Op Koers Online for parents in pediatric oncology

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The present study aims to evaluate efficacy and feasibility of an online group intervention for parents of children with cancer that focuses on the specific issues that play a role in parents coping with a child with cancer. Hypothesis: Participants...

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

Summary

ID

NL-OMON25566

Source
Nationaal Trial Register

Brief title
Op Koers

Condition

- Other condition

Health condition

Pediatric Oncology

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor kinderoncologie
Source(s) of monetary or material Support: Prinses Máxima Centrum voor kinderoncologie.

Intervention

- Psychosocial intervention

Keyword: Op Koers Online

Explanation

Outcome measures

Primary outcome

Primary study parameters reflect psychosocial wellbeing, measured with validated standardized questionnaires that are completed online by the parents. Differences between intervention condition and waitlist-control condition in change over time on wellbeing are tested. Questionnaires used for the primary outcomes: - Patient Reported Outcomes Measurement Information System (PROMIS) item banks - anxiety and depression (Computer adaptive testing) - Hospital anxiety and depression scale (HADS) - anxiety and depression - Distress Thermometer for Parents (DT-P) - parental overall distress, thermometer score only - Situation-Specific Emotional Reaction Questionnaire (SSERQ) - Situation-Specific Emotional Reactions - Pediatric Quality Of Life Inventory Family Impact Module (PedsQL FIM) - Family relationships and Worry - Insomnia Severity Index (ISI) – Insomnia

Secondary outcome

Secondary study parameters reflect coping (online questionnaires) and feasibility (both questionnaires with course leaders and participants, and the recording of logistical and recruitment issues).

Study description

Background summary

RATIONALE Childhood cancer in the family is stressful for all family members and has long-term consequences for the patients as well as their parents and siblings, including the risk of developing psychosocial problems. The standards of psychosocial care for parents of children with cancer state that access to appropriate interventions for parents and caregivers should be facilitated to optimize parent, child, and family wellbeing. Evidence-based interventions targeted at parents of children with cancer are needed. OBJECTIVE The present study aims to evaluate efficacy and feasibility of a cognitive behavioral-based online group intervention that focuses on the specific issues that play a role in parents coping with a child with cancer. The intervention, led by psychologists, aims to improve psychosocial wellbeing and to prevent psychosocial problems by improving coping skills. STUDY DESIGN A Randomized Controlled Trial (RCT) with two conditions (Intervention and Waitlist-control) is proposed to assess the efficacy of the online intervention. Feasibility of the intervention will be assessed

cross-sectionally. STUDY POPULATION Parents are eligible if their child is diagnosed with any cancer at the age of 0-18 years, is within 5 years from diagnosis, and is still living with their parents at the time of recruitment. INTERVENTION The intervention under study is Op Koers Online for parents in pediatric oncology. The main goal of the intervention is to improve psychosocial wellbeing and to prevent psychosocial problems by teaching active use of coping skills. To teach coping skills, cognitive behavioral techniques and acceptance and commitment techniques are used. The intervention consists of protocolled chat sessions with three to six parents under supervision of trained course leaders (psychologist with an assistant).

Study objective

The present study aims to evaluate efficacy and feasibility of an online group intervention for parents of children with cancer that focuses on the specific issues that play a role in parents coping with a child with cancer. Hypothesis: Participants in the intervention group have better coping skills and better psychosocial functioning than participants in the control group, at T1 and T2.

Study design

T0 (before intervention), T1 (directly after intervention 6-8 weeks after T0), T2 (six months after T0). The intervention condition will have an additional measurement at T3 (one year after T0).

Intervention

The intervention under study is Op Koers Online for parents in pediatric oncology. The main goal of the intervention is to improve psychosocial wellbeing and to prevent psychosocial problems by teaching active use of coping skills. To teach coping skills, cognitive behavioral techniques and acceptance and commitment techniques are used. The intervention consists of protocolled chat sessions with three to six parents under supervision of trained course leaders (psychologist with an assistant).

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Parents are eligible for the study - if their child was diagnosed before with childhood cancer at the age of 0-18 years; - if their child is within 5 years from diagnosis for childhood cancer (during or after successful treatment) - if their child still lives with his/her parent(s) - if they have access to a laptop/computer with internet connection - when they have provided written informed consent

Exclusion criteria

Parents who meet any of the following criteria are excluded from participation: - parents who are not able to follow a group chat course - parents who are not able to fill out Dutch questionnaires

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2020
Enrollment:	98
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	30-07-2020
Application type:	First submission
Review commission:	METC Utrecht Huispostnr D01.343 Postbus 85500 3508 GA Utrecht 088 755 6376 metc@umcutrecht.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 49373
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8565
CCMO	NL73763.041.20
OMON	NL-OMON49373

Study results

Results posted: 07-10-2020

Actual enrolment: 89

Baseline characteristics
"89 parents were included in analyses (mean age 41.9 years, 86% female, 62%/38% post/during treatment of their child). Beneficial intervention effects ($p < 0.05$) were found at T1 for anxiety, depression, distress, loneliness and relax ation, and at T2 for

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