The effect and feasibility of an intensive exposure treatment for eldery with anxiety and obsessive-compulsive disorders. A multiple baseline study.

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

Summary

ID

NL-OMON57023

Source
ToetsingOnline

Brief title
Intensive exposure treatment for elderly.

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorder, obsessive compulsive disorder

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)

Source(s) of monetary or material Support: Financiering door Pro Persona

Intervention

Keyword: anxiety and obsessive compulsive disorder, eldery, exposure treatment, intensive

Outcome measures

Primary outcome

The primary objective is to investigate whether the intensive exposure treatment of 8 weeks leads to a reduction in complaints with older patients with anxiety or obsessive-compulsive disorders, measured with the Geriatric Anxiety Inventory (GAI) and disorder-specific questionnaires.

Secondary outcome

The secondary objective is whether the treatment leads to a reduction in depressive symptoms and an improvement in the perceived quality of life as well. Feasibility is operationalized in the number of completed therapy sessions, the rate of dropout and satisfaction with the treatment.

Study description

Background summary

As a result of the aging population, there is an increasingly large group of people over 65 years old and of all psychiatric diagnoses, anxiety disorders are the most common in this group. Cognitive behavioral therapy (CBT) with exposure as a crucial part has been the golden standard for years when it comes to treating adults with anxiety and obsessive-compulsive disorders. Unfortunately, not much scientific research on the effect of this treatment in the elderly population has been conducted. Besides that it appears that there is a tendency to apply exposure less often in this target group, as a result of the phenomenon of 'ageism' (stereotypical prejudices relative to others or ourselves based on older age). There is therefore an urgent need for more information about the effect and feasibility of cognitive behavioral therapy with exposure in older clients with anxiety and obsessive-compulsive disorders.

Intensive forms of CBT (consisting of more than two appointments per week), with an emphasis on exposure, are very common in specialist mental health care. The aim of these intensive treatments is to optimize and/or accelerate the effect of treatment. Based on extensive clinical experiences of the expertise center Overwaal, an intensified treatment protocol has been developed for elderly people with persistent anxiety and obsessive-compulsive disorders who are referred to specialized mental health care. This study examines the effect of this eight-week intensive exposure treatment on reported anxiety symptoms. The suitability and applicability of such a treatment for this target group will also be examined.

Study objective

The primary objective of this research is to asses the effect whether an intensive exposure treatment for older patients (aged 65 years and older) with anxiety and- or compulsive disorders is suitable for this target group and leads to a decrease in anxiety and also a reduction of additional depressive symptoms and leads to an improved quality of life.

Study design

This is an effectiveness study in the form of a randomized single case design with repeated measurements (within-subject time-series design). Participants in the study are randomly assigned to a baseline that varies in duration and complaints are monitored in the various phases before, during and after treatment using biweekly measurements.

Intervention

Participants are offered an individual intensive exposure treatment by a team of experts, with an intensive phase of 4 weeks with 4 contact moments per week and a subsequent booster phase of 4 weeks with one contact per week. The treatment takes place at the locations in Arnhen and Nijmegen.

Study burden and risks

The burden consists of completing questionnaires and conducting interviews. The questionnaires are administered twice a week via telephone or video call with an average duration 5-10 minutes during the research period. Four measurements will also take place throughout the study with an average duration of 60 minutes. These measurements will be linked to a treatment contact if possible. Participation in the study is voluntary and has no consequences for the existing treatment offer for the patient. The benefit for participants consists of possible (accelerated) reduction of anxiety and obsessive-compulsive symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Patients aged 65 and older who are in treatment or have been registered through their GP for treatment within the outpatient elderly team of a mental health care organization in Gelderland (Pro Persona).
They were diagnosed with one of the following anxiety disorders using the Mini International Neuropsychiatric Interview-Simplified (MINI-S): panic disorder, with or without agoraphobia, social anxiety disorder, generalized anxiety disorder, or obsessive-compulsive disorder as a main or additional diagnosis.
Other inclusion criteria for the study are:
1) Willingness and ability to follow the 8-week intensive treatment.
2) Sufficient cognitive abilities (score on the Montreal Cognitive Assessment (MOCA) of greater than or equal to 18)
3) Able to read and write the Dutch language.
4) Informed consent for the research after extensive oral and written

information.

Exclusion criteria

Exclusion criteria are: an acute psychotic disorder, a severe mood disorder, severe developmental disorders and substance abuse or dependence. Concomitant use of antidepressants and benzodiazepines (maximum daily equivalence of 30 mg oxazepam) is permitted. Participants will be instructed to keep the current dose constant and to take the medication at regular times throughout the study period.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-11-2024
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL85218.091.24