

Effectiveness of a cognitive-behavioural based group intervention for children with chronic disease

Submission date 02/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/05/2013	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Bob F Last

Contact details
Academic Medical Center (AMC)
Emma Children's Hospital
Psychosocial Department
Room G8-224
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 56 74
b.f.last@amc.nl

Additional identifiers

Protocol serial number
ZonMw: 80-82435-98-8038

Study information

Scientific Title

Effectiveness of a cognitive-behavioural based group intervention for children with chronic disease: a multicentre randomised controlled trial

Acronym

Samen Op Koers

Study objectives

This project is aimed to study the extent to which the cognitive behavioural-based group intervention Op Koers is effective in increasing or stabilising psychosocial wellbeing in children with a chronic disease. This study will also examine the extent to which parental involvement enhances the effectiveness of Op Koers.

Primary hypothesis:

Children participating in Op Koers will show greater improvement on the outcome measures than children in the waiting list group at post-treatment, 6 and 12 months later. Differences between the groups are expected to be largest with respect to the skills central to the program, such as information seeking, relaxation and positive thinking (Op Koers questionnaire). Effects on cognitive coping skills might be moderate right after the program, based on the effects in a previous pilot study, but are expected to increase at 6 and 12 months after the program due to repeated use of these skills. As a result of increased resilience, the differences on social emotional functioning are also expected to increase.

Secondary hypothesis:

Children with parents who participated in Samen op Koers will show greater improvement on the outcome measures compared to both the Op Koers and waiting list condition post-treatment, 6 and 12 months later. Effects are hypothesised to be similar in direction but stronger than for the Op Koers intervention compared to the waiting-list group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medisch Ethische Commissie (Medical Ethical Committee) Academisch Medisch Centrum (AMC) approved on the 21st March 2009 (ref: MEC08/369 #09.17.0515)

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic illness

Interventions

Op Koers is based on techniques proven to be effective in behavioural and cognitive behavioural programs in children with somatic complaints and in children with behaviour and/or anxiety

disorders. Four learning goals are central in Op Koers:

1. Information seeking and information giving about the disease ('good to know better' principle)
2. Use of relaxation during stressful situations (using exercises)
3. Enhancement of social competence (group discussions, role playing)
4. Positive thinking (effective use of the Thinking-Feeling-Doing model; replacement of inaccurate thoughts)

The parent intervention 'Samen op Koers' is built on existing cognitive behavioural programs for parents of children with anxiety problems. 'Samen op Koers' fits into the learning goals of Op Koers. The program combines cognitive behavioural strategies with parenting behaviour training, focusing on positive responsiveness and autonomy granting, including:

1. Promoting and supporting children's acquisition of novel self-help skills
2. Labelling and accepting children's emotional responses (rather than criticising them)
3. Allowing children to struggle and learn by trial and error rather than taking over for them
4. Giving choices (rather than making choices for the children)

The primary purpose of the parental module is enhancing treatment effects of the children's program, by teaching parents to encourage their children in using the learned strategies. The secondary goal of Samen op Koers is to encourage parents to take a positive attitude towards granting autonomy to their children, so that children will actually receive the opportunity to exercise their learned skills by themselves. Overall, the parent interventions are intended to enhance availability of parental support as perceived by the children, expected to result in increases in children's perceived self-efficacy and in the implementation of coping skills, related to their disease and treatment, which in turn will improve social-emotional functioning in children with chronic illnesses (CI).

The total duration of treatment is 6 weeks and the total duration of follow-up is one year.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Social emotional functioning, measured using the Child Behaviour Check List (CBCL), and the Strengths and Difficulties Questionnaire (SDQ). Assessments will be at baseline, post-treatment and at six months and 12 months follow-up.

Key secondary outcome(s)

Assessments will be at baseline, post-treatment and at six months and 12 months follow-up:

1. Health related quality of life (KIDSREEN/DISABKIDS instruments)
2. Self perception (Self-Perception Profile for Children)
3. Copings skills (Coping Skills Inventory [CSI])
4. Parental stress (NOSIK instrument)
5. Parent-child interaction
6. Perceived vulnerability (Child Vulnerability Scale)

Completion date

01/12/2011

Eligibility

Key inclusion criteria

1. Children and adolescents with a chronic disease
2. Aged 8 - 18 years old, either sex
3. Parents visiting the outpatient clinic of one of the five participating hospitals

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. Children receiving special education are excluded, because intellectual disabilities require an adapted program to overcome their communicative difficulties
2. Families will not be excluded based on ethnicity, but participants should be able to fill in Dutch questionnaires

Date of first enrolment

01/11/2009

Date of final enrolment

01/12/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)
(ref: 80-82435-98-8038)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013		Yes	No
Other publications	study design	14/07/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes