Lifestyle monitoring and coaching using the mobile DIAMETER application in primary and secondary care (DIAMETER-1 study): protocol for a study on intervention usage and acceptability

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

Summary

ID

NL-OMON56033

Source
ToetsingOnline

Brief title
Diameter-1

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, Diabetes Mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott Diabetes Care,Abbott Diabetes Care en DiabetesFonds

Intervention

Keyword: Acceptability, Diabetes type 2, eHealth, Self-management

Outcome measures

Primary outcome

The main study parameters concern insight into the usability (phase 1),

intervention usage (phase 2) and acceptability (phase 2) of the Diameter.

Secondary outcome

In phase 2, secondary objectives are to explore behavioural (e.g. physical

activity), physiological (e.g. BMI), psychological (e.g. health-related quality

of life) and clinical outcomes (e.g. glucose control, estimated HbA1c values).

Study description

Background summary

Type 2 Diabetes Mellitus (T2DM) is a major chronic lifestyle-related disorder with a significant impact on quality and costs of care. As patients with T2DM often have insufficient knowledge about proper self-management and are insufficiently motivated for lifestyle change, interventions with more motivational strategies and personalization are needed. The use of real-time monitoring of glucose values, nutrition and physical activity in combination with coaching aimed at lifestyle-related behaviour change may improve patients* diabetes management.

Based on this, we hypothesize that a technology-enabled lifestyle intervention is effective and a step forward in DMT2 management. In the Twente region, we are developing a personalized treatment strategy to improve the lifestyle of DMT2 patients by providing coaching and feedback in daily life via a mobile application, the Diameter. The development of the Diameter is a collaboration

between Ziekenhuisgroep Twente (ZGT) and University of Twente (UT), and will be provided via the Ancora Health platform. The Diameter provides the ability to monitor food intake, physical activity and glucose levels; it provides individual patients and healthcare professionals with insight into lifestyle, blood glucose levels and the effect of lifestyle behavior on glucose levels in daily life. In addition, the Diameter offers evidence-based coaching, developed in collaboration with the Netherlands Organization for Applied Scientific Research (TNO), aimed at improving lifestyle in the areas of physical activity and nutrition.

Study objective

Phase 1. The primary objective is to asses the usability of the Diameter in secondary care to solve main user problems before the start of the second phase.

Phase 2. The primary objective is to assess intervention usage and acceptability of the Diameter as blended-care intervention in primary and secondary care. Secondary objectives are to explore behavioural (e.g. physical activity), physiological (e.g. BMI), psychological (e.g. health-related quality of life) and clinical outcomes (e.g. glucose control, estimated HbA1c values).

Study design

Phase 1. A mixed-methods cross-sectional study will be performed. Patients will use the Diameter for 5 weeks and afterwards a semi-structured interview about the usability of the Diameter and think-aloud test about a non-validated questionnaire will be performed.

Phase 2.This study has a mixed-method design with 3 (regular participants ZGT and primary care) or 4 (participants who decide to follow the Combined Lifestyle Intervention (GLI) COOL next to the Diameter during the study period) data collection points. Patients will start with a two-week period of baseline measurements. Subsequently, patients will use the Diameter as blended-care intervention for 10 weeks. The two-week measurement periods will be repeated twice (T1: week 13-14 and at T2: week 25-26). Between T1 and T2, patients will use a version of the Diameter without daily coaching messages. At T1 and T2, questionnaires will be administered, data on physical activity, food intake and glucose values will be logged, and blood and urine samples will be retrieved from regular care measurements. In addition, open-ended interviews will be performed with 10-15 patients at T1. For participants who also decided to follow the COOL program, some routinely collected measurements as part of the COOL program will be obtained from the patient record.

Intervention

Regular treatment in primary or secondary care or during COOL will be complemented with the Diameter: a mobile application which enables continuous monitoring of nutrition (via food diary), physical activity (via activity tracker Fitbit and self-reported activities) and blood glucose values (via Freestyle libre 2 sensor). The Diameter also provides autonomous lifestyle coaching via daily coaching messages, short weekly e-mails and exercises aimed at goal achievement.

Study burden and risks

Extra visits to the outpatient clinic or general practitioner (GP) are kept to a minimum, as data (excl. questionnaires) will be collected as much as possible during regular hospital/GP visits. For phase 2, extra physiological non-invasive measurements include body impedance and handgrip strength test. The total expected time burden for patients is 120, 420 and 105 minutes for the three phases respectively. In phase 1 and 2, participants are required to wear the Fitbit and Freestyle Libre.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Being diagnosed with type 2 diabetes;
• Being treated in the outpatient clinic at ZGT or in primary care;
• Being familiar with using a smartphone.

Exclusion criteria

• Dependence on renal replacement therapy;
• Severe general diseases or mental disorders making participation in the study impossible;
• Insufficient mastery of the Dutch language;
• Other CGM device than Freestyle Libre.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2022
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Diameter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-04-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-06-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	13-12-2024
Application type:	Amendment
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
ClinicalTrials.gov	NCT05307120
CCMO	NL75953.100.20