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

Submission date 02/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/11/2009	**Overall study status** Completed	
Last Edited 22/05/2013	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.opkoersonline.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.amc.nl/upload/teksten/ekz/folder%20Samen%20Op%20Koers%20mei%202009.pdf (Dutch only)

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 measure
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.

Secondary outcome measures
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 Vulnerabilty Scale)

Overall study start date
01/11/2009

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

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
162

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
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Sponsor information

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

Sponsor details
Postbox 93 245
The Hague
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications	study design	14/07/2011		Yes	No
Results article	results	01/04/2013		Yes	No