The STERK-study for offspring: Screening and Training, Enhancing Resilience in Kids.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20591

Source
Nationaal Trial Register

Brief title
STERK

Health condition

anxiety disorders, depression, mood disorders, children, adolescents, youth, offspring, prevention, at risk, resilience
angststoornis, depressie, stemmingsstoornis, kinderen, jongeren, preventie, risico, training, veerkracht

Sponsors and support

Primary sponsor: Performer: University of Groningen, department of Clinical Psychology. Participating sites: Accare Groningen, UCP Groningen, Leiden LUMC, Leiden Curium LUMC, PSY-Q Leiden, GGZ Rivierduinen, GGZ Fryslan, Kinnik
Source(s) of monetary or material Support: ZonMW prevention, grant number 120620024

Intervention

Outcome measures

Primary outcome

Time to onset of depression or anxiety disorders in the offspring (based on the structured interview iDISC).

Secondary outcome

1. Number of days with depression or anxiety (iDISC);

2. Child (RCADS) and parent (IDS, BAI) symptoms;

3. Quality of life (EQ5D);

4. Costs (economic evaluation).

Study description

Background summary

The present study investigates whether a 10-session CBT program can postpone or prevent the onset of mood or anxiety disorders in a sample of 204 children (aged 8-17 years) of parents who are or have been treated for anxiety or mood disorders. Anxiety and mood disorders are highly prevalent and pose a huge burden on patients. Their offspring is at increased risk for developing these disorders as well, and we have recently developed a High Risk Index that enables us to select ultra high risk children within his population. The current study qualifies for both a selected (offspring of anxiety and mood disordered patients with the additional risk factors) and an indicated (elevated symptoms) prevention program. Offspring of anxious or depressed patients (aged 8-17 years; N=204) with an ultra high risk are selected for participation in the intervention trial. These children report sub-threshold symptoms and / or meet two of three criteria for the High Risk Index (female gender, both parents affected, history of a parental suicide (attempt)). All parents receive care as usual for their emotional disorder. Children are randomised to one of two treatment conditions, namely (a) 10 weekly individual child CBT sessions and 2 parent sessions) or (b) Minimal information. Assessments are held at pre-test, post-test and at 12 and 24 months follow-up. Primary outcome is the time to onset of depression or anxiety disorders in the offspring. Secondary outcome measures include number of days with depression or anxiety, child and parent symptoms, quality of life, and cost-effectiveness. In line with models on aetiology of mood and anxiety disorders as well as mechanisms of change during interventions, we selected possible moderators of treatment outcome, namely coping, parent-child interaction, self-associations, optimism/pessimism, temperament, and emotion processing.

Study objective

1. The STERK-intervention will prevent early onset of anxiety and mood disorders in offspring (compared to a minimal information condition);

2. The STERK-intervention is cost-effective;

3. The effectiveness of the STERK-training will be influenced by several factors, such as the severity of the parental symptoms (past and current), self-associations, optimism/pessimism, and the parent-child relationship.

Study design

1. Screening (T0);

2. Pre-training (T1);

3. Post-training (T2, 4 months after T1);

4. Follow-up 1 (T3, 12 months after T1);

5. Follow-up 2 (T4, 24 months after T1).

Intervention

1. STERK-training, a 10-session individual behavioural training + 2 parent sessions (themes: behavioral activation, exposure, social network, positive emotions, situations and personality traits, resilience);

2. Minimal information on paper.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aged 8-17 years;

2. Parent with primary anxiety or mood disorder (current or past, with a history of treatment).

Inclusion for the intervention phase:

Subthreshold anxiety or mood symptomatology OR meeting criteria for the High Risk Index (female, both parents with disorder, past of suicidal behaviour in a parent).

Exclusion criteria

1. Psychosis in parent;

2. Severe substance misuse in parent;

3. Current mental disorder in the child that requires an intervention.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	204
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-05-2011
Application type:	First submission

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
NTR-new	NL2750
NTR-old	NTR2888
Other	ZonMw / METC : 120620024 / 2009.200;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A