

Feeling Safe-Netherlands: recovery-oriented cognitive behaviour therapy to promote wellbeing and feeling safer

Submission date 05/07/2022	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/07/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many people do not feel safe around other people. This leads to fear, loneliness, hopelessness and often reduced mental wellbeing. This study investigates the (long-term) effects of two therapies on well-being and feeling safer. Additionally, the study will investigate how these therapies work:

1) Cognitive behavioural therapy (CBT) is the standard therapy for people with threat beliefs. The therapy focuses on fostering a shared understanding of what caused and maintains problems. In therapy, people can give new meaning to their experiences and find other ways of coping.

2) Feeling Safe is a proven effective psychological intervention developed in the UK. In the Feeling Safe-NL programme, people also work together with a peer counsellor. With the therapist, the factors that maintain feeling unsafe (trauma-imagery, insomnia, self-esteem, worry, anomalous experiences, safety behaviours) are assessed. After this, people choose from a personalised menu of brief CBT modules (booklets) aimed at reducing the maintenance factors one-by-one. While people work together with a therapist to reduce the factors that hamper recovery, people work together with a peer counsellor to promote personal recovery. This is done by identifying and using strengths and building experience knowledge. Additionally, experiences can be shared, and meaningful activities can be undertaken.

Both therapies consist of approximately 20 sessions of 90 minutes over 6 months.

Who can participate?

Adults (aged 16 years or older) who are help-seeking or in outpatient care who experience threat beliefs and low well-being.

What does the study involve?

Participants are randomly allocated to either CBTp or the Feeling Safe-NL Programme. Before starting therapy and after 6 (post-therapy), 12, and 18 months, they complete a set of interviews and questionnaires at the mental healthcare institution where they receive their treatment.

What are the possible benefits and risks of participating?

The two therapies aim to improve well-being and feel safer. They have been investigated in people with threat beliefs before and have been shown to be safe and effective in improving well-being and reducing threat beliefs. The medical ethical committee has judged the study as inducing "no increased risk" for participants.

Where is the study run from?

1. Parnassia, Den Haag, The Netherlands
2. Antes, Rotterdam, The Netherlands
3. GGZ Oost-Brabant, Boekel, The Netherlands
4. Altrecht, Utrecht, The Netherlands
5. GGZ inGeest, Amsterdam, The Netherlands
6. Pro Persona, Arnhem, The Netherlands
7. Rivierduinen, Leiden, The Netherlands

When is the study starting and how long is it expected to run for?
February 2022 to December 2026.

Who is funding the study?

Netherlands Organisation for Health Research and Development (ZonMw).

Who is the main contact?

1. Dr David van den Berg (principal investigator). Email: david.vanden.berg@vu.nl
2. Drs Eva Tolmeijer (project leader and scientific/public contact). Email: eva.tolmeijer@vu.nl

Study website

<https://feeling-safe.nl>

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

NL77046.029.21

Study information

Scientific Title

A comparison of the effects of the combination of Feeling Safe and peer counselling (the Feeling Safe-NL Programme) and regular cognitive behaviour therapy for people with threat beliefs.

Acronym

FSNL

Study objectives

The primary objective is to test whether the Feeling Safe-NL programme is more effective in improving wellbeing over time than CBTp (from baseline to 18-month follow-up). The secondary objectives are to test whether the Feeling Safe-NL programme is more effective than CBTp in reducing conviction and distress of the main threat belief and general paranoid ideation and improving patient chosen outcomes of therapy and activity levels over time (from baseline to 18-month follow-up). We also assess outcomes at the different time-points (6-, 12- and 18-month follow-up). Additionally, we investigate the mediators of improved wellbeing and reduced threat beliefs and whether the Feeling Safe-NL programme is more cost-effective than CBTp.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/02/2022, Medical Ethics Committee of VU Medical Centre Amsterdam (METc VUmc, De Boelelaan 119, room 08A-08, PO Box 7057, 1081 HV Amsterdam, the Netherlands; +31 (0)20 44 45 58 5; metc@vumc.nl), ref: 2021.0650 - NL77046.029.21

Study design

Single-blind pragmatic randomized controlled trial with two parallel groups

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Threat beliefs held with at least 60% conviction and low wellbeing in people who are help-seeking or in outpatient care.

Interventions

Participants are randomly assigned to CBTp or the Feeling Safe-NL Programme using our independent randomisation bureau. In both arms, people will receive approximately 20 therapy sessions over a period of 6 months. To support the therapies in both arms, optional daily monitoring is available via brief questionnaires of which the outcomes are visualised. Therapists will be trained in both therapy protocols and will deliver both conditions.

The Feeling Safe-NL Programme is delivered according to the protocols of Freeman et al. (2021). The empirically-based maintenance factors of threat beliefs (trauma-imagery, insomnia, self-esteem, worry, anomalous experiences, safety behaviours) are assessed. Brief CBT modules are

used to reduce specific maintenance factors of threat beliefs while a peer counsellor concurrently addresses personal recovery to promote wellbeing. This approach enables synergy between the work of the therapist, peer counsellor, and participant. The overarching goals of the Feeling Safe-NL programme are to feel safer, happier, and get people back to doing what they want to do.

CBTp is delivered according to the protocols of Van Der Gaag, Staring, Van Den Berg and Baas (2018). The participant and therapist collaboratively work on understanding the problems of the participant and on completing the case formulation, which provides relevant information concerning the origin and maintenance of the person's threat beliefs. The intervention phase starts after the case formulation is completed. The therapist and participant work together on achieving personalised treatment goals.

Intervention Type

Behavioural

Primary outcome measure

Wellbeing as measured by the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS). This will be measured at baseline, 6-month follow-up (post-treatment), 12-month follow-up, and 18-month follow-up.

Secondary outcome measures

Measured at baseline, 6-month follow-up (post-treatment), 12-month follow-up, and 18-month follow-up:

1. Conviction and distress level of the main threat belief (Psychotic Symptom Rating Scale, PSYRATS)
2. General paranoid ideation (Revised-Green et al. Paranoid Thought Scale, R-GPTS)
3. Patient chosen therapy outcomes (Choice in Outcome in Cognitive Behaviour Therapy for psychosis, CHOICE)
4. Activity (time budget).

Overall study start date

09/02/2022

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Help-seeking or in outpatient care.
2. Experience threat beliefs held with at least 60% conviction (PSYRATS-Del).
3. Wellbeing of 43 or less (WEMWBS).
4. Sixteen years or older.

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

190

Key exclusion criteria

1. Insufficient understanding of the Dutch language.
2. Currently receiving individual therapy or peer counselling with a frequency of at least once every month.
3. Unable to understand and sign the informed consent form.

Date of first enrolment

01/03/2022

Date of final enrolment

31/07/2025

Locations**Countries of recruitment**

Netherlands

Study participating centre**Parnassia**

Zoutkeetsingel 40

The Hague

Netherlands

2512 HN

Study participating centre**GGZ Oost Brabant**

Kluisstraat 2

Boekel

Netherlands

5427 EM

Study participating centre**Altrecht**

Lange Nieuwstraat 52/52A

Utrecht
Netherlands
3512 PK

Study participating centre

Antes

Pieter de Hoochweg 14
Rotterdam
Netherlands
3014 BH

Study participating centre

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Van Hilligaertstraat 21
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1072 JX

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Pro Persona

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Arnhem
Netherlands
6815 AG

Study participating centre

Rivierduinen

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Sponsor information

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Sponsor type

Research organisation

ROR

<https://ror.org/008xxew50>

Funder(s)

Funder type

Government

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

The results regarding all hypotheses - as described in the 'study hypothesis' section - will be published unreservedly. The researchers aim to publish in high-impact peer-reviewed journals. The sponsor will have no influence on the publication of the results.

Intention to publish date

31/12/2027

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Therapy-specific questionnaires and visual feedback were developed within the online m-Path platform as part of the Feeling Safe-NL trial	05/10/2023	06/10/2023	Yes	No
Other publications		20/03/2025	23/04/2025	Yes	No