Controlling Anxiety in Late Life

Gepubliceerd: 21-03-2017 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29127

Bron
Nationaal Trial Register

Verkorte titel
CALL

Aandoening

Anxiety complaints in the elderly

Ondersteuning

Primaire sponsor: Initiator: Leiden University, Leiden University Medical Center
Overige ondersteuning: De Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of symptoms of anxiety will be assessed with the GAD-7

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Anxiety problems are among the most prevalent and disabling mental health problems in older adults and an important risk factor for developing anxiety, depressive and various somatic disorders. Few older adults with anxiety symptoms receive adequate preventive interventions. It is therefore a high public and mental health priority to develop low-threshold interventions that are acceptable, effective and sustainable. Blended care in which a limited amount of face-to-face contacts with the POH-GGZ is combined with an evidence-based preventive web-based intervention may especially appeal to older adults and help to bridge this intervention gap.

Objective: The primary aim of the proposed RCT is to evaluate in older adults with mild to moderately severe anxiety symptoms whether blended care (i.e, the online-based psychological treatment “Living to the Full in the Third Life Phase” (LF-TLP) combined with four face-to-face contacts with a POH-GGZ) compared to treatment-as-usual (i.e., treatment according to the NHG guideline for anxiety complaints) is more cost-effective. The secondary objective is to examine predictors, moderators and mediators of intervention responses.

Study design: A pragmatic parallel-groups cluster randomized single-blind trial. POH-GGZ will be randomized to Living to the Full 55+ or TAU. There will be four main measurements via an on
online-survey program and interviews conducted by telephone: before the start of the intervention (T1), directly following the intervention (T2: 3 months after baseline), and again six and twelve months after baseline.

Study population: A total of 240 older participants (55 – 75 years) will be recruited.

Main
inclusion criterion is the presence of mild to moderate anxiety symptoms. Persons with severe anxiety and/or depressive symptomatology will be excluded.

Intervention: The online-intervention Living to the Full 55+ 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. In addition, four face-to-
face sessions will be provided by the POH-GGZ. TAU will be delivered by the POH-GGZ as optimized treatment-as-usual and consists of psycho-education and cognitive behavioral exercises

according to the NHG guideline Anxiety.

Doel van het onderzoek

The primary aim of the study is to evaluate whether the blended care intervention Living to the Full 55+ as an indicated prevention for anxiety complaints is more (cost-) effective than Treatment As Usual (TAU). We hypothesize that in comparison to TAU, Living to the Full 55+ will result in a significantly greater reduction of anxiety symptoms and associated outcomes on the short
and long term in a cost-effective way.

Exploratively, we want to examine to what extent certain baseline characteristics are predictive of outcome (effect modification) and to what extent changes in emotion regulation, behavioral avoidance, treatment expectancy, self-efficacy and the quality of the relationship with the clinician (in this case; the counselor at a GP practice, called the POH-GGZ) mediate the intervention effects.

Onderzoeksopzet

Baseline and 3, 6 and 12 months after baseline.

Onderzoeksproduct en/of interventie

The web-based intervention Living to the full is based on the Acceptance and Commitment Therapy-based selfhelp intervention ‘Living to the full'.

The program consists of nine lessons to be completed in 12 weeks. The modules are based on six core processes to
promote cognitive flexibility: acceptance, cognitive defusion, contact with the present moment, self as context, values, and committed action. Each
module uses experiential exercises and metaphors, text messages, tailored stories for motivation, and an option to personalize the homepage. Furthermore participants are instructed to practice daily mindfulness exercises of 10-15 minutes provided on audio and downloadable within the web-based intervention. In addition, participants will have four face-to-face sessions with their POH-GGZ to evaluate their progress using the intervention, discuss problems and
asking for support and advice.

TAU will be provided as optimized care as usual. A protocol for older adults with anxiety

complaints will be developed, based on the NHG-guideline 'Anxiety'. The protocol is comprised of psycho-educative texts and
exercises based on problem-solving therapy and cognitive behavioural therapy (such as relaxation or exposure exercises). In order to prevent treatment diffusion the delivery of interventions resembling Living to the Full (i.e., eHealth interventions in general and ACT and mindfulness-based interventions in particular) are not allowed. As in the Living to the Full 55+ group, the participants in the TAU group will be offered four face-to-face sessions with the POH-GGZ.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

(a) presence of mild to moderate anxiety symptoms, operationalized as a score between 4 and 15 on the GAD-7

(b) age between 55 and 75 years;

(c) having internet-access;

(d) able to invest approximately 30 minutes per day up to three hours per week;

(e) able to communicate in Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

(a) persons with severe anxiety (GAD-7 > 15) and/or depressive symptomatology (PHQ-9 score > 20);

(b) at least two areas of role functioning with severe role impairment (SDS > 8);

(c) few anxiety (< 4 on the GAD-7) symptoms;

(d) receiving psychological or psychopharmacological (with the exception of stable benzodiazepine or SSRI use) treatment for emotional complaints within the last 3 months;

(e) lifetime diagnosis of bipolar disorder or schizophrenia;

(f) high suicide risk;

(g) dementia or other severe cognitive impairments;

(h) unstable severe medical condition;

(i) dependence on drugs or alcohol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	240
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-03-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6131
NTR-old	NTR6270
Ander register	50-53120-98-004 : ZonMW projectnummer

Resultaten