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Effectiveness of online psychosocial group interventions for adolescents with a chronic illness and parents

Submission date
28/11/2017

Recruitment status
No longer recruiting

Registration date
30/11/2017

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the Netherlands, the estimated prevalence of children and adolescents with a chronic illness is 500,000 (14%). 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 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 can face more stress because of intensified care taking, emotional pressure and possible financial problems than parents whose children are healthy. Next to 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 tense. In short, not only the adolescent with a chronic illness is affected by the consequences of the illness. The resilience of parents is tested as well. For that reason, attention is needed to prevent and/or to overcome psychosocial problems in these vulnerable adolescents and parents. Online interventions are easy accessible: participants can participate from home and because of the lack of face-to-face contact, the threshold to participate may be lower. Research has shown that online interventions are as effective as face-to-face interventions. The aim of this study is to find out whether adolescents with a chronic illness and/or parents profit from participating in the Op Koers Online intervention.

Who can participate?
Adolescents (aged 12-18 years) with a chronic illness and parents of children (aged 0-18 years) with a chronic illness

What does the study involve?
Participants are randomly allocated to either the treatment group or the waitlist (control) group. Participants in the treatment group follow the intervention Op Koers Online and fill out questionnaires, four times in total, over a one-year period. Participants in the waitlist group fill

out the questionnaires. These participants have the opportunity to follow the Op Koers Online course after the study period (one year). The Op Koers Online intervention consists of eight (for adolescents) or six (for parents) weekly sessions of 90 minutes, which take place at a set time, in a secured chatroom with groups of three to six participants. The interventions are guided by two course leaders who are trained and use a detailed manual. All participants and course leaders log in at the same time. Participants can log in to the homework site to view the intervention material (information sheets and videos), submit homework for every session and view additional information (only parents). Four months after the last session, there is a booster session. For both interventions, the goal is to prevent and/or to treat psychosocial problems by teaching active use of coping skills. Central in the interventions is the Thinking-Feeling-Doing model. With this model, course leaders teach participants the relationship between what persons think, feel and how they act. Through exercises, participants learn how to recognize negative thoughts and how to transform them into more positive or helping thoughts.

What are the possible benefits and risks of participating?
Considering the positive effects of the Op Koers face-to-face program, it is expected that Op Koers Online will have a positive effect on psychosocial wellbeing. It is expected that the psychosocial functioning of adolescents and parents will improve. The intervention is not invasive. The burden with participation is minimal; completing questionnaires, 4 times, about 45 minutes each.

Where is the study run from?
The study runs from the Emma Children's Hospital, Academic Medical Center (AMC) in Amsterdam, the Netherlands. There are eight participating hospitals in the study. However, patients do not necessarily have to visit the outpatient clinic of one of the participating hospitals to participate: every patient in the Netherlands can apply for the study.

When is study starting and how long is it expected to run for?
June 2016 to December 2019

Who is funding the study?
FondsNutsOhra (Netherlands)

Who is the main contact?
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Study website
http://www.opkoersonline.nl

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Fonds NutsOhra: 100.977

Study information

Scientific Title
Effectiveness of online psychosocial group interventions for adolescents with a chronic illness and parents: two parallel randomized multicenter controlled trials

Acronym
Op Koers Online

Study objectives
The aim of this trial is to study the extent to which the cognitive behavioral-based online group intervention Op Koers Online is effective in increasing disease related coping skills and increasing or stabilizing psychosocial wellbeing in adolescents (aged 12-18 years) with a chronic disease, and in parents of children (aged 0-18 years) with a chronic disease. Adolescents and parents participating in Op Koers Online will show greater improvement on the primary outcome measures than adolescents and parents on the waiting list group at post-treatment, 6 months and 12 months follow-up. Differences between the groups are expected to be largest with respect to the (coping) skills central to the program, such as information seeking, relaxation and positive thinking (measured with the Op Koers questionnaire). Effects on coping skills might be moderate right after the program, based on the effects in the previous study on Op Koers

face-to-face, 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee (METC) of the Academic Medical Center (AMC), 02/06/2016, ref: METC2016_o52#B2016370; protocol number NL56656.018.16

Study design
Parallel multicenter randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic illness

Interventions
Participants are randomised into either the treatment group or waitlist (control) group. Participants in the treatment group follow the intervention Op Koers Online and fill out questionnaires, four times in total, in a one-year period. Participants in the waitlist group fill out the questionnaires. These participants have the opportunity to follow the Op Koers Online course after the study period (one year).

The interventions consist of eight (for adolescents) or six (for parents) weekly sessions of 90 minutes, which take place at a set time, in a secured chatroom with groups of three to six participants. The interventions are guided by two course leaders who are trained and use a detailed manual. All participants and course leaders log in at the same time. Participants can log in to the homework site to view the intervention material (information sheets and videos), submit homework for every session and view additional information (only parents). Four months after the last session, there is a booster session.

For both interventions, the goal is to prevent and/or to treat psychosocial problems by teaching active use of coping skills. Central in the interventions is the Thinking-Feeling-Doing model. With this model, course leaders teach participants the relationship between what persons think, feel

and how they act. Through exercises, participants learn how to recognize negative thoughts and how to transform them into more positive or helping thoughts. Every intervention group starts the first session with an extensive meeting (questions such as: who are you, what do you do, which illness do you/does your child have, what are your expectations of the course, etc) to create a feeling of safety within the group and in the chat box.

'Op Koers Online' for adolescents
The intervention aims to empower adolescents with CI by teaching the use of active coping strategies. This is done with techniques from cognitive-behavioral therapy (CBT), which focusses on recognizing cognitive distortions and on teaching coping and problem solving skills, by transforming negative thoughts into more positive and proactive ones.
Learning goals are increasing the use of five coping skills taught with CBT techniques (relaxation, cognitive restructuring and social skills): 1) information seeking and giving, 2) use of relaxation during stressful situations, 3) increase knowledge of self-management and medical compliance, 4) improvement of social competence and 5) positive thinking. Each coping skill is taught during one specific session, but elements of the coping skills are also addressed in the subsequent sessions. The coping skills are taught by psycho-education (e.g. video's, group discussions), through exercises (e.g. virtual board games) and homework assignments (e.g. practicing relaxation exercise in daily life). Learning goals are: 1) information seeking and giving about the illness, 2) use of relaxation during stressful situations, 3) increase knowledge of self-management and compliance, 4) enhancement of social competence and 5) positive thinking.

'Op Koers Online' for parents
The intervention aims to empower parents of children with CI by teaching the use of active coping strategies. Strategies to help parents focusing on elements they think are important in life, and to act conform these elements, are taught with the use of CBT techniques and Acceptance and Commitment Therapy (ACT). ACT, part of CBT, is an intervention strategy to learn participants how to accept a new situation (such as: having a child with CI) and to establish new routines. Goal is to increase or create psychological flexibility. This is done with mindfulness, exercises and reflection which helps participants to remind and recognize what barriers they face in achieving goals and living consistent with their values, and how to adjust behavior in these situations. There is growing evidence for the effectiveness of ACT.
Learning goals are increasing the use of five coping skills taught with CBT and ACT techniques: 1) use of relaxation during stressful situations, 2) increase knowledge of self-management and compliance, 3) positive thinking, 4) positive parenting and 5) open communication and seeking and accepting support.
The subject of every session is presented with an illustrative circle. The circle shows different 'rings' of life to the participants (in the middle: parent, first ring: the family, second ring: the hospital, third ring: family and friends, fourth ring: surroundings; e.g. work, school) and helps to frame the subject into daily life. Participants answer questions concerning the subject (questions are displayed in the right screen of the chat box) and react on each other (giving tips, asking questions, sharing experiences). Since the questions are broad, participants decide the specific topics discussed during the session. The focus lies on sharing experiences and social/emotional support from the group. Compared to the intervention for adolescents, the intervention for parents is less protocolled. There is more room for personal input, are more (spontaneous) group discussions and less videos, games and exercises during the session.

Intervention Type
Behavioural

Primary outcome measure

Psychosocial functioning (measured using CBCL/YSR for adolescents and HADS for parents) and disease-related coping skills (measured using Op Koers questionnaire). Assessments take place at baseline, after 8 (adolescents) or 6 (parents) weeks of treatment, and at 6- and 12-month follow-up period

Secondary outcome measures
Adolescents:
1. Self-esteem, measured using Perceived Competence Scale for Adolescents (CBSA)
2. Quality of life, measured using Pediatric Quality of Life Inventory – self report (PedsQL)

Parents:
1. Impact of the illness on family functioning, measured using the Pediatric Quality of Life Inventory – Family Impace Module (PedsQL – FIM)
2. Parental distress, measured using the Distress Thermometer for Parents (DTP)
3. Social involvement, measured using the Inventory Social Involvement (ISI)
4. Illness cognitions, measured using Illness Cognition Questionnaire for Parents (ISQ)

Assessments take place at baseline, after 8 (adolescents) or 6 (parents) weeks of treatment, and at 6- and 12-month follow-up period

Overall study start date
01/06/2016

Completion date
01/12/2019

Eligibility

Key inclusion criteria
Adolescents:
1. Adolescents with a chronic disease (definition of Mokkink et al, 2007: an illness that requires at least six months of continuous medical care, permanent life style changes and continuous behavioral adaptation to the unpredictable course of the illness)
2. Aged 12 - 18 years old
3. Being able to type, read and understand the Dutch language
4. Access to a computer with internet

Parents:
1. Having one or more children (aged 0 - 18 years) with a chronic disease (using the definition of Mokkink et al)
2. Being able to type, read and understand the Dutch language
3. Access to a computer with connection to the internet

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
192 (96 adolescents and 96 parents)

Key exclusion criteria
Both adolescents and parents:
1. Patients with intellectual disabilities are excluded, their disabilities require an adapted program to overcome their communicative difficulties
2. Not being able to type, read and understand the Dutch language
3. Not having access to a computer with connection to the internet

Date of first enrolment
01/09/2016

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Emma Children's Hospital, Academic Medical Center
Amsterdam
Netherlands
1100VC

Sponsor information

Organisation
Fonds NutsOhra

Sponsor details
James Wattstraat 100
Amsterdam
Netherlands
1097DM

Sponsor type
Charity

Website
www.fondsnutsohra.nl

ROR
https://ror.org/04ev7sy32

Funder(s)

Funder type
Charity

Funder Name
Fonds NutsOhra

Alternative Name(s)
NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
During data collection the trialists plan to publish the protocol article (including statistical analysis plan) in BMC Pediatrics (beginning of 2018). An article about the pilot data of the intervention for adolescents is planned for submission in the first half of 2018, possibly in CPPP, and an article about the development of the intervention for parents is planned for submission in 2018. After the RCT is finished and all data is complete, two articles are planned about the effectiveness of the intervention for adolescents and the intervention for parents, and one more in-depth article concerning the intervention(s). For all articles, planned publication in a high-impact peer-reviewed journal. Publication will be in the second half of 2020.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/07/2018		Yes	No
Results article	results for parents	19/02/2021	12/02/2021	Yes	No