Effectiveness of a cognitive-behavioral based group intervention for children with chronic disease: A randomized controlled trial.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33686

Source
ToetsingOnline

Brief title
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Condition

- Other condition
- Age related factors

Synonym
nvt

Health condition

Alle chronische ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: chronically ill children, cognitive-behavioral therapy, group intervention, parental support

Outcome measures

Primary outcome

Intervention related as well as social- and emotional outcomes are studied.

Most of these measures

have been shown to be effective in identifying treatment effects in earlier

studies with Op Koers. When available and reliable, short versions of

questionnaires are used. (see Primaire onderzoeksvariabelen/uitkomstmaten)

Secondary outcome

See: Secundaire onderzoeksvariabelen.

Study description

Background summary

Children with a chronic illness (CI), like asthma, diabetes, sickle cell anemia, cystic fibrosis, and inflammatory bowel diseases, are twice as likely to develop psychosocial problems as healthy children.
About 25% of children with a chronic illness need any mental health services.
To adequately prevent children with CI from developing psychosocial problems, evidenced based intervention programs are needed. However, in the Netherlands, these programs do not exist. As a first

effort, in the Emma
Kinderziekenhuis AMC, a standardized group-based intervention program was developed, called Op
Koers. Based on cognitive-behavioural principles, children learn to use skills to help them to cope with
the consequences of their disease. Children that participated in Op Koers reported significant
improvement of social-emotional functioning than before the intervention. Parents were, however, not
involved in this program, while they may be the best support of their ill child. To enhance the effect of
intervention, a complementary program for parents called Samen Sterk was developed. Samen Sterk is
aimed to support parents in encouraging their children in using learned cognitive skills, which may be
especially important for achieving long term effects. Samen Sterk is expected to strengthen the
intervention effects of Op Koers, enhancing the positive effects of intervention on the adjustment of
children with CI.

Study objective

Effects will be evaluated in a randomized controlled design. First, the effects of Op
Koers on social-emotional outcomes will be compared with a control group. Secondly, the additional
value of Samen Sterk will be investigated in relation to both conditions. Effects of the different conditions
will be investigated in a moderate (6 months) to long term (12 months) schedule. Five hospitals will
cooperate in this study to provide a sample size sufficient for comparing effects of interventions and to
explore whether the intervention will catch on in academic as well as non-academic medical settings. If
proven effective, Op Koers will be made available to all medical centers. The ultimate goal of this study
is that children with a chronic illness and their parents will have access to an evidence based program
that limits the mental health consequences of their physical health.

Study design

The design includes a randomized control trial with three groups: 1) control group (waitlist), 2) child
intervention Op Koers, 3) child intervention Op Koers combined with parent

program Samen Sterk.
Groups will be stratified according to age, because of differences in cognitive development. The
recruitment of children and their parents, as well as conducting the group intervention will be done in
co-operation with five participating hospitals. Supervised by the main researcher, local psychologists at
each hospital are involved with informing medical staff and participants and the organization of the
assignment procedure. A post-doc researcher (part-time) and a PhD student are involved with the
organization and coordination of the project, and with analyzing the data and reporting and implementing
the results of the study.
Longitudinal analyses (linear mixed model analysis) will be performed to test the effects of the
intervention (primary and secondary hypothesis). In secondary analyses, moderator variables will be
included to investigate whether the intervention effects are associated with characteristics of the child
and the family (gender, age, medical diagnosis, severity of disease, attendance during group sessions).

Intervention

Op Koers is based on techniques proven to be effective in behavioral and cognitive behavioral programs
in children with somatic complaints (Kibby et al., 1998) and in children with behavior and/or anxiety
disorders (Kendall, 1991). 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), and 4) positive thinking (Effecive use of the Thinking-Feeling-Doing model; replacement of
inaccurate thoughts).
The parent intervention *Samen Sterk* is built on existing cognitive behavioral programs for parents of
children with anxiety problems (Barrett et al., 1998; Wood et al., 2006). *Samen Sterk* fits into the
learning goals of Op Koers. The program combines cognitive behavioral strategies with parenting
behavior training, focusing on positive responsiveness and autonomy granting, including: a) promoting
and supporting children*s acquisition of novel self-help skills, b) labeling

and accepting children*s
emotional responses (rather than criticizing them), c) allowing children to struggle and learn by trial and
error rather than taking over for them, and d) giving choices (rather than making choices for the
children). 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. Secondary goal
of Samen Sterk 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 CI.

Study burden and risks

The burden for the participants consists of completing the questionaires. The amount of time is 45 minutes each occasion. There are no risks for patients or their parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Children with a chronic illness (8-18)

Exclusion criteria

1. Insufficient knowledge of dutch language. Children and their parents need to understand the content of the intervention and the essence of the questionnaires.
2. Children with intellectual disabilities.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	270
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL26290.018.08