Evaluating an educational care pathway supported by smart technology and self-monitoring for patients with type 2 diabetes in a tertiary endocrinology setting

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON51058

Source
ToetsingOnline

Brief title
DiaBox

Condition

- Diabetic complications
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

Synonym
diabetes, diabetes mellitus type 2

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes, Lifestyle, Self-management, Self-monitoring

Outcome measures

Primary outcome

The primary endpoints are usability, feasibility and acceptability of the

educational care pathway.

Secondary outcome

Secondary endpoints include perceived learning about diabetes and its relevant

lifestyle factors, patient activation towards diabetes self-management, and

glucose regulation.

Study description

Background summary

Type 2 diabetes (T2D) reduces the quality of life and life expectancy significantly. Furthermore, as the prevalence of T2D increases, both the impact on our healthcare system and the economic burden grow. Lifestyle changes can be effective in achieving partial or complete remission of T2D; however, long-term maintenance of health behaviour can be challenging. Knowledge about the disease and about the influence of lifestyle on health is crucial for optimal disease (self-)management. We have developed a novel educational care pathway, aiming to increase patients* knowledge about T2D and its related lifestyle factors, to empower patients in managing their disease, and to improve glucose regulation.

Study objective

The primary aim of this study is to examine the feasibility, usability, and

acceptability of the educational care pathway for both patients and healthcare professionals. The secondary aim is to investigate the preliminary effects on patients* perceived learning about diabetes and its associated factors, activation towards disease management, and glucose regulation.

Study design

The study entails a mixed methods sequential explanatory design and will be conducted in the endocrinology department of the Leiden University Medical Center in The Netherlands. The quantitative research consists of questionnaires administered at baseline (T0) and at the end of the eight-week educational care pathway (T1). The qualitative part is conducted at T1 and consists of focus groups with patients, and in-depth interviews with healthcare professionals.

Intervention

The intervention is an eight-week care pathway that combines education, self-monitoring and a smartphone application. The education will be provided in both individual and group consultations, plus online videos that explain the pathogenesis of diabetes, as well as the effect of food, activity, sleep and stress on glucose regulation. The pathway will be supported by a so-called *diabetes box* that includes self-monitoring devices and a smartphone application. This allows the participants to monitor blood glucose, physical activity, sleep, stress, and their diet. The smartphone application provides a platform where all the measurements are visualized and combined, and where teaching material can be accessed.

Study burden and risks

The information included in the educational care pathway is in line with information provided to the patient in current regular care. We do not expect any health risks to be associated with the use of self-monitoring and smartphone application. The time investment for the pathway is approximately six to nine hours for the five consultations, 60 minutes for the video*s and 60 minutes for the self-monitoring. The time investment is thus larger compared to regular care that generally includes two appointments of 10 and 45min. In addition, participants will spend 20 minutes to complete the questionnaires and, for a small subgroup, 90 minutes for focus groups. Potential benefits of the new educational care pathway are increased knowledge and activation, and improved glucose regulation. To conclude, the potential benefits are expected to outweigh the burden of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Type 2 diabetes mellitus or post transplantation diabetes as diagnosed by a medical specialist or a general practitioner
Aged 18 years or older
Own a smartphone
Have wireless Internet access at home

Exclusion criteria

Disabling (near) deafness and/or blindness without means to compensate
When patients are deemed to be unfit to participate in group consultations; this decision is left to the discretion of the responsible healthcare professional

Total pancreatectomy in medical history or during the study
Received solid organ transplant less than one year ago
Pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	32
Type:	Anticipated

Medical products/devices used

Generic name:	The Diabetes Box
Registration:	No

Ethics review

Approved WMO

Date:	08-09-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76573.058.21