Effects of the use of the final PAL System release on Type 1 Diabetes Mellitus self-management determinants in children aged 7-14

Published: 20-08-2018
Last updated: 11-04-2024

The primary objective is to evaluate the effect of the PAL-system on diabetes self-management determinants and behaviour and as a result on the health of children with T1DM. The PAL-System consist of a robot and a MyPAL-app, containing an avatar of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON46455

Source
ToetsingOnline

Brief title
Effect of PAL on self-management in children with T1DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Insulin-dependent diabetes, type I diabetes

Research involving
Human

Sponsors and support

Primary sponsor: TNO

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Children, PAL system, Self-management, Type I Diabetes Mellitus

Outcome measures

Primary outcome

The hypothesized main study outcomes are (1) an improvement in the intervention group in Type 1 Diabetes health outcomes: HbA1c values (measured with a finger prick) and glucose values (collected by a glucometer, as part of the standard diabetes management regime) of PAL 3.0 during phase 1. And (2) an improvement of diabetes knowledge (questionnaire).

Secondary outcome

The hypothesized secondary outcomes during phase 1 are (1) improvements in Diabetes-related Quality of Life (measured with the PedsQoL-DM questionnaire by both child and parent(s)), (2) self-management determinants and behaviour (measured with the Self-Care Inventory, SC, questionnaire and self-management goal achievement in the PAL-system), and (3) system usability (SUS, only intervention group).

The expected outcome in phase 2 is a further improvement of the usability and use of the PAL-System V3.5, with additional features, in comparison to V3.0.

Study description

Background summary

The EU H2020 PAL project aims at developing a multi-system technology (i.e. the PAL-system) that can support young patients with Type 1 Diabetes Mellitus

(T1DM), aged 7 to 14, their families and the medical staff, and accompany them in a shared educational path towards a proper management of the disease, possibly having an impact on their diabetes health outcomes and related knowledge.

Study objective

The primary objective is to evaluate the effect of the PAL-system on diabetes self-management determinants and behaviour and as a result on the health of children with T1DM. The PAL-System consist of a robot and a MyPAL-app, containing an avatar of the robot. Children can play educational activities with the robot in the hospital and with the avatar at home and have talks about their day and their diabetes. Also, children can work on personal diabetes objectives, set together with their health care professional (HCP) and parents. Parents and HCP can monitor to what extend children achieve their objectives, through dedicated, secured web pages, part of the PAL-System. HCP can also tailor through their webpage the content of the activities to offer children additional support to achieve their objectives.

The secondary objective is to evaluate the usability and use of the system, both from children*s perspective and their parents and healthcare professionals.

Study design

The study design will be a randomized controlled trial with a wait-list control group. The children will be randomly assigned either to an intervention group (group A) or a control-wait list group (group B). The intervention group will be accustomed through the use of a first version of PAL (V.3.0) for 3 months. After 3 months the effectiveness, in terms of T1DM-related indicators, of PAL 3.0 will measured. After a summer break, both groups will be asked to play with a second version of PAL (V.3.5) for another period of 3 months, after which the added value of several extended features will be evaluated in regard to their impact on usability and use of the PAL-system.

Intervention

The children meet the robot in the hospital and play an educational activity. Also, they set with their HCP and parents personal diabetes self-management objectives, to work on at home through their MyPAL-app. For example, they want to sleep over at a friend, which means they need to know how to count carbs and recognize when they have high and low glucose values. At home, to work on their objectives, they play educational activities with the avatar (including, quiz, memory, and sorting game) and conversations about their day (e.g., did they do sports, how did they feel) and their diabetes (e.g., their most recent glucose value). After approximately 3 months, they return to the hospital, they play

another activity with the robot and review the objectives with their HCP.

Study burden and risks

Possible burdens: extra hospital visits, extra finger prick HbA1c, use of app takes time and places emphasis on sickness. We know from the previous experiments that this works two ways: some children see it as a burden because it places extra emphasize on their sickness (they want to lead normal lives), while others (younger/just diagnosed) are more proud of the app/robot and enjoy playing and learning. Some also see the diary and sorting activity as a burden because it not user friendly enough.

Contacts

Public
TNO

Schipholweg 77
Leiden 2316 ZL
NL
Scientific
TNO

Schipholweg 77
Leiden 2316 ZL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Children should be between 7 and 14 years old
- Diagnosed with type I Diabetes Mellitus (T1DM) - The diagnosis is older than six months
- The child is treated at one of the participating hospitals
- The child and at least one parent have a good command of the Dutch language
- An informed consent form should be signed by the child and both his/her parents

Exclusion criteria

The participant will be excluded if he/she has an co-existing medical condition that, according to the treating physician, is expected to interfere with the study results. For example intellectual disability, autism spectrum disorders, epilepsy and cerebral palsy).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL65421.100.18