FRIENDS for Life: process and effect evaluation of an indicated school-based prevention programme for childhood anxiety and depression

Published: 17-03-2011
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The aim of the study is to evaluate the effectiveness of FRIENDS for Life as an indicated school-based prevention programme for children with early or mild signs of anxiety or depression.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON38199

Source
ToetsingOnline

Brief title
FRIENDS for Life

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, Anxiety disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam

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

Intervention

Keyword: Anxiety, Children, Indicated prevention, School-based intervention

Outcome measures

Primary outcome

Symptoms of anxiety and depression

Secondary outcome

Programme-integrity

Childrens' evaluation of the programme

Parents' evaluations of the programme

Response to FRIENDS for Life in gender, age, and ethnic group

Study description

Background summary

Anxiety disorders and depression are highly prevalent in children and affect children*s current and future functioning. Childhood anxiety and depression show considerable persistence into adulthood and are likely to deteriorate when left untreated. FRIENDS for Life is a cognitive-behavioural programme that teaches children the skills to cope more effectively with feelings of anxiety and depression. The effect of the programme has been established in Australia, the UK and the USA. However, the effect size varies per study. In addition, the fact that FRIENDS for Life has been shown to be effective in international studies does not automatically imply its effectiveness and suitability in the Netherlands. Differences in school systems, cultural norms and values, and characteristics of participating children may result in differences in the effectiveness of prevention programmes between countries. Although FRIENDS for Life is increasingly being implemented at Dutch schools as a preventive intervention, its effectiveness has never been investigated in the Dutch situation.

Study objective

The aim of the study is to evaluate the effectiveness of FRIENDS for Life as an indicated school-based prevention programme for children with early or mild signs of anxiety or depression.

Study design

Controlled study

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. FRIENDS for Life consists of 10 weekly sessions plus 1 booster session. The programme also includes 2 parent sessions. The programme will be carried out at schools, irrespective of the study.

Study burden and risks

Children who participate in the study, have already participated in FRIENDS for Life. Children fill in questionnaires 6 and 12 months after the intervention. This will take approximately 15 minutes a time. A random sample of 30 children will asked to participate in an online focus group. There is no risk associated with filling in the questionnaires or participating in the online focus groups.
The study can only be conducted with children aged 10-12 years, because the intervention is specifically designed for this group.
A random sample of 30 parents will be contacted by telephone. This will take approximately 10 minutes of their time. There is no risk associated with participating.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children scoring highest on the Revised Child Anxiety and Depression Scale (RCADS) and/or children nominated by teachers and care coordinators are eligible for participation in FRIENDS for Life. Teachers and care coordinators nominate children who display mild symptoms of anxiety and/or depression (i.e., are shy, nervous, afraid, inhibited, depressed, unhappy, worried)

Exclusion criteria

Presence of a clinical anxiety or depressive disorder, externalising behaviour problems, substantial learning disabilities or a developmental delay. Children who are not motivated or not willing to take part in the programme.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-08-2010
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-04-2012
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

ID: 23152
Source: NTR
Title:

In other registers

Register	ID
Other	Netherlands Trial Register (NTR2397)
CCMO	NL32979.029.10
OMON	NL-OMON23152