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

Gepubliceerd: 06-05-2011 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20591

Bron
Nationaal Trial Register

Verkorte titel
STERK

Aandoening

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

Ondersteuning

Primaire 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
Overige ondersteuning: ZonMW prevention, grant number 120620024

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Psychosis in parent;

2. Severe substance misuse in parent;

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	204
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-05-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2750
NTR-old	NTR2888
Ander register	ZonMw / METC : 120620024 / 2009.200;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A