

VRIENDEN voor het Leven. FRIENDS for Life.

No registrations found.

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

Summary

ID

NL-OMON23152

Source

NTR

Health condition

Preventie van angst- en depressieve stoornissen
Prevention of anxiety and depression

Sponsors and support

Primary sponsor: VU Medisch Centrum

Source(s) of monetary or material Support: ZonMw, Gemeente Amsterdam

Intervention

Outcome measures

Primary outcome

Symptoms of anxiety and depression.

Secondary outcome

1. Programme integrity;
2. Children's evaluation of the programme;

3. Parent's evaluation of the programme;
4. Response to FRIENDS for Life in gender, age, and ethnic group.

Study description

Background summary

The aim of the project is to evaluate the effectiveness of FRIENDS for Life as selective school-based prevention programme for children aged 8-12 years with early or mild signs of anxiety or depression. Various aspects of the programme's effectiveness and implementation will be investigated:

1. This controlled trial includes a pre-intervention assessment and three follow-up assessments (directly after, and 6 and 12 months after the end of the programme). The primary outcome measure is symptoms of anxiety and depression;
2. We will investigate whether differences occur in the extent to which specific groups of children (with regard to severity of symptoms at the start of the programme, gender, age, and ethnic group) benefit from FRIENDS for Life;
3. A process evaluation will be conducted to investigate whether the programme has been executed according to protocol (programme integrity) and to evaluate children's and parents' opinions about FRIENDS for Life using online focus groups and interviews.

Countries of recruitment: the Netherlands.

Study objective

N/A

Study design

Outcome name: RCADS.

Timepoints: Pre-intervention, immediately after intervention, 6 months after intervention, 12 months after intervention.

Outcome name: Peer-nominations.

Timepoints: Pre-intervention, immediately after intervention, 6 months after intervention, 12 months after intervention.

Methods of measurement:

1. Questionnaires:
 - A. Revised Anxiety and Depression Scale (RCADS);
 - B. Peer-nomination measure.
2. Programme-integrity:
 - A. Observations;
 - B. Programme and attendance logs.
3. Parents' evaluation: Telephone interviews;
4. Childrens' evaluations: Online focusgroups.

Intervention

FRIENDS for Life is a cognitive-behavioural programme that teaches children the skills to cope more effectively with feelings of anxiety and depression and builds emotional resilience, problem-solving abilities and self-confidence. The programme is based on the theoretical model of prevention and early intervention of anxiety, which addresses cognitive, psychological and behavioural processes that interact in the development, maintenance and experience of anxiety. FRIENDS for Life consists of 10 weekly sessions plus 1 booster sessions. Booster session 1 will be held one month after finishing the programme. The programme also includes 2 parent sessions. Parent sessions will be held after session 3 or 4 of the programme. A FRIENDS for Life group consists of about ten children aged 10-12 years (grades 7 and 8 of Dutch primary schools) and is run by two prevention workers per group. Prevention workers of a local mental health care organisation organise and conduct the programme.

Control group: Care as usual.

Contacts

Public

Postbus 2200
M. Kösters
Amsterdam 1000 CE
The Netherlands
+31 (0)20 5555087

Scientific

Postbus 2200
M. Kösters
Amsterdam 1000 CE
The Netherlands
+31 (0)20 5555087

Eligibility criteria

Inclusion criteria

10 children of grade 7 and 8 of Dutch primary school (age 10-12) scoring highest on the Revised Anxiety and Depression Scale (RCADS) and identified by teacher and care coordinator as having mild symptoms of anxiety and/or depression.

Exclusion criteria

1. Presence of a clinical anxiety or depressive disorder;
2. Externalising behaviour problems;
3. Substantial learning disabilities or a developmental delay (teachers' evaluations);
4. Children who are not willing or not motivated to participate in the programme.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-08-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	30-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38199
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2271
NTR-old	NTR2397
CCMO	NL32979.029.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38199

Study results

Summary results

N/A