A RCT of an internet-based intervention for mild to moderate anxiety in younger and older adults

Published: 19-09-2014
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON40802

Source
ToetsingOnline

Brief title
A RCT of an internet-based intervention for anxiety

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, stress

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: ERC Advanced Grant

Intervention

Keyword: aging, anxiety, eHealth, RCT

Outcome measures

Primary outcome

Anxiety symptom severity will be measured by self-report (GAD-7) and presence of anxiety disorder by diagnostic interview (MINI-Plus).

Secondary outcome

Secondary outcome measures are level of depressive symptoms (PHQ-9), presence of depressive disorder (MINI-Plus), functional impairments (SDS), positive mental health (MHC-SF), experiential avoidance (AAQ-II), trait cognitive emotion regulation (CERQ), executive functioning (ATQ), quality of life (EQ-5D), costs associated with psychiatric illness (TIC-P), and client satisfaction (CSQ-8).

Potential baseline predictor and moderator variables will be measured at T0. The following variables will be tested as predictors or moderators of treatment response and/or compliance: demographic variables (age, gender, nationality, marital status, living conditions, education, work status, children), recruitment source, internet usage, self-esteem (four items), mastery (four items), affective social support (two items) and confident/problem solving social support (four items), and comorbid diseases.

Mediator variables and their corresponding dependent variable will be measured weekly during the online-intervention. Mediator variables include: anxiety and

depression (PHQ-4), cognitive emotion regulation (single item-scales) and

perceived support from the counselor (SRS).

Study description

Background summary

Anxiety disorder is among the most ubiquitous and debilitating mental health problems in older adults. Only about 10% of older adults with anxiety disorders are receiving appropriate treatment. Meta-analyses on the treatment of late-life anxiety suggest that late-life anxiety disorder can be effectively treated with both cognitive-behavioral therapy and selective serotonergic reuptake inhibitors. There is a dearth of studies examining whether the treatment response of older adults is comparable to that of younger adults. Online self-help courses with a limited amount of coaching are promising low threshold and cost-effective interventions in anxiety disorders.

Study objective

The primary aim of the proposed RCT is to evaluate whether younger and older adults with mild to moderately severe anxiety symptoms gain similar treatment benefits from an online-based psychological treatment (Acceptance and Commitment Therapy: ACT) compared to a Waiting List Control Condition (WLC). The secondary objective is to examine predictors, moderators and mediators of intervention responses. The third objective is to examine the cost-effectiveness of ACT.

Study design

A parallel-groups pragmatic randomized single-blind trial. Participants will be randomized to ACT or WLC using stratified (on age and anxiety disorder) permuted block randomization. There will be four main measurements via an on online-survey program and interviews conducted by telephone: one before the start of the intervention (T1), one directly following the intervention after 3 months (T2), and the third one 6 and the fourth one 12 months after baseline. Process measurements of emotion regulation, perceived support and anxiety/depression will be collected on a weekly basis during treatment.

Intervention

The online-intervention consists of nine weekly online modules, divided in three parts, which have to be completed in 12 weeks. Furthermore participants are instructed to practice daily mindfulness exercises of 10-15 minutes. Weekly

E-mail support will be provided by junior psychologists, supervised by a formally registered clinical psychologist.

Study burden and risks

There are no anticipated risks for taking part in this study. The burden is kept to a minimum: a screening questionnaire (+/- 5 minutes) and four other assessments (30 to 60 min. each), being the T1, T2, T3, and T4 with questionnaires and interviews (not at T3).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(a) presence of mild to moderate anxiety symptoms
(b) age between 18 and 75 years;

Exclusion criteria

(a) severe anxiety or depression symptomatology
(b) severe role impairments on various life domains
(c) other severe psychiatric disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	554
Type:	Anticipated

Ethics review

Approved WMO Date:	19-09-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL50505.058.14