Questionnaire (FFMQ)
2. Psychological flexibility, assessed using the Acceptance and Action Questionnaire II (AAQ-II)
3. ACT processes assessed using the Comprehensive Assessment of Acceptance and Commitment Therapy Processes (CompACT)
4. Cognitive fusion, assessed using the Cognitive Fusion Questionnaire (CFQ)
5. How attuned participants are to living by their values, assessed using the Valuing Questionnaire (VQ)
6. Self-efficacy, assessed using the General Self-Efficacy Scale (GSE)
7. Symptoms of ADHD, assessed using the 18-item Adult Self Report Scale (ASRS)
8. Readiness for change, assessed using the University Rhode Island Change Assessment Scale (URICA)
9. Negative automatic thoughts, assessed using the Automatic Thoughts Questionnaire (ATQ)
10. Disinhibition and sadism, assessed using the Triarchic Psychopathy Scale
11. Pupillary dilation, assessed using eye tracking technology (with a TX-120 Tobii eye tracker) during standard attentional tasks (Attention Network Task, diminishing values, Sustained Attention to Response test) 1 week prior to the intervention and 1 week following the intervention
12. How often participants completed the set 'homework' over the previous week, assessed by asking participants to complete a homework scale between each intervention session
13. Patient satisfaction with the intervention, assessed using an adapted version of the Helping Alliance Questionnaire II (HAQ-II) following the end of the intervention
14. An adapted version of the client/patient satisfaction scale will be used to at the end of the intervention to give participants the opportunity to evaluate the service they received

Overall study start date
01/07/2018

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. Students at Cardiff University
2. Aged 18 and over

3. Able to give informed consent
4. Able to read, write and understand English
5. Individuals with normal or corrected vision will be invited to take part in the eye tracking tasks

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 participants in each intervention condition = 120 participants in total for feasibilitiy

Key exclusion criteria
Staff members at the University are not able to participate

Date of first enrolment
20/09/2018

Date of final enrolment
23/10/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Psychology Tower at Cardiff University
School of Psychology
Cardiff University
Tower Building
70 Park Place
Cardiff
United Kingdom
CF10 3AT

Sponsor information

Organisation
Cardiff University

Sponsor details
School of Psychology
Cardiff University
Tower Building
70 Park Place
Cardiff
Wales
United Kingdom
CF10 3AT
+44(0)2920874007
WatersCS@cardiff.ac.uk

Sponsor type
University/education

Website
http://psych.cf.ac.uk/aboutus/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Not defined

Funder Name
School of Psychology, Cardiff University

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
The findings of the current research will advance the evidence base that informs student counselling and psychological wellbeing services. The findings will be published in peer review journals and presented at national and international conferences.

Intention to publish date
30/03/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration