

Op Koers Online voor ouders in de kinderoncologie

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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...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aanpak	Overige aanpak
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25566

Bron

NTR

Verkorte titel

Op Koers

Aandoening

- Overige aandoening

Aandoening

Pediatric Oncology

Betreft onderzoek met

Mensen

Ondersteuning

Primaire sponsor: Prinses Máxima Centrum voor kinderoncologie

Overige ondersteuning: Prinses Máxima Centrum voor kinderoncologie.

Onderzoeksproduct en/of interventie

- Psychosociale interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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 six weekly protocolled chat sessions with three to six parents under supervision of trained course leaders (psychologist with an assistant).

Contactpersonen

Publiek

Princess Maxima Centre for pediatric oncology
Mala Joosten

0650006729

Wetenschappelijk

Princess Maxima Centre for pediatric oncology
Mala Joosten

0650006729

Deelname eisen

Leeftijd

Volwassenen (18-64 jaar)

Volwassenen (18-64 jaar)

65 jaar en ouder

65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Anders

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 07-10-2020
Aantal proefpersonen: 98
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO
Datum: 30-07-2020
Soort: Eerste indiening
Toetsingscommissie: METC Utrecht

Huispostnr D01.343

Postbus 85500

3508 GA Utrecht

088 755 6376

metc@umcutrecht.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49373
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Datum resultaten gemeld: 07-10-2020

Totaal aantal deelnemers: 89

Karakteristieken onderzoekspopulatie

"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 relaxation, and at T2 for

URL result

Type

ext

Naam

wiley.com

URL