ISRCTN25766661 https://doi.org/10.1186/ISRCTN25766661

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

Submission date
05/07/2022

Recruitment status
No longer recruiting

Registration date
07/07/2022

Overall study status
Ongoing

Last Edited
01/08/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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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
30/06/2025

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
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Study participating centre
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Van Hilligaertstraat 21
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Wagnerlaan 2
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6815 AG

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2333 ZZ

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VU Amsterdam

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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		05/10/2023	06/10/2023	Yes	No
Other publications	Therapy-specific questionnaires and visual feedback were developed within the online m-Path platform as part of the Feeling Safe-NL trial	20/03/2025	23/04/2025	Yes	No