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

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Primary Objective: 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).Secondary objectives: To test whether the Feeling Safe-NL programme is more effective...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50990

Source
ToetsingOnline

Brief title
FSNL

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
Paranoia, threat beliefs

Health condition

andere psychische stoornissen waarbij sprake is van overmatige achterdocht

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw - klinisch toegepast onderzoek in de geestelijke gezondheidszorg

Intervention

Keyword: cognitive behaviour therapy, peer support, threat beliefs, wellbeing

Outcome measures

Primary outcome

Wellbeing (Warwick-Edinburgh Mental Wellbeing Scale, WEMWBS; Tennant et al.,

2007). The WEMWBS can detect clinically meaningful change (Collins et al.,

2012; Maheswaran, Weich, Powell, & Stewart-Brown, 2012).

Secondary outcome

Secondary outcome:

Conviction of Main Threat Belief (Psychotic Symptom Rating Scale, PSYRATS;

Haddock, McCarron, Tarrier, & Faragher, 1999)

Distress of Main Threat Belief (PSYRATS)

Paranoid ideation (Revised-Green Paranoid Thought Scale, R-GPTS; Freeman, Loe,

et al., 2019)

Patient Satisfaction (Greenwood et al., 2010)

Acitivty (Jolley et al., 2006)

Mediators:

Trauma-imagery (Trauma Screening Questionnaire, TSQ; Brewin et al., 2002; De

Bont et al., 2015)

Insomnia (Insomnia Severity Index, ISI; Bastien, Vallières, & Morin, 2001)

Self-esteem (Brief Core Schema Scale, BCSS; Fowler et al., 2006)

Worry (Dunn Worry Questionnaire, DWQ; Freeman et al., 2019)

Voices (Voices Impact Scale, VIS; Strauss, 2016)

Safety Behaviours (Oxford Agoraphobic Avoidance Scale, OAAS; Lambe et al., 2021; Oxford Paranoia Defence Behaviours Questionnaire, OPDBQ; under review)

Reasoning Biases (Fast and Slow Thinking Questionnaire, FAST; Hardy et al., 2020; Explanations of Experiences, EoE; Freeman et al., 2004; Maudsley Assessment of Delusions Schedule-Possibility of being Mistaken, MADS-PM; Wessely et al., 1993)

Personal Recovery (Questionnaire about the Process of Recovery, QPR; Neil et al., 2009)

Resilience (The Brief Resilience Scale, BRS; Smith et al., 2008).

Other study parameters:

Therapeutic relationship (Counsellor Rating Form-Short form, CRF-S; Corrigan & Schmidt, 1983)

Working alliance (Working Alliance Inventory-Short Form Revised, WAI-SR; Paap & Dijkstra, 2017)

Health-economic evaluation (treatment Inventory of Costs in Patients with psychiatric disorders (TIC-P), the standardized 5-level EuroQol 5-dimensional questionnaire (EQ-5D-5L)).

Study description

Background summary

Threat beliefs, also referred to as persecutory delusions or paranoia, are strong unfounded fears that people intend to harm you. Threat beliefs are highly prevalent and transdiagnostic experiences that are associated with the persistence of mental health problems and long-term treatment trajectories. Severe threat beliefs are associated with poor outcomes involving impairment in multiple functional domains and psychological well-being in the lowest 2% of the general population. Psychological mechanisms underlying threat belief formation and maintenance appear consistent across diagnoses, with traumatic stress and insomnia being two of the strongest causal factors. On the 15th of June 2020, Zorginstituut Nederland (ZIN) sent the *Verbetersignalement Psychose* to the State Secretary for Health, Welfare, and Sports. The most important conclusion of this report is that only a small minority of the patients with psychosis receive the guideline intervention cognitive behaviour therapy for psychosis (CBTp). The report emphasises the necessity of implementing CBTp in routine clinical practice, and to test new (cost-)effective psychological treatments for psychosis. This is exactly the ambition of the current research project, which is a collaboration between scientists, clinicians, and experts by experience. We aim to reduce threat beliefs and improve wellbeing with a recovery-oriented intervention that is cost-effective and easy to implement. We acknowledge that recovery involves more than the absence of mental health problems and concerns a highly personal process of enhancing resilience. To this end, we build on the translational Oxford Feeling Safe Programme that involves a personalised treatment in which the causal psychological factors that drive threat beliefs are targeted one-by-one. This is done with brief CBT modules that are selected by patients from a personalised menu of treatment options. This will now be tested as the Feeling Safe-NL Programme, which aims to promote wellbeing by synergistically reducing the causal factors that hamper recovery, while concurrently addressing personal recovery with peer-support. We will test whether this new translational, recovery-oriented, transdiagnostic, modular, and peer-supported treatment is more (cost-)effective in improving wellbeing and reducing threat beliefs than CBTp.

Study objective

Primary Objective:
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).

Secondary objectives:
To test whether the Feeling Safe-NL programme is more effective in reducing conviction and distress of the main threat belief, general paranoid ideation, patient chosen outcomes of therapy and activity levels over time (from baseline to 18-month follow-up) than CBTp. 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.

Study design

We will conduct a two-armed single-blind pragmatic superiority randomised controlled trial (n=190) to test whether Feeling Safe-NL helps patients improve their wellbeing and feel safer more effectively than CBTp. We will include out-patients with threat beliefs that are held with at least 60% conviction and the presence of at least two of the seven most important causal maintenance factors of threat beliefs, such as trauma-imagery and insomnia. Participants will be randomised (1:1) to Feeling Safe-NL or the gold-standard CBTp (protocolized, formulation-based), both provided over a period of 6 months. In line with the treatment protocols, participants in both conditions are offered the possibility to monitor their wellbeing, threat beliefs, maintenance factors (trauma-imagery, insomnia, self-esteem, worry, anomalous experiences, safety behaviours), personal recovery goals, and resilience. Data will be visualised in a novel and patient-friendly way to enhance usability for both patients and therapists. Standard care will continue as usual and be monitored. Blinded assessments will be conducted at 0, 6- (post-treatment), 12- and 18-months follow-up. The primary outcome is wellbeing and the secondary outcome is the level of conviction of the main threat belief. We will use Linear Mixed Models (LMM) and Generalised Estimating Equations (GEE) analyses for the main outcomes. For cost-effectiveness analyses, the clinical end-terms are a clinically relevant change in wellbeing and quality-adjusted life-year gained. We will also use mediation analyses to assess mechanisms of therapeutic change. All main analyses will be intention-to-treat (ITT). The project also includes qualitative assessments of the experiences of participants, therapists, and experts by experience with the Feelings Safe-NL programme.

Intervention

Feeling Safe-NL

1) Rationale
The aim of Feeling Safe-NL is to reduce obstacles that hamper the recovery process while concurrently addressing 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 (Freeman & Waite, 2017). The empirically-based maintenance factors of threat beliefs (trauma-imagery, insomnia, self-esteem, worry, anomalous experiences, safety behaviours) are assessed. A personalised menu of treatment options is provided to the patient and modules are selected based on patient

choice, allowing maintenance factors to be tackled one-by-one in separate brief therapy modules. This approach helps to address both the complexity and unicity of presenting problems and commonly associated feelings of hopelessness.

Participants will have an initial introductory meeting with the professional peer counsellor and therapist. All share their pitfalls/vulnerabilities and things they like or do well, to promote the experience of openness and trust. Information about the Feeling Safe-NL programme is provided, and the collaboration is discussed. Participants will be asked to invite loved ones or relevant resource group members to this meeting. In the following two meetings, the participant and the peer counsellor share personal experiences and work on identifying strengths, wishes, and possibilities for different aspects of life using the Strengths Assessment (Rapp & Goscha, 2011). This results in a report with a strengths profile and wishes and needs profile. The strengths profile is the starting point for peer counselling. The therapist discusses the wishes and needs profile with the participant during their first assessment, after which a personalised menu of treatment options is offered to the participant. On average three therapy modules will be selected and participant and therapist work together on reducing maintenance factors one-by-one in brief CBT modules. The therapist and client formulate recovery goals at the beginning of therapy. The participant and the therapist meet every week to work on the obstacles that hamper attainment of these recovery goals. The peer counsellor and participant work together according to the sponsor model (Brown, 1995): the expert by experience is available to support the participant during the Feeling Safe-NL programme, and the participant can decide when and how to have contact. Possibilities and impossibilities are discussed, and the peer counsellor asks if he/she can contact the participant following a period of no contact to check how the person is doing. The peer counsellor and the participant work together on improving wellbeing through sharing of experiences, finding meaning in past and current experiences, and engaging in meaningful activities. The participant, therapist, and peer counsellor meet near the end of every therapy module to evaluate progress and discuss the transition to the next therapy module. This enhances the synergy between the work of the therapist and peer counsellor together with the participant. On the one hand, obstacles are removed while on the other hand personal recovery is promoted, both with an aim of attaining wellbeing. The participant, loved ones or resource group members, therapist, and peer counsellor meet at the end of The Feeling Safe-NL Programme to evaluate the therapy and discuss how the improved wellbeing and feelings of safety can be maintained.

Cognitive behaviour therapy for psychosis (CBTp)

1) Rationale
The aim of CBTp is to reduce the dysfunctional emotional and behavioural consequences of threat beliefs. Cognitive interventions are used to challenge cognitions and raise awareness of cognitive biases. Behavioural interventions

are used to reduce avoidance behaviours, stimulate gradual exposure to the alleged threat to challenge the expectancy of negative outcomes and to test more functional coping strategies.

Participants will have an initial assessment with a psychologist in which the therapy goals are identified. Following this assessment, people will receive protocolized formulation-based CBTp for threat beliefs (Van Der Gaag, Staring, Van Den Berg, & Baas, 2018). The treatment starts with an introductory meeting in which the patient and therapist get to know each other. The therapist also provides information about the rationale and set-up of the treatment, including the frequency and duration of sessions. Participants will be asked to invite loved ones or relevant resource group members to this meeting.Following the introduction, the inventory phase starts. In this phase, more information is gathered using the conspiracy interview and thought records. 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 patient*s threat beliefs. The therapist and client also work together on formulating treatment goals. The intervention phase starts after the case formulation is completed. Generally, cognitive interventions (psycho-education, historic testing, and evidence for and against the threat beliefs) are used first with an aim of creating more nuances in the fixed
threat beliefs and encouraging patients to participate in behavioural experiments and exposure assignments. This cycle may need to be repeated to challenge each relevant dysfunctional belief. In this phase, the patient and therapist always agree on assignments to do between sessions. The last phase is the consolidation phase in which the therapist and participant review the participant*s earlier difficulties and examine whether all of them have now been overcome. They evaluate the steps the participant has taken to restore her everyday life, and the actions that are still needed. The participant is asked to write down the most important changes and learning points from the treatment. This written evaluation can be taken home so that it can be used in case of recurring symptoms. Together with the participant, the therapist goes through the form for the prevention of recurring paranoid thoughts. Loved ones or relevant resource group members will be involved in this phase.

Study burden and risks

Minimal burden due to short one hour assessments. The administration of questionnaires is also a standard part of cognitive behaviour therapy (standard care). As a result, the extra burden is less than 30 minutes. Only the assessments of demographics, the therapeutic relationship and cost-effectiveness is not routinely used in clinical practice. There are no risks associated with the therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Help-seeking or in outpatient care.
2) Experience threat beliefs, held with at least 60% conviction (Psychotic Symptom Rating Scale - Delusions).
3) Low wellbeing, score of 43 or less (Warwick-Edinburgh Mental Wellbeing Scale).
4) Sixteen years or older.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-03-2022
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	09-02-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2024
Application type:	Amendment
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
CCMO	NL77046.029.21