

EMPOWERING PARENTS IN PEDIATRIC ONCOLOGY WITH AN ONLINE COGNITIVE-BEHAVIORALBASED GROUP INTERVENTION: A RANDOMIZED CONTROLLED TRIAL

Published: 30-07-2020

Last updated: 15-05-2024

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. The intervention, led by...

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

Summary

ID

NL-OMON49373

Source

ToetsingOnline

Brief title

Empowering parents in pediatric oncology

Condition

- Other condition

Synonym

mental health, psychosocial wellbeing

Health condition

preventief voor problemen in het psychosociaal welzijn

Research involving

Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie

Source(s) of monetary or material Support: Ministerie van OC&W, KIKa (Grant in aanvraag; indien afgewezen andere middelen aanwezig)

Intervention

Keyword: e-health, parents, pediatric oncology, psychosocial intervention

Outcome measures

Primary outcome

Main 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 psychosocial wellbeing are tested.

Secondary outcome

Secondary study parameters reflect coping (online questionnaires) and feasibility (questionnaires for course leaders and participants and the recording of logistical and recruitment time).

Study description

Background summary

Parents of a child with cancer are more worried and stressed than parents of healthy children. This is a consequence of intensive care and coordination tasks but also of the emotional burden that coincides with the illness. An online group course could be a good way to support parents with this and to teach them skills that help them cope with the circumstances. Parents receive information and tips, and the course provides a platform for parents to share

their experiences.

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. The intervention, led by a psychologist, aims to improve psychosocial wellbeing, and to prevent psychosocial problems by improving coping skills.

Study design

A Randomized Clinical 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.

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 burden and risks

The intervention is a non-invasive, psychosocial, cognitive behavioral-based intervention, which has previously been proven effective without any burden or adverse effects in parents of children with chronic illness. The only burden of participation in the study is time-related. All participants are asked to fill out the self-report questionnaires three (waitlist-control group) or four (intervention group) times, which takes approximately 30 minutes at each measurement occasion. The practical burden of participation regarding travelling time and distance is low because it concerns an online intervention. The intervention consists of 7 chat sessions, one and a half hour each.

Contacts

Public

Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL

Scientific

Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

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 and is not deceased
- if their child is within 5 years from diagnosis for childhood cancer
- 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

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

Ethics review

Approved WMO	
Date:	30-07-2020
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25566

Source: Nationaal Trial Register

Title:

5 - EMPOWERING PARENTS IN PEDIATRIC ONCOLOGY WITH AN ONLINE COGNITIVE-BEHAVIORALBASE ...
28-05-2025

In other registers

Register	ID
CCMO	NL73763.041.20
OMON	NL-OMON25566