# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
03/02/2019		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
20/03/2019	Completed	[X] Results	
<b>Last Edited</b> 01/07/2022	Condition category  Mental and Behavioural Disorders	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

#### Contact name

Dr Derek Richards

#### **ORCID ID**

https://orcid.org/0000-0003-0871-4078

#### Contact details

E-mental Health Research Group School of Psychology Trinity College Dublin Dublin Ireland D08 DR9P +353(0)879343678 drichard@tcd.ie

#### Type(s)

**Public** 

#### Contact name

Dr Angel Enrique

#### ORCID ID

https://orcid.org/0000-0003-0585-4008

#### Contact details

E-mental Health Research Group School of Psychology Trinity College Dublin Dublin Ireland D02 PN40 +353(0)879343678 enriquea@tcd.ie

# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

**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

#### Study type(s)

Prevention

#### 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(s)

- 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)

# Key secondary outcome(s))

- 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)

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

# Sponsor information

### Organisation

SilverCloud Health

#### **ROR**

https://ror.org/05319p535

# Funder(s)

#### Funder type

Industry

#### Funder Name

SilverCloud Health

# **Results and Publications**

#### 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			01/07/2022 Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes