

Measuring the effectiveness of brief web-based acceptance and commitment therapy to improve psychological well-being in college students

Submission date 11/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/06/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/09/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The college years are often thought of as being a carefree time in a young person's life, however, research suggests that attending university for the first time can also cause a person a great deal of stress. Wellness or other support programs for students are one way that universities are trying to prevent and alleviate psychological (mental) distress, but most of these programs focus on physical methods such as exercise or relaxation over other techniques which focus more directly on mental health. A possible approach which could be effective is using an internet-based programme to deliver treatment (online interventions). Online interventions are thought to be a good part of a university wellbeing programme since it is cost-effective and doesn't trigger the negative judgement of others (stigmatisation), as it would be available to all without pre-identifying those at risk of mental health problems. This study will look at a type of therapy called acceptance and commitment therapy (ACT). ACT is a type of taking therapy which uses acceptance and mindfulness (a way of observing experiences in the present moment, without judgment) strategies, together with commitment and behaviour change strategies, to help a person to deal with difficult situations they may face. The aim of this study is to find out whether an internet-based ACT programme could have a positive impact on the mental health of undergraduate students.

Who can participate?

Healthy university or college students aged 18 years and over.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group listen to three ACT mindfulness-based recordings at least once a week for three weeks. The recordings vary in length but all last for less than 30 minutes. Those in the second group are placed on a waiting list and continue as normal during the study period. At the start of the study and then again one week after the first group has completed the programme and three weeks later, participants in both groups complete a number of online questionnaires about their mental wellbeing.

Following this, participants in the waiting list group are given access to the ACT mindfulness programme.

What are the possible benefits and risks of participating?

Participants who take part in the ACT mindfulness programme may benefit from an improvement to their general mental health. There are no notable risks involved with participating in this study.

Where is the study run from?

University College Dublin (Ireland)

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

December 2012 to June 2013

Who is funding the study?

University College Dublin (Ireland)

Who is the main contact?

Miss Sinead Hartley

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled trial of brief web-based Acceptance and Commitment Therapy on the psychological well-being of college students

Acronym

ACT

Study objectives

The aim of this study is to provide preliminary evidence for the effectiveness of a brief web-based ACT intervention that targets mindfulness (using the ACT mindfulness components: contact with the present moment, acceptance, cognitive defusion, and self as context), on the mental health of college students.

Hypothesis:

The ACT intervention will show superior effects in increasing general mental health, and in reducing psychological distress, compared with a waiting list as a control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Taught Graduate Research Ethics Committee - School of Psychology, University College Dublin, 15/01/2013

Study design

Single-centre wait-list randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Psychological well-being

Interventions

Participants are randomly allocated to one of two groups.

Treatment group: Participants are required to listen to a sequence of three online ACT mindfulness-based audios at least once over a three-week period. The first exercise, "Awareness of breathing" (23 minutes), aims to promote the on-going non-judgmental contact with psychological and environmental events as they arise. The second ACT mindfulness exercise, "Leaves on a stream" (13 minutes), encourages a non-judgemental approach to the language of thoughts, and targeted acceptance. The third audio, "The observing self" (16 minutes), targets self-concepts and conceptualisations of self.

Wait-list control group: Participants continue as usual for the duration of the three-week intervention. Participants are given access to an identical treatment condition after the experimental group has concluded the study (three weeks post-intervention).

One week following the intervention, all study participants are emailed and asked to complete post-treatment questionnaires (GHQ-12, DASS-21, AAQ-II) via a direct link. Three week follow-up questionnaires (GHQ-12, DASS-21, AAQ-II) are administered via an emailed direct link to all participants once post-treatment measures are completed. Participation in the study is concluded for those in the treatment condition once 3-week follow-up responses are received.

Intervention Type

Behavioural

Primary outcome measure

Psychological well-being is measured using the General Health Questionnaire (GHQ-12) at baseline, one week post-intervention and three weeks follow up.

Secondary outcome measures

Psychological Distress is measured using the depression, anxiety and stress subscales of the Depression Anxiety Stress Scales (DASS-21) at baseline, one week post-intervention and three weeks follow up.

Overall study start date

01/12/2012

Completion date

01/06/2013

Eligibility

Key inclusion criteria

1. Aged 18 and over
2. Currently registered as a university or college student
3. No formal diagnosis of mental health disorders
4. No previous experience of mindfulness or mindfulness-based exercises
5. Computer literate

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Participants are 113 adults aged 18 years or over (M: 25.06; SD: 10.06) with a male to female ratio of 24:89. An initial sample of 224 people was assessed for eligibility and 50 (22%) were excluded. A further 61 participants (35%) withdrew or did not respond following randomisation.

Key exclusion criteria

1. Any previous formal diagnoses of mental health disorders
2. Any previous experience of mindfulness or mindfulness-based exercises
3. Less than 18 years of age
4. Not currently registered as a university or college student (i.e. at third-level education)

Date of first enrolment

01/02/2013

Date of final enrolment

01/05/2013

Locations**Countries of recruitment**

Ireland

Study participating centre

University College Dublin

Belfield

Dublin

Ireland

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Sponsor information**Organisation**

University College Dublin

Sponsor details

School of Psychology
Newman Building
Belfield
Dublin
Ireland
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Sponsor type

University/education

Website

<http://www.ucd.ie/psychology>

ROR

<https://ror.org/05m7pjf47>

Funder(s)

Funder type

University/education

Funder Name

University College Dublin

Results and Publications

Publication and dissemination plan

Planned publication in the journal BMC Psychology.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request