Cost-effectiveness of schema therapy for treatment-resistant anxiety disorders: A multicentre RCT

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

Summary

ID

NL-OMON56961

Source
ToetsingOnline

Brief title
Schema therapy for anxiety

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, anxiety disorders

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: anxiety disorders, cost-effectiveness, schema therapy, treatment-resistance

Outcome measures

Primary outcome

The primary outcome is the reduction in anxiety symptoms (difference over 36 months), related to societal costs. For the cost-utility analysis, (mental health) quality of life, health care utilisation and productivity losses will be collected. The measurements will be conducted at baseline and 1, 3, 6, 12, 24 and 36 months after baseline.

Secondary outcome

Secondary outcomes are remission from the primary anxiety disorder and from comorbid diagnoses (baseline, 12, 24 and 36 months), general mental health (baseline and 12, 24 and 36 months), schemas (baseline and 12 and 36 months), schema modes (baseline and 3, 6, 12 and 36 months), functioning and recovery (baseline and 12, 24 and 36 months), positieve and negative effects of psychotherapy (12 months) and satistfaction with treatment (12 months).

Study description

Background summary

1 in 4 Dutch citizens will experience an anxiety disorder at least once in their lifetime. Unfortunately, standardized treatments (such as cognitive behavioural therapy (CBT) and medication) are ineffective for 30-60% of patients. When the anxiety disorder persists despite treatment, we refer to it as treatment-resistant. Schema therapy focuses on adjusting beliefs (schemas) and survival strategies formed early in life that are related to the persistence of anxiety symptoms. Schema therapy has highly positive and long-lasting effects in individuals with personality disorders. It also seems

to work well for treatment-resistant anxiety disorders, but it remains unclear whether this treatment is cost-effective. In this randomised controlled trial amongst 172 patients with treatment-resistant anxiety disorders, half of the patients will receive a maximum of 40 sessions of individual schema therapy (ST), while the other half will receive usual care (UC; often a continuation of CBT or medication). We will compare the effectiveness of both treatments on anxiety symptoms, quality of life and societal and health care costs. We expect ST to be superior to UC in terms of reduction of anxiety symptoms and improved quality of life, against lower social costs, especially in the longer term (24 to 36 months).

Study objective

The primary objective of this study is to evaluate the cost-effectiveness of individual ST (max. 40 sessions) vs. UC in patients with treatment-resistant anxiety disorders from a societal perspective. The second objective is to explore whether certain patient characteristics are related to the effectiveness of ST (e.g., gender, ethnic background, or the presence of a comorbid depression/personality disorder/autistic characteristics). The third objective is to promote implementation by gaining insight into how patients and their relatives evaluate ST, assess fidelity to ST, and identify factors that influence implementation to inform implementation beyond the trial context (process evaluation).

Study design

A multicentre RCT with a cost-effectiveness analysis and an embedded process evaluation.

Intervention

Patients will be randomized to the intervention group (schema therapy; ST) or the control group (usual care; UC). ST is an integrative psychotherapy, with a high emphasis on the therapeutic relationship (*limited reparenting*), use of trauma focussed techniques, experiential and cognitive techniques, role-play and behavioural exercises to improve the ability of patients to have their emotional needs met. The ST treatment protocol used in this study is adapted specifically for patients with treatment-resistant anxiety disorders based on observational studies conducted at GGZ inGeest and Propersona. Especially in the second half of treatment emphasis is placed on exposure to feared situations. Although exposure is also part of CBT, the essential difference is that the exposure is integrated in ST and introduced following addressing the underlying maladaptive schemas and personality factors that form a barrier to profit from exposure. Individual schema therapy consist of a maximum of 40 sessions within 1 year.

Usual care is optimal care following the Quality Standard for anxiety disorders. As there is no gold standard psychotherapy for treatment-resistant anxiety disorders, UC often consists of another trial of CBT and medication, but may also be another form of treatment offered by the participating centres. There are no restrictions to UC, except that it may not be ST. Actual content of UC will be tracked.

Study burden and risks

Schema therapy is included in the multidisciplinary guidelines for treating personality disorders and is found to be safe and effective. In regular care, shcema therapy is provided for patients with various disorders, also in vulnerable groups (i.e. patients with borderline personality disorder). We expect negligible risks of participating in ST based on earlier studies. Schema therapy may evoke emotional responses, especially at the start of treatment and during exposure. However, these emotions are needed to achieve lasting changes and the patient will be supported by the therapist during difficulties. Moreover, a relative will be invited in the beginning of the therapy, to collaboratively inform the patient and his or her relative about what to expect in schema therapy and how to cope with any upcoming emotions related to the therapy. In both conditions, patients are asked to complete several interviews and questionnaires, which are a time investment of in total 9.3 hours spread out over 3 years. The several questionnaires and interviews may be emotionally challenging for some patients, as they are being confronted with their anxiety symptoms. To ensure that the measurement occasions are as comfortable as possible, patients may take breaks or continue the measurements at a later point in time. Patients will be financially compensated for their time (max. 15 euros per questionnaire). The participant will receive support from their therapist, the principal investigator (clinical psychologist) or the PhD student (psychologist) when needed. UC is standard care and therefore a negligible risk is expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18-65
- Primary diagnosis of an anxiety disorder (panic disorder, agoraphobia, social anxiety disorder, generalised anxiety disorder, separation anxiety disorder and specific phobia) according to DSM-5.
- Fulfilling criteria of treatment-resistance based on a systematic literature search i) at least one unsuccessful cognitive behavioural therapy (CBT) trial of >= 8 weeks; and ii) at least one unsuccessful pharmacological treatment with a serotonergic antidepressant of >= 8 weeks OR valid reasons for not wanting to or not being able to receive medication, and iii) moderate to severe anxiety symptoms (Beck Anxiety Inventory score > 11). Adequacy of previous treatment will be checked.

Exclusion criteria

Substance use dependence
Acute suicidality
Received schema therapy in the past
Insufficient Dutch or English

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	172
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	19-08-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NCT06298695
CCMO	NL85408.018.24