Defeating Fear with Exposure therapy delivered by mental health nurses in primary care for Anxiety Disorders in older adults - a cluster-randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57146

Source
ToetsingOnline

Brief title
Exposure therapy for late-life anxiety (DeFEAD65+)

Condition

- Anxiety disorders and symptoms

Synonym
phobia worry

Research involving
Human

Sponsors and support

Primary sponsor: Pro Persona
Source(s) of monetary or material Support: ZonMW

Intervention

- Psychosocial intervention

Keyword: anxiety disorder, elderly, exposure, randomised controlled trial

Explanation

N.a.

Outcome measures

Primary outcome

Anxiety severity as assessed with the Geriatric Anxiety Inventory (GAI),
societal costs with the Trimbos and iMTA questionnaire on Costs associated with
Psychiatric illness (TIC-P) and quality of life using the EuroQol 5 Dimension 5
Level version (EQ-5D-5L) during the 12-week treatment period and 1-year
follow-up.

Secondary outcome

Outcome: Agorafobie (Mobility Inventory; MI), Social Anxiety (Liebowitz Social
Anxiety Scale for adults; LSAS), Generalized Anxiety Disorder (Generalized
Anxiety Disorder-7 questionnaire; GAD-7), Worry (Penn State Worry
Questionnaire; PSWQ), Depression (Quick Inventory of Depressive Symptomatology
- self report; QIDS-SR), Quality of Life (Recovering Quality of Life - Utility
Index; ReQoL-UI), Somatic Symptom Severity (Patient Health Questionnaire - 15;
PHQ-15), Limitations (WHO Disability Assessment Schedule; WHODAS), Well-being
(visual analogue scale).

Process ET-specific: Therapeutic alliance (Session Rating Scale; SRS),
Therapeutic alliance (Working Alliance Inventory; WAI), Expectancy (Expectancy
and credibility list), Change of threat expectancy, Safety behavior (Safety
Behaviours Scale; SBS), Experiential Avoidance (Brief Experiential Avoidance
Questionnaire; BEAQ), Cognitive-Behavioural Avoidance (Cognitive-Behavioural
Avoidance Scale; CBAS), Self-efficacy (General Self-Efficacy Scale; GSE),
Metacognitions (Metacognitions Questionnaire-30; MCQ-30).

Process general: Ageism (Expectations Regarding Aging; ERA-12), Life Events
(Life Events Checklists for DSM-5; LEC-5), Cognitive functioning (Stroop &
Self-Reference Encoding Task; SRET & Digit Symbol Substitution Test; DSST),

Cognitive functioning (Montreal Cognitive Assessment; MoCa).</p>

Study description

Background summary

Anxiety disorders are common and have a high disease burden throughout the life span. Nonetheless, older people with anxiety disorders remain undiagnosed and thus undertreated. Ageism, changes in symptom phenomenology at older age, and transportation barriers are reasons for underdiagnosis/-treatment. Moreover, when treated, older patients generally receive pharmacotherapy, while adverse effects increase with age and 75% of older persons prefer psychotherapy. The most effective psychotherapy, i.e. exposure therapy, has not yet been evaluated for older adults with anxiety in primary care.

Exposure Therapy (ET) is the most effective intervention for all anxiety disorders in adults. It has the potential to reduce the risk of chronicity, inappropriate healthcare use, inappropriate drug use, and unnecessary referral to specialist mental health care providers, which often include long, costly treatment trajectories. Exposure is well-suited to be delivered by mental health nurses (MHNs; or POH-GGZ in Dutch) in primary care centres (PCCs), because older people visit their general practitioner (GP) regularly and PCCs in the Netherlands have the availability of MHNs. However, they are currently not equipped to offer exposure. Introducing MHN-led exposure is likely to be (cost-) effective as it matches patients' preferences and prevents inadequate or costly treatments.

We hypothesize that ET (8 sessions in 12 weeks), performed by trained MHNs will be more effective and cost-effective in reducing anxiety symptoms and improving quality of life of older adults suffering from anxiety disorders from pre-treatment to post-treatment and in the 1 year follow-up, compared to Usual Care (UC).

Study objective

The primary objective of this study is to evaluate the (cost-)effectiveness of ET for late-life anxiety disorders delivered by trained MHNs in primary care, in terms of anxiety and quality of life, compared to UC. UC is not restricted, and the GP is encouraged to work according to the guidelines of the Dutch College of GPs.

a. The secondary objectives include investigating whether there are differences regarding secondary outcomes, such as disorder-specific anxiety symptoms, comorbid depressive symptoms, general functioning (i.e. disability and mental

health related quality of life) and the use of psychoactive medications (i.e., antidepressants and benzodiazepines) between ET and UC from pre- to post-treatment as well as follow-up, without adding specific interventions designed to improve these outcomes.

b. Moreover, various predictors and moderators of the treatment outcomes will be explored, including cognitive functioning, ageism in both the participants and MHNs, therapeutic alliance and expectations about the treatment.

c. Furthermore, we aim to investigate potential mechanisms of change in ET for late-life anxiety by utilizing self-report measures and exposure log worksheets/registration forms. Specifically, we will examine the role of changes in threat expectancy, avoidance and safety behaviours, self-efficacy, metacognitions (i.e. beliefs about cognition) and worry during the treatment phase.

Study design

The design of this study is a multi-centre cluster-randomised controlled trial in PCCs with two parallel treatment groups: a) ET (n = 85) and b) UC (n = 85).

Intervention

One group will receive ET and the other group will receive UC for their anxiety symptoms in primary care. Patients assigned to ET will receive 8 (30-minute) sessions within 12 weeks and homework assignments, with the first session lasting 45-60 minutes, delivered by trained MHNs.

Study burden and risks

ET, a well-established psychological intervention, has shown efficacy and safety in younger and middle-aged individuals. Limited research in older age groups (65 years and above) also indicates positive trends in both safety and efficacy. While every psychological intervention carries some inherent risk, contrary to common concern, there is no evidence suggesting that planned exposures pose a greater risk than any other psychological intervention. Thus, potential risk associated with participating in this study can be regarded as negligible.

The time and burden of participating in this study is considered acceptable. This was discussed with a focus group of older individuals, including experts by experience from the patient association for anxiety disorders (ADF Foundation) and visitors to Ons Raadhuis, a meeting center for older adults in the study region. They indicated that the burden was manageable, provided that questionnaires could be completed digitally or on paper/pencil with support. Additionally, the Exposure Treatment of 8 sessions over 12 weeks was also

considered acceptable. The focus group expressed concerns that older individuals might be spared treatment due to age or perceived frailty rather than the treatment being too burdensome. It was felt that assuming an Exposure Treatment might be too heavy was underestimating older adults' capabilities to decide for themselves.

It's worth noting that in the previous study we conducted (NL54470.091.16), we achieved successful participation from older adult patients with depression in a similar setting. Comparing the target populations, it's reasonable to anticipate higher participation among anxious older adults, as they typically exhibit more energy compared to patients with depression who often experience energy loss. Moreover, potential challenges related to our target population are addressed by offering the option to complete questionnaires at home, either with independent research assistants present or via telephone.

Overall, although participation in this study requires a time commitment from patients, we anticipate that they will benefit from the offered exposure therapy, leading to an improvement in their anxiety symptoms.

Contacts

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Trial sites

Trial sites in the Netherlands

Radboud Universitair Medisch Centrum
Target size: 55

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Participants need to meet the criteria for a primary DSM-5 anxiety disorder, namely Generalized Anxiety Disorder, Agoraphobia, Social Anxiety Disorder, Panic Disorder or Anxiety Disorder Not Otherwise Specified (NOS).

Exclusion criteria

Exclusion criteria include somatic and/or another psychiatric morbidity that could interfere with treatment, severe suicidality, chronic and interfering substance or alcohol abuse, having received previous psychotherapy focusing on the anxiety disorder in the past year.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Other type of control
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2025
Enrollment:	170
Duration:	12 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	24-09-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-11-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-03-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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
ClinicalTrials.gov	NCT06770517
CCMO	NL87105.091.24
Research portal	NL-005444