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Student psychological intervention trial

Submission date
05/12/2022

Recruitment status
No longer recruiting

Registration date
06/01/2023

Overall study status
Completed

Last Edited
29/03/2023

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
A number of recent studies have documented the increasing incidence of depression, anxiety and other psychological disorders among the student population. Although many students reported mental health problems, a low percentage of these students were willing to seek help using the on-campus counselling service or other available options. Research has suggested that there may be a reluctance among students, due to embarrassment, fear of stigma or a lack of awareness of their problems. Online interventions may facilitate help-seeking among young people, as they are mostly anonymous and private, which may reduce the stigma associated with seeking help. Furthermore, many students report a preference for self-management when it comes to dealing with mental health problems, therefore the self-directed nature of online interventions may be appealing. Recently, online therapeutic programmes, based on the principles of cognitive behavioural therapy (CBT), have shown promise in improving psychological wellbeing. The primary aim of this study is to determine whether a new guided, online therapy programme is effective in improving the wellbeing of students at college and university.

Who can participate?
Students aged 18 years old and over registered at Ulster University or Letterkenny Institute of Technology

What does the study involve?
This study will involve a telephone interview, conducted by a trained researcher, and participants will be sent a link to an online mental health questionnaire. Participants will be randomly assigned to one of two groups: treatment as usual (TAU) only, or TAU plus a web-based intervention. If assigned to the intervention group, they will be given access to the web-based intervention. If they are part of the TAU group, they will be provided with information about the care available at their institution (UU/LYIT) and encouraged to contact them to avail of the services. Following the intervention or TAU, participants will be sent a link to the online post-treatment questionnaires and asked to complete follow-up questionnaires at 6 and 12 months after beginning the study. At 12 months they will be asked to take part in a follow-up phone interview. Some students may also be asked to consider taking part in a focus group to establish the factors that influence uptake, adherence and the success of the intervention in targeting depression and anxiety.

What are the possible benefits and risks of taking part?
It is hoped that students will benefit from the intervention, with their symptoms of depression and/or anxiety reduced. Furthermore, the information gained will provide valuable information on the effectiveness of online interventions for treating depression and anxiety. There is minimal risk associated with taking part in this study. There is a very small risk that students could become distressed during the study. If they become distressed or upset or anxious, this will be communicated to student support services.

Where is the study run from?
Ulster University (UK) and Letterkenny Institute of Technology (Ireland)

When is the study starting and how long is it expected to run for?
January 2020 to March 2023

Who is funding the study?
Cross-border Healthcare Intervention Trials In Ireland Network (CHITIN) is a unique cross-border partnership between the Public Health Agency in Northern Ireland and the Health Research Board in the Republic of Ireland, to develop infrastructure and deliver Healthcare Intervention Trials (HITs). The HITs will help prevent and cure illness and promote improved health and wellbeing in Northern Ireland (NI), the Republic of Ireland (ROI) and Irish cross-border areas. The CHITIN project is funded by the EU's INTERREG VA programme of €10.6m (including a 15% contribution from the Department of Health in NI and ROI) awarded to the HSC Research & Development Division of the Public Health Agency NI and to the Health Research Board in ROI for the CHITIN project.

Who is main contact?
Dr Elaine Murray (Principal Investigator), e.murray@ulster.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
271769

Study information

Scientific Title
A randomised controlled trial of an online cognitive behavioural therapy-based guided intervention for college students with mild to moderate levels of depression and/or anxiety

Acronym
SPIT

Study objectives
The online guided cognitive behavioural therapy (CBT)-based guided intervention reduces symptoms of anxiety and/or depression in students compared to treatment as usual

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2020, Ulster University Research Ethics Committee (Research Governance, Ulster University, Room BD-04-005, 2-24 York Street, Belfast, BT15 1A, UK; +44 (0)28 9536 5028; researchgovernance@ulster.ac.uk), ref: 20/REC/0007

Primary study design
Interventional

Study design
Multicentre randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of anxiety and/or depression in college students

Interventions
Randomization for the RCT will be conducted after informed consent is obtained and it is ascertained the participants meet the inclusion criteria. A researcher independent of the study will generate the random sequence using Sealed Envelope, an online randomisation tool.

Intervention group
Students who are assigned to the intervention arm will be given access to the web-based intervention which will be available to them 24/7. The intervention is a CBT-based guided intervention which aims to reduce symptoms of mild/moderate levels of depression and/or anxiety. Participants will receive seven weekly online sessions based on the principles of CBT:
1. Reducing incongruence
2. Tackling problems
3. Psychoeducation
4. Cognitive restructuring
5. Challenge management
6. Challenges in daily routine practice
7. Plan for the future

An additional session will be administered after the completion of the 7th online session to review the techniques learned, evaluate how they have been able to apply them, and consider how to maintain the benefits. All sessions consist of text, exercises and audio-visual components and last between 45 and 60 minutes. In addition to the online sessions, participants will have access to a diary, calendar, homework assignments, and the messaging system, with written support provided by trained guides via the messaging function of the intervention platform.

Control group/Treatment as usual (TAU)
Students in the TAU group will receive details about the standard care available at the respective institution (UU/LYIT) and they will be encouraged to avail of these services.

All participants will have unrestricted access to usual care services, such as on-campus well-being advisors, GP visits, and specialised mental health care.

At the post-treatment (one week after the last session of the intervention) students in each group will be sent an email with a link to the online post-treatment questionnaires (PHQ-9, GAD-7 anxiety scale, EQ-5D and CSQ-8). Groups will complete follow-up assessments at 6 and 12 months (PHQ-9, GAD-7 and EQ-5D). At 12 months students will also repeat the MINI interview by phone. Follow-up saliva and/or blood samples will be taken at the three post-treatment assessments. Students who complete both the post-treatment and follow-up assessments will be offered a Smartwatch activity tracker to the value of 30 euros.

Intervention Type
Behavioural

Primary outcome(s)
Depression scores measured using the Patient Health Questionnaire-9 (PHQ-9) and anxiety scores measured using the Generalised Anxiety Disorder Assessment (GAD-7) both at baseline, 1-week post-intervention and 6 months post-intervention

Key secondary outcome(s)
1. Health-related wellbeing measured using the EuroQol five-dimension scale questionnaire (EQ-5D) at baseline, 1-week post-intervention and 6 months post-intervention
2. Client satisfaction with treatment measured using the Client Satisfaction Questionnaire (CSQ-8) at baseline, 1-week post-intervention and 6 months post-intervention

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1. Students who experience mild to moderate depression (score above 4 on the PHQ-9) and/or anxiety symptoms (score above 4 on the GAD-7)
2. Currently registered at Ulster University or Letterkenny Institute of Technology
3. Over 18

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
71

Key exclusion criteria
1. Participants under the age of 18
2. Students who reside outside the UK or Ireland
3. Students with co-morbid bipolar disorder, psychotic disorders or high risk of suicide assessed by the MINI International Neuropsychiatric Interview (MINI)
4. Students with severe depression (score above 14 on the PHQ-9) and/ or anxiety symptoms (score above 14 on the GAD-7 scale)
5. Those currently receiving/ having received psychological treatment for depression and/or anxiety in the past 12 months

Date of first enrolment
03/03/2021

Date of final enrolment
11/03/2022

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Ireland

Study participating centre
Ulster University
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Study participating centre
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Sponsor information

Organisation
University of Ulster

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
Interreg

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	30/09/2020	22/12/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes