Reducing Pain in Pediatric Oncology Patients at Home. Effectiveness of the KLIK Pijnmonitor App

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We hypothesize that children who have the app at their disposal (intervention group) experience 20% less clinically significant pain at home than children who do not use the app (control group).

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24832

Bron
NTR

Verkorte titel
RELIEF-2

Aandoening

Treatment- and illness related pain due to pediatric cancer

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: 80-84400-98-512

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary objective of the RELIEF-2 study is to investigate the effectiveness of the KLIK Pijnmonitor in reducing clinically significant pain in children at home by comparing the proportion of clinically significant pain between the intervention group and the control group. Thus, the primary outcome is the prevalence of clinically significant pain in children at home.

Toelichting onderzoek

Achtergrond van het onderzoek

The RELIEF-study was initiated in response to a study carried out at the Sophia Children's Hospital in Rotterdam (Simon et al., 2020. Pain at Home During Childhood Cancer Treatment. Severity, Prevalence, Analgesic Use and Interference with Daily Life, Pediatric Blood and Cancer). In this study, pain was assessed in children with cancer receiving chemotherapy at the outpatient clinic. The majority of children experienced clinically significant pain at home and families frequently indicated that no medication was used to manage pain. As a result, the KLIK Pijnmonitor app was developed to decrease pain in children with cancer at home. The app provides families with professional help and educa-tional information to improve pain management in the home setting.

In the RELIEF-1 study, feasibility of the app, adherence to the app, user experiences with the app, and determinants of implementation were assessed in a small group of families (N=27) and healthcare professionals (HCP's) (N=7) (Simon et al., in preparation for publica-tion). Results were used to further improve the KLIK Pijnmonitor app and the processes in-volved.

In the RELIEF-2 study, effectiveness of the app will be assessed in order to answer the question: do children who use the app experience less clinically significant pain (i.e. score >4 on 'worst pain' or 'average pain in the last 24 hours') at home than children who do not use the app (i.e. receive care as usual)?

Doel van het onderzoek

We hypothesize that children who have the app at their disposal (intervention group) experience 20% less clinically significant pain at home than children who do not use the app (control group).

Onderzoeksopzet

At T0 (before group allocation) and T1 (during week 3 of the study period), study participants will complete questionnaires.

Onderzoeksproduct en/of interventie

The intervention group will have the KLIK Pijnmonitor app at their disposal. This includes the opportunity (note: not requirement) to report pain intensity whenever a child is in pain and

therewith receive feedback from HCP’s when pain is clinically significant. Moreover, the app features educational information about pain(management). The control group does not have the app at their disposal, but continues to receive care as usual (i.e. families are responsible for contacting the hospital themselves when their child is in pain.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, children must be between the ages of 0 and 18 years; be in active treatment (at least three months after diagnosis and with at least two months of treatment remaining). Furthermore, study participants (child or parent) need to understand and speak the Dutch language, and own a smartphone on which the application can be downloaded (available at Apple Store and Google Play Store).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	168
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8910
Ander register	METC Utrecht : To be decided

Resultaten