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Assessment of the effectiveness and acceptability of an online intervention for adapting well in the face of adversity, trauma, tragedy, threats or significant sources of stress

Submission date
03/02/2019

Recruitment status
No longer recruiting

Registration date
20/03/2019

Overall study status
Completed

Last Edited
01/07/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
College students have a high prevalence of depression and anxiety. Starting at college is considered a stress factor. Therefore, it is particularly relevant to develop interventions specifically addressed to students to foster supportive environments and resilient communities. This study aims to assess the effectiveness and acceptability of an Internet-based intervention programme for adapting well in the face of adversity, trauma, tragedy, threats or significant sources of stress (resilience), based on princliples of positive psychology to promote resilience and well-being among college students.

Who can participate?
Any registered student at the University of Dublin, Trinity College Dublin over 18 years of age can participate

What does the study involve?
We will compare the Internet-delivered intervention with human support; the Internet-delivered intervention with automated support; and a waiting-list control group who will receive the Internet-delivered intervention after the first 8 weeks of the study

What are the possible benefits and risks of participating?
Participation in a psychological intervention (the efficacy of which is currently unknown) and disclosure of information of a sensitive nature may be upsetting for some participants, therefore potentially posing a risk of psychological distress. However, it is not anticipated that the study will involve any physical harm to participants. If a member of the research team or a supporter are made aware of any physical harm, they will remind the participant that they do not have to continue participating in the study, ascertain whether the participant would like to continue participating and provide them with a list of support services.
Participants will benefit from the programme as part of promoting a mentally healthy lifestyle as a relevant component to promote resilience. These components included interactive tools to

aim is to increase self-compassion and self-esteem, to improve social relationships and communication style. Also, the participants can benefit from exercises of gratitude and balanced optimism. The programme intervention is based in positive psychology, and also include physical aspects of resilience: exercise, sleep and diet.

Where is the study run from?
Student Counselling Service, Trinity College Dublin, Dublin, D02 PN40

When is the study starting and how long is it expected to run for?
The study will start in February 2019 and run for approximately 6 weeks

Who is funding the study?
SilverCloud Health (Ireland)

Who is the main contact?
Dr. Derek Richards, drichard@tcd.ie

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AEIR2019

Study information

Scientific Title
Assessing the efficacy and acceptability of an Internet-delivered intervention for resilience: a pilot study for a randomised control trial

Acronym
AEIR

Study objectives
The current study sought to examine the acceptability and efficacy of an internet-delivered programme for resilience with automated or human support compared to a waiting list group in a sample of college students. The hypothesis is that the intervention Space for Resilience programme would be efficacious, with significant changes within the treatment group and differences post-treatment between the active treatment groups (human support group and automated support group) and the waiting list control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/01/2019, Trinity College Dublin School of Psychology REC (Room 1.42, Trinity College Dublin, College Green, Dublin 2, Ireland; +353(0)1896 2428; psych.ethics@tcd.ie), ref: SPREC112018-12

Study design
The study is a randomised controlled trial to examine the efficacy and acceptability of the Internet-delivered intervention for resilience. Participants will be randomised into three groups: (a) the internet-delivered intervention with human support, (b) the internet-delivered intervention with automated support and (c) a waiting-list control group.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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
Resilience, which is defined in this study as a dynamic mental health adaptation, which individuals are able to face and recover from significant distress or trauma.

Interventions
The present research will use a three-armed pilot randomised controlled trial (RCT) design. Independent variables include group (K=3; intervention with automated support, intervention with human support and waiting list control group) and time of testing (K=2; pre-intervention and post-intervention).

Human support: Participants in the intervention with human support group will be assigned to a supporter from the TCD student counselling service. Supporters will be receive training in how to use the SilverCloud Health platform and the intervention programme prior to starting their role as a supporter and will be supervised by an experienced clinical psychologist. The role of the supporter is to motivate participants and provide asynchronous feedback to programme users. Participants in the human support group will receive fortnightly support from their supporter via the platform

Automated support: Participants in the automated support group will receive support through automated e-mails sent over the course of the eight weeks. This will include a welcome message and information on modules and tools Participants in the automatic support group will receive fortnightly automatic messages by email.

Waiting list control group: Participants in the waiting list control group will begin the intervention after eight weeks when participants in the active treatment groups (intervention with human or automated support) have completed the intervention

Intervention Type
Behavioural

Primary outcome measure
1. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC) at baseline and post-treatment (8 weeks)
2. Happiness measured using the Pemberton Happiness Index (PHI) at baseline and post-treatment (8 weeks)

Secondary outcome measures
1. Gender, age, education, occupation, socioeconomic status, and clinical history measured using the Sociodemographic & History Questionnaire at baseline.
2. Depression measured using the Patient Health Questionnaire – 4 items (PHQ-4) at baseline and post-treatment (8 weeks)
3. Self-esteem measured using the Rosenberg Self-Esteem Scale (RSE) at baseline and post-treatment (8 weeks)
4. Stress measured using the Perceived Stress Scale – 4 items (PSS-4) at baseline and post-treatment (8 weeks)
5. Satisfaction with treatment measured using the Satisfaction with Treatment (SAT) scale at baseline and post-treatment (8 weeks)

Overall study start date
05/10/2018

Completion date
05/05/2019

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Registered student at the University of Dublin, Trinity College Dublin

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

Total final enrolment
82

Key exclusion criteria
1. Psychotic or bipolar disorder
2. Risk of suicide
3. Currently in psychotherapy

Date of first enrolment
04/02/2019

Date of final enrolment
13/03/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Trinity College Dublin
Student Counselling Service, Trinity College Dublin
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Sponsor information

Organisation
SilverCloud Health

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Sponsor type
Industry

Website
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ROR
https://ror.org/05319p535

Funder(s)

Funder type
Industry

Funder Name
SilverCloud Health

Results and Publications

Publication and dissemination plan
Trial protocol publication, main results publication, conferences and webinars.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/11/2020	14/01/2021	Yes	No
Protocol article		01/09/2019	01/07/2022	Yes	No