The Caring Universities project - Examining the effectiveness of a web-based intervention for symptoms of depression and/ or anxiety

Published: 27-03-2017
Last updated: 15-05-2024

The aim of the present study is to conduct a randomised controlled trial (RCT) to assess the effectiveness of a guided web-based transdiagnostic intervention in treating student depression and anxiety.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON47291

Source
ToetsingOnline

Brief title
The Caring Universities project

Condition

- Mood disorders and disturbances NEC

Synonym
anxiety, low mood

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: ZonMw; Protestants Fonds voor de Geestelijke Volksgezondheid

Intervention

Keyword: anxiety, depression, effectiveness, university students

Outcome measures

Primary outcome

The endpoints of the RCT are the patient health questionnaire (PHQ-9) for depression and the Generalised Anxiety Disorder - 7 items scale (GAD-7) for anxiety. These scales will be administered at the screening (along with the e-survey), post-treatment and follow-up assessments (6 and 12 months post-randomisation).

Secondary outcome

The secondary endpoints are the Euroqol 5 Dimensions (EQ-5D) that will be administered at baseline, 6 and 12 months post-randomisation and the Client satisfaction with treatment * 8 items (CSQ-8) that will be administered at the post-treatment.

Study description

Background summary

College years are considered to be a peak period for the first onset of common mental disorders. Poor mental health is associated with physical, interpersonal and cognitive impairments and low academic attainment. Universities can use electronic media to screen for students with mental disorders but also to treat 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 web-based transdiagnostic intervention in treating student depression and anxiety.

Study design

The present study employs a RCT design.

Intervention

The intervention will be a guided web-based transdiagnostic intervention targeted at 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 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

Public
VU Amsterdam

Van der Boechorststraat 1 1
Amsterdam 1081 BT
NL
Scientific
VU Amsterdam

Van der Boechorststraat 1 1
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* subject must meet all of the following criteria:
(a) participation in the niet-WMO study (2017.105) including consent to be contacted again for the RCT.
(b) Being 18 years of age or older
(c) Being enrolled as a student in a university or college in the Netherlands
(d) Speak Dutch or English fluently
(e) Students who experience mild to moderate depression (as defining by scoring above the cut-off score of 4 on the Patient health questionnaire [PhQ-9]) and/ or anxiety symptoms (as defining by scoring above the cut-off score of 4 on the Generalised Anxiety Disorder scale * 7 items [GAD * 7])

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in the RCT:
(a) Risk for suicide according to the self-report measure (e-survey)
(b) Co-morbid bipolar disorder according to the MINI diagnostic interview.
(c) Students with severe depression (as defining by scoring above the cut-off score of 14 on the PhQ-9) and/ or anxiety symptoms (as defining by scoring above the cut-off score of 14 on the GAD-7 scale).
(d) Currently receiving/ have received psychological treatment for depression and/or anxiety in the past 12 months
(e) Having slow or no Internet connection (e.g. no broadband Internet or something comparable)

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):	19-03-2018
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	iCare Prevent (MindDistrict)
Registration:	No

Ethics review

Approved WMO Date:	27-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-11-2018
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

ID: 25368
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60156.029.16
OMON	NL-OMON25368