New SkyCare - Type 2 Diabetes part: improvement and implementation study of virtual health care for patients with type 2 diabetes.

Published: 18-11-2021
Last updated: 31-01-2025

To provide high-quality remote care to patients with type 2 diabetes, using an eHealth platform with support from a medical service center. The present study is optimisation and implementation research. Notably, the aim is not implementation but...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON57252

Source
ToetsingOnline

Brief title
SkyCare-T2D-imp

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
adult-onset diabetes, type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: EIT Health

Intervention

Keyword: automated care, eHealth, telemedicine, type 2 diabetes

Outcome measures

Primary outcome

The primary and secondary study parameters/outcome of the study are:

• To provide a reliable and easy-to-use platform for remote care,

including the use of a medical service center with high accessibility,

usability,

acceptance and satisfaction of users.

• To maintain stable regulation: HbA1c, blood pressure, and body weight.

• To maintain adequate: health-related quality of life (PAID-5),

patient activation (PAM-6), patient satisfaction.

Secondary outcome

see above

Study description

Background summary

In times of the COVID-19 pandemic, hospital visits have been drastically reduced to prevent infections and focus on COVID-19 care. As a result, the number of visits to care providers decreased by 70%, and fewer patients visited the hospitals because of non-COVID emergency conditions (such as acute myocardial infarction). Notably, mortality increased independently of COVID-19 related complications: the loss of healthy life years due to not delivered care for non-COVID problems was estimated in the range of 100.000-400.000 in the first half of 2020 in the Netherlands.

Remote monitoring by telephone and video calling has become a standard approach: no less than 90% of the appointments at outpatient clinics took place in this way during the first worse period of this crisis. However, this alternative approach is laborious and results in incomplete monitoring of patients. As a result, digital applications to improve the quality of remote care have gained importance.

The multidisciplinary care for type 2 diabetes is well-described in guidelines and consists of the following pillars: improving lifestyle including support for smoking cessation, carefully prescribed glucose-lowering drugs to avoid hypoglycaemia while reducing hyperglycaemic periods, antihypertensives, and cholesterol-lowering medication. Regular monitoring takes place of HbA1c, blood pressure, body weight, albumin excretion in the urine, fundoscopy, vibration and monofilament sense, an inspection of the feet, cardiovascular signs and symptoms. Moreover, self-management is safe and successfully prevents cardiovascular disease and other complications, not with superior but with similar efficacy as usual care.
Therefore, telemedicine would be an appropriate approach to keep patients and care providers connected; and deliver high-quality remote care, reducing the collateral damage of COVID-19.

We expect that diabetes care, according to the guidelines, can be supported by eHealth. New SkyCare is a novel eHealth platform that will implement existing eHealth devices and connect patients and health care providers. This new platform perfectly matches the currently changing situation of non-COVID care. It offers a secure way to monitor patients with type 2 diabetes at home for a long time without creating noise for the care providers. The latter will be accomplished by algorithms based on the first steps of the guidelines and by the support of a medical service center. The treating physicians supervise this service center. It gives opportunities to scale up to large patients* groups and other conditions in the short term.

The purpose of the present project is the improvement and implementation of the diabetes platform of New SkyCare in all lines of care. Successful implementation will improve the technology readiness level of New SkyCare, making it ready for future efficacy studies.

Study objective

To provide high-quality remote care to patients with type 2 diabetes, using an eHealth platform with support from a medical service center.

The present study is optimisation and implementation research. Notably, the aim is not implementation but implementation research on usability and feasibility of the system. If successful, the optimised version can be used for future randomised clinical assessment of safety and efficacy.
We introduce historical controls to get a first impression about the system's

performance and enable power calculations for future research.

Study design

PDSA guided improvement and implementation research.

Study burden and risks

The burden of using New SkyCare will be assessed in the improvement PDSA cycles and with the patient satisfaction questionnaire.

The overall risk of using this eHealth platform will be negligible, as the target population consists of stable patients with type 2 diabetes and the monitoring of the participants will be more frequent than in the current usual care: the automated medical decisions are all supervised by physicians. Measurements exceeding the thresholds will be triaged on severity by an automated system and evaluated by the medical service center staff. Severe deviations from the thresholds will result in an alarm to the 24/7 medical service center, mildly abnormal values will be evaluated daily during office hours. The medical service center receives supervision from an internist of the research team. A medical doctor is on call day and night.
Severe deviations from the protocol will be handled as an emergency, and the participants will be advised to visit the local Urgent Care Centre or A&E Department.

Increased medicalisation of the participants may result in health risks. However, self-management has been shown to be safe. Our follow-up is probably too short to expect more adverse effects based on increased medicalisation than in the cited study. Therefore, we estimate this risk as very low, but we will attempt to identify negative effects based on close monitoring and increased consumption of care after the improvement and implementation.

Similarly, some minor risk is involved in the frequent measurement of the body weight, as more frequent weighing than weekly has been related to a negative mood, reduced self-esteem and body dissatisfaction. We, therefore, advise participants to measure body weight only twice a month.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015GD

NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Type 2 diabetes;
• Stable chronic disease three months prior to inclusion;
• Treated with diet and lifestyle, oral anti-diabetic medication, and/or subcutaneous anti-diabetic medication, including insulin;
• Owns a smartphone (Android 7 or newer; IOS 11 or newer) and
o is able to use apps in Dutch;
o is able to receive push notifications;
o is able to use Bluetooth Low Energy;
o has access to a Wi-Fi connection at home.
• Able to understand and decide on written informed consent in Dutch;
• Able to perform activities of daily living (ADL) independently.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Treatment with subcutaneous insulin pump;

• Female subject who is pregnant or breastfeeding or planning to become pregnant or breastfeed during the study;
• Other types of diabetes mellitus;
• Major health conditions:
o liver, heart or lung transplant;
o untreated cancer, current chemotherapy or radiotherapy;
o acute infections, sepsis, or acute organ failure;
o cystic fibrosis;
o life expectancy less than one year;
• Alcohol or other drug abuse or psychosis in the year prior to the study;
• History of bariatric surgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2022
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	New Skycare
Registration:	No

Ethics review

Approved WMO Date:	18-11-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL78060.078.21