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

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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...

Ethical reviewApproved WMOStatusPendingHealth condition typeAnxiety disorders and symptomsStudy typeInterventional

# 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

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### 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 2 - A RCT of an internet-based intervention for mild to moderate anxiety in younger ... 4-05-2025 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

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Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	554
Туре:	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** CCMO **ID** NL50505.058.14