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

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The aim of the present study is to conduct a randomised controlled trial (RCT) to assess the effectiveness of a guided and unguided web based transdiagnostic intervention in treating university and PhD students with depression and/or anxiety.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48683

Source
ToetsingOnline

Brief title
The UvAcare project - Intervention

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
anxiety, mood disorder

Health condition

psychische stoornissen: angststoornissen en -symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anxiety, depression, effectiveness, university students

Outcome measures

Primary outcome

The primary outcome of the RCT are the PHQ-9 for self-reported symptoms of depression and the GAD-7 for self-reported symptoms of anxiety. These scales will be administered at pre-treatment, mid-intervention (5 weeks post-randomisation), 8 weeks post-randomisation and at 6 and 12 month follow-up measurements.

Secondary outcome

The secundary outcomes are the EQ-5D for quality of life, the Audit-C for alcohol use, the SIAS-6 (social interaction anxiety), the DAST-10 for drug use, the ASM for avoidance support and the Mini-SPIN for social anxiety. In addition, the Client Satisfaction Questionnaire - 8 items (CSQ-8) and medical service consumption (TiC-P) will be monitored. Finally, academic achievement, social isolation, loneliness, cognitive interpretation bias, perfectionism, attachment and burn-out are assessed with self-report measures.

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 12-50% 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 and PhD students with mental disorders but also offer interventions for those in need.

Study objective

The aim of the present study is to conduct a randomised controlled trial (RCT) to assess the effectiveness of a guided and unguided web based transdiagnostic intervention in treating university and PhD students with depression and/or anxiety.

Study design

The present study employs a RCT design.

Intervention

The intervention will be a guided or unguided web-based transdiagnostic intervention targeting symptoms of depression and/ or anxiety. The intervention consists of 7 online sessions with duration ranging from 4 to 7 weeks depending on individual progress. A booster session will be administered four weeks after the completion of the 7th online session.

Study burden and risks

To our knowledge, there are no risks associated with the usage of the web-based interventions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(a) Being enrolled as a student or PhD student at the University of Amsterdam (UvA)
(b) Being 16 years or older
(c) Students who experience symptoms of depression (as defined by a score 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

(a) Co-morbid bipolar disorder and/or psychotic disorder according to the MINI
(b) Currently receiving psychological treatment for depression and/or anxiety
(c) Having slow or no Internet connection (e.g. no broadband Internet or something comparable)
(d) 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-01-2019
Enrollment:	1100
Type:	Actual

Medical products/devices used

Generic name:	iCare Prevent
Registration:	No

Ethics review

Approved WMO Date:	24-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2020
Application type:	Amendment

Review commission: METC Amsterdam UMC

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
CCMO	NL64929.018.18