Effectiveness of an online cognitive behavioral group intervention for adolescents with a chronic disease and parents: A randomized multicenter controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47709

Source
ToetsingOnline

Brief title
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Condition

- Other condition
- Age related factors

Synonym
nvt

Health condition

alle chronische ziektes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Fonds Nuts Ohra

Intervention

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

Outcome measures

Primary outcome

Parents and adolescents are asked to fill in a questionnaire at four different times: before the intervention (baseline), after the intervention (T1), six months after the start of the intervention (T2) and twelve months after the start of the intervention (T3). The questionnaires will be filled in in the secured website of Op Koers Online. Participants receive an automatic email to fill in the questionnaires. They use the same login code to fill in the questionnaire as to participate in the course. The questionnaires that are used, are all related to the intervention or are focused on psycho-emotional outcomes. In previous studies, most questionnaires have shown to be effective in identifying intervention effects of Op Koers (Scholten et al., 2013).

To measure the amount and disposition of psychosocial problems of adolescents with a chronic illness and parents, and to measure effectiveness, several questionnaire will be given:

Primary study parameters:

Adolescents:

- Child Behavior Checklist (Achenbach, 1991)

Parents:

Hospital Anxiety and Depression Scale (HADS) (Spinhoven et al., 1997)

Secondary outcome

Adolescents:

* Youth Self-report (YSR) standardised and validated questionnaire that gathers information about emotional and behavioural problems of the adolescent. (Verhulst, Van de Ende, & Koot, 1997).

* Perceived Competence Scale for Adolescents (CBSA) standardised and validated questionnaire that gathers information of the adolescent about self-worth. (Treffers et al., 2002).

* Pediatric Quality of Life Inventory * self report (PedsQL) standardised and validated questionnaire that gathers information about the adolescents perceived quality of life. (Engelen, Haentjens, Detmar, Koopman, & Grootenhuis, 2009).

* Op Koers questionnaire (Last et al., 2007) intervention related outcome measure.

* Evaluation questionnaire to assess the intervention content, design, course leaders and satisfaction with the course.

Ouders:

* Pediatric Quality of Life Inventory * Family Impact Module (PedsQL-FIM)

standardised and validated questionnaire that gathers information about the parent*s perceived quality of life and the impact of the chronic illness on family life (Medrano, Berlin, & Davies, 2013).

* Distress Thermometer for Parents, standardised and validated questionnaire that maps the degree of mental pressure, stress and wellbeing of the parent. (Haverman et al., 2013).

* Inventory Social Involvement, standardised and validated questionnaire that gathers information about the parental perceived social involvement from his or her surrounding (Dam-Baggen, 1989).

* Illness Cognition Questionnaire for Parents, standardised and validated questionnaire that measures to what extent the concepts helplessness, acceptation and illness benefits are present as illness cognitions in a parent (Evers et al., 2001).

* Op Koers questionnaire: intervention related outcome measure.

* Evaluation questionnaire to assess the intervention content, design, course leaders and satisfaction with the course.

Study description

Background summary

In the Netherlands, the estimated prevalence of children and adolescents with a chronic illness is 500.000 (14%). The term *chronic illness* refers to a medical condition that is not (yet) curable and the illness exists for at least three months and doesn*t cure spontaneously. Children and adolescents with a chronic illness often face uncertainty about the future, frequent hospital visits, medical treatment, fatigue, limitations when participating in social and/or sport activities and absenteeism at school. These aspects have a big influence on the daily functioning of these children and adolescents. Due

to this, they are at heightened risk for psychosocial problems such as anxiety, sadness, social withdrawal and adaptation problems. Consequently, these problems can have a negative influence on their possibilities to develop in the same way peers do and to participate in society.
Parents of children and adolescents with a chronic illness experience more worries and stress because of intensified care taking and emotional pressure then parents whose children are healthy. Besides the intensified social-emotional support that parents are supposed to give to their child with a chronic illness, the relationships with other household and family members, friends and colleagues can become more tensed.
In short, not only the child with a chronic illness is affected by the consequences of the illness. The resilience of all members in the household is tested. By strengthening the core, meaning the child with the chronic illness, and the layer that encloses this core, meaning the household, this will have a positive reciprocal effect on the wellbeing of the child as well as on the important supportive surroundings. For that reason attention is needed to prevent psychosocial problems in these vulnerable children and their family members. However, easy accessible evidence-based healthcare for this target group is lacking. Online interventions are easy accessible and lower down barriers for healthcare. Additionally, research shows that online interventions are as effective as face-to-face interventions.
This study will show whether adolescents with a chronic illness and/or parents will profit from participating in the Op Koers Online courses. Considering the positive effects of the face-to-face program, we expect that Op Koers Online will have a positive effect on psychosocial wellbeing. We expect that psychosocial functioning of adolescents and parents in the intervention will improve.

Study objective

The main objective of the study is to research the effectiveness of two online cognitive behavioural therapeutic courses; a course for adolescents with a chronic illness and a course for parents of children and adolescents with a chronic illness. The following research questions will be leading when determining effectivity:
1. Does participation in Op Koers Online for adolescents with a chronic illness have a positive effect on psychosocial functioning of the adolescent?
2. Does participation in Op Koers Online for parents have a positive effect on psychosocial functioning of the parent?

Study design

Research on Op Koers Online for adolescents and Op Koers Online for parents will be conducted in two separate randomised controlled multicentre trials with two conditions: intervention condition (Op Koers Online) and waiting list condition. This design offers the opportunity that multiple family members from

one family can participate in the research. However, this is not required.
Earlier studies on the effectiveness of Op Koers and comparable effect studies showed moderate effects. Based on a repeated measures design with four measure points in time and a within subject correlation of 0.5, 84 adolescents and 84 parents are needed to show a moderate intervention effect (d=0.05) over time, with a two-sided 0.05 significance level and 80% power. Taking into account a dropout of 15% over time, 96 adolescents and 96 parents need to participate to meet the intended power. Due to this, 48 adolescents and 48 parents will be randomised in the intervention group and the same amount will be randomised in the waitlist condition. When on average five participants are in one course, there will be 10 courses for adolescents and 10 courses for parents in the intervention condition.

A total of 66 young people and 81 parents were included. Based on the expected drop-out rate of 15%, we will be able to include the outcomes of at least 56 young people and 69 parents in the analysis. This is realistic based on the data collection until 26 November 2018. We performed new power calculations. We have performed power calculations based on the smaller than intended sample size numbers. The smaller sample number does not have any major adverse consequences.
For the adolescents the power is 65%, instead of the desired 80%, to be able to demonstrate a difference of 0.5 SD between intervention and control group. However, we are able to demonstrate a difference of 0.6 SD, instead of the target 0.5 SD, with a power of 80%.
For the parent intervention the power is 75%, instead of the desired 80%, to be able to demonstrate a difference of 0.5 SD between intervention and control group. However, we are able to show a difference of 0.53 SD, instead of the intended 0.5 SD, with a power of 80%.

In total, nine hospitals will participate in the study
Emma Children*s hospital AMC (Amsterdam),
VU Medical Centre (Amsterdam),
De Kinderkliniek (Almere),
Antonius Hospital (Sneek),
Jeroen Bosch Hospital (*s-Hertogenbosch),
Deventer Hospital (Deventer),
Canisius-Wilhelmina Hospital (Nijmegen),
Hospital St Jansdal (Harderwijk) en
Scheper Hospital (Emmen).

The peripheral hospitals and the VU Medical Centre will give one course for the adolescents and one for the parents each. The Emma Children*s hospital will give two courses for the adolescents and two for parents in the intervention condition. In every hospital, participants will be invited to participate in the study through an invitation letter. When do agree to participate, adolescents will have an intake by phone and parents will have a face-to-face intake. After intake, the randomisation will be conducted. Participants will be

randomised in the intervention or waitlist condition. In case the participant is randomised in the intervention condition, he/she will start the course in October 2016 (adolescent) and January 2017 (parent). If the participant is randomised in the waiting list condition, the participant is able to do the course one year later when effectiveness is proven.

At four points in time, all participants fill in online questionnaires at www.opkoersonline.nl; before randomisation, directly after the course, directly after the booster session (six months after baseline) and 12 months after starting the course.
We use intention-to-treat analyses. Longitudinal multilevel analyses (SPSS: linear mixed model analyses) with raw data will be performed to measure the effect of the intervention (primary and secondary hypotheses). With explorative analyses, possible effects on the raw data of the secondary outcomes of adolescents and parents will be measured.

Intervention

All Op Koers Online courses will be given in a secured chat environment and a secured chat box, in which participants log in every week at the same time. Op Koers Online for adolescents consists of eight sessions (weekly) and one booster session (6 months after the start of the course). Op Koers Online for parents consists of six sessions (weekly) and one booster session (6 months after the start of the course).

Participants are able to do their homework assignments in between the sessions, in their own chat environment. De assignments suit the sessions and become available after each session. Apart from the sessions in the chat box, parents are not able to chat with each other. The courses are guided by one healthcare psychologist and one co-therapist, who use a detailed manual. Every session lasts 1,5 hour.
Op Koers Online is based on techniques proven to be effective in behavioural and cognitive behavioural programmes. A specific model is used to explain to participant how thoughts, feelings and behaviour is related to each other and influences each other. This *thinking-feeling-doing* model makes it possible to recognise negative thoughts and feelings and helps to learn new behaviour.

In the course for adolescents, four learning goals are the focus of attention: 1) searching information and giving information about your illness (*it is better to know*-principle), 2) use of relaxation techniques during stressful situations (relaxation exercises), 3) enlarging social competences (video*s and group discussions) and 4) positive thinking (*thinking-feeling-doing*-model and detecting worrying thoughts).

In the course for parents, every session a certain *circle* in which the parent lives, is the focus of attention. To match the course to the needs of parents, themes in a particular circle that are relevant to the participating parents

are discussed in the chat session. To make the course as effective as possible, the focus lies more on amassing independently compounding information. They can access this information in their personal online environment. Per session, parents can find a summary of the themes that have been discussed, tips that parents gave each other psycho-education and assignments. These assignments serve a transition goal to bring the learned active coping skills in practice.

Study burden and risks

The intervention is not invasive and there is no external pressure that is out of control for the adolescent and/or parent. Op Koers Online is focused on enlarging personal skills. The intervention will be offered online and participants can participate when they are at home. Adolescents do not need to travel to participate in the intervention. Parents only travel once to the hospital, if they want the acquaintance to be face-to-face, otherwise it will be done on the phone. Parents can also participate in the intervention when they are at home. The interventions consist of 7 or 9 sessions, with a duration of 1,5 hour. Our experiences with Op Koers Online show that it is much appreciated by participants that they do not need to travel to be able to participate. As a result, adolescents have less school absenteeism and for parents it*s more easy to combine with their work. Risk are negligible for the adolescents and parents. The burden with participation is minimal; the burden for participants consists of completing questionnaires. The amount of time is 45 minutes each occasion.
The study can only be done with cooperation of pediatric patients. Only if we include adolescents with a chronic illness and parents of children and adolescents with a chronic illness, we are able to study the effect of Op Koers Online in these groups.

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)
Elderly (65 years and older)

Inclusion criteria

- Adolescents with a chronic illness,
- Age: between 12 - 18 years old
- being able to read and typ in Dutch;- Parents of a child/adolescent with a chronic illness
- Age of the child between 0 - 18 years old
- being able to read and typ in Dutch

Exclusion criteria

1. Insufficient knowledge of the Dutch language. Adolescents and 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:	Recruitment stopped
Start date (anticipated):	22-09-2016
Enrollment:	147
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	27-03-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL56656.018.16