Sugarsquare: Online treatment environment for parents of a child with Diabetes Mellitus Type 1.

Gepubliceerd: 01-10-2012 Laatst bijgewerkt: 18-08-2022

Use of an online treatment environment will lead to decrease in parenting stress.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24521

Bron
Nationaal Trial Register

Verkorte titel
Sugarsquare for Parents

Aandoening

Diabetes Mellitus Type 1 (T1DM)

Ondersteuning

Primaire sponsor: Radboud University Medical Center, Nijmegen
Overige ondersteuning: Dutch Innovation Funds Healthcare-insurers

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Parenting stress (NOSIK; de Brock, Vermulst, Gerris & Abidin, 1992).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Type 1 Diabetes Mellitus is a chronic metabolic disorder, which demands a complicated disease self-management. This stresses parents and child to adapt their lifestyle to the demands of the disease and is highly dependent on the skills and motivation of the parents and child. To support parents in the disease self-management, a low level, easy approachable way of communication with the treatment team is of great importance. A quick, demand-driven way of working by the treatment is endorsed by parents in this. Peer contact also seems to contribute to parents' self-management, as well as good alignment of the treatment team. Recent research shows that ICT can play a significant role in facilitating these. In the present study, we will implement an online policlinic aimed at patient-caregiver communication and peer contact in seven centres for paediatric diabetes care.

Objective:

The primary goal of Sugarsquare is to decrease parenting stress in the parents of children with Type 1 Diabetes Mellitus by supporting them in their disease management. We further aim to decrease problems parents and children perceive in incorporating diabetes self-management in everyday family life, which is expected to improve parents' and child's well-being and increase parents' satisfaction of quality of care. We additionally try to improve alignment of the treatment team. We expect to improve the child's glycemic control, decrease the number of hospitalizations and to improve contact between parents and treatment teams. We also aim to describe which applications will appeal to parents the most.

Study design:

We will test effect of the intervention by means of a randomized controlled trial. Participants will randomly be assigned to an experimental group and a control group. The experimental group will use the intervention from the start of the study; the control group will use the intervention from 6 months following the start of the study. Data will be collected by means of questionnaires at start of the study (baseline), halfway the study period (at 6 months following start of the study) and at the end of the study period (at 12 months). Further, participants will weekly answer questions aimed to assess their care consumption of the past week. To lower threshold and to make it as easy as possible for parents to respond, all questionnaires will be send and answered through a secured link on the internet.

Study population:

The study population consists of parents of children with Type 1 Diabetes Mellitus. Intervention (if applicable): Sugarquare is an online policlinic, on which parents can find a chat application and a forum application for peer contact. Further, parents will find an overview of their child's treatment on a secured, individual section on which they can discuss their child's treatment with the treatment team. Parents can further find reliable information on the disease and an overview of ongoing studies and recent study results. Interaction of individual treatment team members with parents will be visible for all other treatment team members.

Main study parameters/endpoints:

Parenting stress, assessed by means of the Parenting Stress Index Short Form (PSI-SF) is the primary outcome in the present study. Our power calculation is based on this questionnaire.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This study will be performed using healthy parents of children diagnosed with type 1 diabetes, under the age of 13. Parents are responsible for their child and therefore one the most important actors in the treatment of their child. By intervening in parents, we expect to have significant influence on the child's treatment. Parents will not have to visit their treatment centre for the study more often than accordingly care as usual. Burden therefore only consists of filling out the questionnaires. Risks are negligible.

Doel van het onderzoek

Use of an online treatment environment will lead to decrease in parenting stress.

Onderzoeksopzet

T0: Baseline;

T1: 6 months following baseline (halfway through the trial);

T2: 12 months following baseline (end of the trial).

Onderzoeksproduct en/of interventie

Sugarquare is an online policlinic, on which parents can find a chat application and a forum application for peer contact. Further, parents will find an overview of their child's treatment

on a secured, individual section on which they can discuss their child’s treatment with the treatment team. Parents can further find reliable information on the disease and an overview of ongoing studies and recent study results. Interaction of individual treatment team members with parents will be visible for all other treatment team members.

The control group will start the intervention after 6 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Parent of at least one child with T1DM;

2. Who is under the age of 13 at start of the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Parents who are not able to understand Dutch written language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2012
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-10-2012
Soort:	Eerste indiening

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	NL3511
NTR-old	NTR3643
Ander register	CCMO : 36650.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A