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Internet Delivered Treatment for generalized Anxiety symptoms in students

Submission date	Recruitment status	[X] Prospectively registered
18/06/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The percentage of the world population affected with anxiety disorders is considered to be high, affecting about 14% of the population of Europe each year. High levels of anxiety disorders have been reported in third level students, affecting 25-30% of this population. In the adult student population in Ireland, 36% suffer from anxiety and 30% from stress. The transition and management of academic demands at third level places great pressures upon students. These together with external circumstances such as the increase in the student monetary contribution to third level places demands on students to do well. The absence of resources can often mean that many do not seek treatment, which can lead to failure and dropout that can negatively impact on their future performance and self-image. Other factors that delay access include, for instance, a lack of trained professionals, personal stigma and waiting lists. Anxiety disorders can be treated successfully, and brief forms of cognitive behaviour therapy have been recommended. One possibility is to deliver low-intensity interventions online. Internet use in Ireland is high and young adults are regular users. Therefore, the current study seeks to investigate the effectiveness of an online self-administered treatment for generalized anxiety, with support.

Who can participate?
Students at the University of Dublin, Trinity College (Dublin, Ireland) with symptoms of generalized anxiety disorder can participate.

What does the study involve?
Students will be randomly allocated to one of the two groups:
1. Active treatment group: a computerized cognitive behavior program consisting of six sessions, with support.
2. Waiting list control group: the participants in this group will not receive any treatment for the duration of the intervention for the active treatment group. They will have to wait until the beginning of the second semester of the academic year (January) to receive the computerized cognitive behavior program.
All participants will receive the same treatment.

What are the possible benefits and risks of participating?
There may be improvements in anxiety and health status.

Where is the study run from?
We will aim to recruit a sample of 100 participants. All participants will be recruited from the student body at the University of Dublin, Trinity College (Dublin, Ireland).

When is the study starting and how long is it expected to run for?
We hope to begin recruitment in October 2013 and thereafter the trial will run until April 2014. The first 6 weeks will be with an active treatment group and a waiting list control. Thereafter waiting list control participants will begin treatment in the second semester of the academic year (January).

Who is funding the study?
SilverCloud Health Ltd and Trinity College Dublin student counselling service.

Who is the main contact?
Dr Derek Richards,
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Contact information

Type(s)
Scientific

Contact name
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Study information

Scientific Title
Internet-Delivered Treatment for generalized Anxiety symptoms in routine care: Protocol for a randomized controlled trial

Acronym
IDTA

Study objectives

High levels of anxiety disorders have been reported in third level students, affecting 25-30% of this population. In Ireland clinical anxiety has been reported at 36% and clinical stress at 30% of the adult student population. Given the presence of elevated levels of psychopathology (anxiety, stress, depression) in the student population there is a need for interventions. Current psychological services are overstretched and many barriers, such as costs, and personal stigma, exist that prevent people seeking help when they need it. These together with external circumstances such as the reintroduction of college fees places great demands on students to do well. Brief psychological interventions, particularly Cognitive Behavior Therapy (CBT), have demonstrated their efficacy and have the potential to significantly reduce the burden of anxiety disorders. One potential avenue for research and development is that of delivering low-intensity interventions online. Students are a computer literate group and high users of the internet and related tools. The bulk of the evidence-base for the efficacy and effectiveness of low-intensity internet-delivered treatments for anxiety has been established through research trials although some research from service-based settings exist. Based on the success that has been achieved with supported online treatments we hypothesize that participants in the trial will demonstrate significant decreases in anxiety symptoms post-intervention and a corresponding positive change in quality of life. The current study seeks to make a contribution to understanding the relevance of a low-intensity internet-delivered treatment for anxiety in a service-based naturalistic setting in Ireland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Psychology, Trinity College Dublin - Approval pending

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Generalized anxiety disorder

Interventions
Internet intervention for generalized anxiety symptoms in routine primary care.

1. An active treatment group:
The active condition consists of 6 modules of internet-delivered CBT, over 6 weeks, with clinical support providing weekly feedback on progress and exercises. The intervention teaches the principles of CBT and also different cognitive and behavioral strategies that participants can learn to help manage their anxiety. The content includes cognitive restructuring, behavioral exposure, worry exposure (staying with feared outcomes), relaxation training, problem solving, among others. CBT for GAD has as its aim to help the user overcome emotional avoidance and learn that their anxiety is not debilitating, but can be managed and indeed recede over time.

2. A waiting list control.
Participants in the waiting list control group will not receive any treatment for the duration of the intervention for the immediate treatment group (6 weeks). Post-treatment the waiting list participants will continue for 6 weeks after which point they will be given access to treatment under the same conditions as the immediate treatment group received. The rationale for waiting-list participants to have to wait 6 weeks post-treatment before beginning the intervention is that we are following the academic calendar. That means, that the first treatment group will be recruited for October and finish treatment at the beginning of December. At that point many students are sitting exams, also there is a large Christmas break where many students leave. Students at this time are therefore occupied with exams and then take a break, both of which would interrupt treatment or potentially interfere with the treatment offered. It seems reasonable therefore to begin the waiting-list in treatment at the beginning of the new semester (January).

The study seeks to observe and evaluate the effect of the treatment on changes in anxiety symptoms in participants. Data will be collected at baseline and at the end of treatment, week 6 and at follow-up, week 12 (3-months) and week 24 (6-months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Anxiety symptoms: Generalized Anxiety Disorder 7 Items (GAD-7) measured at baseline and at the end of treatment, week 6 and at follow-up, week 12 (3-months) and week 24 (6-months).

Key secondary outcome(s)
1. Sociodemographic and History questionnaire
2. Penn State Worry Questionnaire (PSWQ)
3. Center for Epidemiologic Studies Depression Scale (CES-D)
4. Work and Social Adjustment Scale (WSAS)
5. Credibility and Expectancy Questionnaire (CEQ)
6. Helpful Aspects of Therapy Form (HAT)
7. Satisfaction with Treatment (SAT)
8. Reasons for dropout

All above outcomes measured at baseline and at the end of treatment, week 6 and at follow-up, week 12 (3-months) and week 24 (6-months).

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. At least 18 years of age, either sex
2. Significant DSM-IV congurent generalized anxiety symptoms (GAD-7 ≥10)

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
137

Key exclusion criteria
Currently in face-to-face counselling for anxiety

Date of first enrolment
01/10/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
Ireland

Study participating centre
University of Dublin
Dublin
Ireland
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Sponsor information

Organisation
University of Dublin (Ireland)

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Industry

Funder Name
SilverCloud Health Ltd. (Ireland)

Funder Name
Trinity College Dublin (Ireland) - provided student counselling service

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2016	18/02/2021	Yes	No
Protocol article	protocol	27/04/2014		Yes	No