The UvAcare project: Examining the effectiveness of a web-based intervention for symptoms of depression and/or anxiety in university students.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26795

Source
Nationaal Trial Register

Brief title
N/A

Health condition

All university (PhD) students at the University of Amsterdam (UvA) with at least mild to moderate symptoms of depression and/or anxiety.

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: University of Amsterdam

Intervention

Outcome measures

Primary outcome

The primary outcomes of the RCT are the patient health questionnaire (PHQ-9) for depression and the Generalised Anxiety Disorder – 7 items scale (GAD-7) for anxiety. By using a mixed linear model analysis we will analyse the outcome measures.

Secondary outcome

The following secondary outcome measures are included in the RCT: drug and alcohol use (DAST-10 and AUDIT-C), client satisfaction with treatment (CSQ), academic achievement (PSS) and self-reported number of European Credit Transfer System (ECTS), Quality of life (EQ-5D), and medical service use (TiC) questionnaires were included to examine the (cost-) effectiveness of the intervention. Treatment adherence was measured with the average number of sessions completed, the number of participants that completed all sessions, time spent per module, and the number of times the participant logged onto the platform. Finally, some potential predictors of outcome are assessed at baseline, i.e., social anxiety (Mini Spin and SIAS-6) and perfectionism (DEQ-SC).

Study description

Background summary

College years are considered to be a peak period for the first onset of common mental disorders. Recent studies have shown that 12 to 50% of university students experience one or multiple psychological symptoms. Mental health is associated with physical, interpersonal and cognitive impairments. Universities can use electronic media to screen for students with mental disorders and also offer treatment for those in need. The aim of the present study is to conduct a three-armed randomised controlled trial (RCT) to assess the effectiveness of a therapist-guided or computer-guided web-based transdiagnostic intervention in treating university students and PhD students with depression and/or anxiety. Participants will be young adults (≥ 16 years) enrolled as Bachelor, Master or PhD students at the University of Amsterdam. Those who experience symptoms of depression and/or anxiety will be invited to participate in the RCT. The intervention will be either a therapist-guided or computer-guided online transdiagnostic intervention targeting symptoms of depression and/or anxiety. The intervention consists of 7 online sessions. A booster session will be administered four weeks after the completion of the 7th online session. These two conditions will be compared to one another and to care-as-usual (CAU). The primary outcome of the RCT are the patient health questionnaire (PHQ-9) for depression and the Generalised Anxiety Disorder scale (GAD-7) for anxiety. The GAD-7 and PHQ-9 scales will be administered at baseline, mid-intervention, post-intervention and at 6 and 12-month (post-baseline) follow-up. In addition, every week (in the CAU condition) or before each treatment session (in both guided conditions), selected items to measure anxiety, depression, and suicidal risk will be administered to monitor changes in severity.

Study objective

College years are considered to be a peak period for the first onset of common mental disorders. Recent studies have shown that 12 to 50% of university students experience one or multiple psychological symptoms. Mental health is associated with physical, interpersonal and cognitive impairments. Universities can use electronic media to screen for students with mental disorders and also offer treatment for those in need.

The aim of the present study is to conduct a randomised controlled trial (RCT) to assess the effectiveness of a therapist-guided or computer-guided web-based transdiagnostic intervention, compared with a care-as-usual control condition, in treating university students and PhD students with depression and/or anxiety.

Study design

Baseline measurement (t1), mid-intervention (5 weeks after baseline; t2), post-treatment (8 weeks after baseline; t3), follow-up 6 months after baseline (t4), follow-up 12 months after baseline (t5).

At all time points, the following measurements will be assessed: GAD-7, PHQ-9, EQ-5D (except for time point 2), Mini Spin, SIAS-6, DAST-10, AUDIT-C, and PSS (except for time point 2).
At time point 1 only, the MINI psychiatric interview, as well as the DEQ-SC will be administered.
At t3, the CSQ and the medical service use (TiC) questionnaires will be assessed. The TiC will also be assessed at time points 4 and 5.
Additionally, all participants receive a short questionnaire including questions about depression, anxiety and suicidal risk every week during the intervention (prior to each session).

Intervention

The intervention will be either a therapist-guided or computer-guided web-based transdiagnostic intervention targeting symptoms of depression and/or anxiety. Both the therapist-guided or computer-guided intervention consist of 7 online sessions. A booster session will be administered four weeks after the completion of the 7th online session. These two types of the intervention will be compared to one another, and to the active control group that receives care-as-usual (CAU).

Contacts

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Eligibility criteria

Inclusion criteria

• Being enrolled as a student or PhD student at the University of Amsterdam (UvA).

• Being 16 years or older

• Students who experience mild, moderate, or severe symptoms of depression (as defined by scoring above the cut-off score of 15 and within the range of 15 to 60 points on the Center for Epidemiological Studies Depression Scale [CES-D]) and/or anxiety (as defined by scoring above the cut-off score of 4 on the Generalised Anxiety Disorder scale - 7 items [GAD-7]).

Exclusion criteria

• Co-morbid recent or current bipolar disorder and/or psychotic disorder according to the Mini-Neuropsychiatric Interview (MINI).

- Active high risk for suicide
• Currently receiving psychological treatment for depression and/or anxiety.

• Having slow or no internet connection (e.g. no broadband internet or something comparable).

• No informed consent before participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	31-01-2019
Enrollment:	276
Type:	Unknown

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	10-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7328
NTR-old	NTR7544
Other	METC AMC : 2018_085

Study results

Summary results

Van der Heijde, CM., Vonk, P., Meijman. FJ. (2015). Self-regulation for the promotion of student health. Traffic lights: the development of a tailored web-based instrument providing immediate personalized feedback, Health Psychology and Behavioral Medicine, 3:1, 169-189, DOI: 10.1080/21642850.2015.1049950

Blankers, M., Salemink, E., Wiers, RW. (2015). Cognitive Behavioural Therapy and Cognitive Bias Modification in Internet-Based Interventions for Mood, Anxiety and Substance Use Disorders. Springer International Publishing, 193-215, DOI 10.1007/978-3-319-20852-7_10.