Nursing Prehabilitation Intervention Supported with Technology for Vascular Surgery in People with Type 2 Diabetes

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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-OMON53292

Source
ToetsingOnline

Brief title
VITAAAL study

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: ZGT wetenschapsvoucher van 50.000 euro

Intervention

Keyword: Diabetes mellitus type 2, Prehabilitation

Outcome measures

Primary outcome

Usability and feasibility are assessed with the UTAUT questionnaires and an

open-ended at the end of the intervention

Secondary outcome

Secondary objectives are to explore behavioural (e.g. physical activity),

physiological (e.g. BMI), psychological (e.g. health-relatedquality of life)

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

Study description

Background summary

Type 2 Diabetes Mellitus (T2DM) is the most common chronic lifestyle-related disorder with a significant impact on quality and healthcare expenditures. Insufficient glycemic control and low fitness level prior to a surgical intervention results in more postoperative complications which leads to a longer hospitalization, higher costs and mortality. A prehabilitation intervention in persons with T2DM prior to surgery should be aimed to improve glucose regulation and translate into better outcomes. However, the classic interventions such as Combined Lifestyle Intervention are labor-intensive and require a high degree of organization and therefore are not used as standard care. The use of biofeedback can provide a solution to this. Biofeedback with a continuous glucose sensor in combination with lifestyle monitoring by activity trackers and coaching prior to surgery is a promising but unexplored prehabilitation strategy. The Nursing Prehabilitation Intervention Supported with Technology for vascular in People with Type 2 Diabetes (VITAAAL) intervention is a form of blended care. It focuses on improving vitality and glycemic control before surgery with the Diameter application, using intermittently scanned glucose monitoring, nutrition habits and physical activity blended with coaching from a nurse practitioner (NP) diabetes. Because VITAAAL is a novel intervention, the aim of this pilot study is to investigate its usability and feasibility. The pilot study consists of three phases. After

the first phase, a specific prehabilitation module will be designed and programmed in the Diameter app. This module will be based on the results and experiences in phase one. In phase two and three the patients will use the adjusted version of the Diameter app that contains implemented findings of the previous phase.

Study objective

The primary objective is to assess the usability and feasibility of the VITAAAL intervention as blended-care intervention. Secondary/exploratory objectives are to evaluate clinical outcomes (e.g. Time in Range, estimated HbA1c, body weight, and physical activity), psychological parameters (e.g. self-management skills).

Study design

In a mixed methods single center pilot study, patients will undergo the VITAAAL intervention during 4 to 8 weeks depending on their waiting time for their surgical intervention. The study consists of three phases. The aim is to include 6 patients in phase one and two and 12 patients in phase three. After each phase, an interim analysis with questionnaires and an interview will be performed to improve the VITAAAL intervention and a prehabilitation module will be programmed in the Diameter app which will be used and evaluated in the second and third phase of the pilot study. The intervention is preceded by a three-day period of blinded baseline measurements.

Intervention

During the VITAAAL intervention patients use the Diameter app to monitor their physical activities (in connection with a Fitbit), nutrition (using the Diameter app) and glucose levels (in connection with Freestyle Libre 2 sensors). Before the intervention starts, a three-day period of blinded baseline measurements is performed to measure current habits, motivation and possibilities. Then, individual aims for improving vitality are formulated in consultation with the NP diabetes. Afterwards, patients continue measuring their habits unblinded with the Diameter for the following weeks and weekly evaluate their goals with the NP to receive new instructions and/or to adapt the goals. During admission for surgery patients keep measuring their physical activity and glucose regulation as during the intervention, they do not keep track of nutrition during admission. Interviews and questionnaires are conducted shortly before admission. 12 weeks after surgery complications and admission duration are identified.

Study burden and risks

Participation in the study requires two visits at the outpatient clinic.

Invasive measurements will not be performed. All other contacts are telephone- or video calls. The total expected time burden for patients is 105 minutes for two visits at the outpatient clinic and 20 minutes for each phone call. Patients are asked to fill in questionnaires twice (at baseline and before hospitalization) by regular post or secure email and a telephone interview before admission with a total time of 53 minutes for all questionnaires and 45 minutes for an interview. Patients are required to use the Fitbit and Freestyle Libre. The risks of participation on patients* health in all phases of this study are minimal. Low glucose values can occur, but due to the intensive contact with the NP diabetes, medication can be adjusted in time to prevent hypoglycemia. Possible benefits for users are that the intervention may lead to better glycemic control before surgery which reduces the risk of postoperative complications, and the intervention could enhance patients* motivation and competence to self-manage their lifestyle.

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

- Patients with T2DM who need a scheduled vascular surgery, consisting of AAA surgery endovascular or classical abdominal approach, aortic stenosis surgery or Fontaine II.
- Patient with T2DM who need orthopedic surgery consisting of Total Knee Prosthesis (TKP), Half Knee Prosthesis (HKP) or Total Hip Prothesis (THP)
- Aged 18 years or older
- Being familiar with using an Android smartphone (version 5.0 or higher);
- Participant can understand and weigh up information provided by researcher and can understand what the consequences of participation are.

Exclusion criteria

- Need for acute surgery
- Dependency on renal replacement therapy
- Known with (pre)proliferative diabetic retinopathy with or without macula oedema.
- Any general diseases or mental disorder rendering participation in the study impossible
- Drug abuse
- Insufficient mastery of the Dutch language

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2023
Enrollment:	24

Type:	Actual

Medical products/devices used

Generic name:	Diameter
Registration:	No

Ethics review

Approved WMO Date:	29-08-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-10-2024
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
CCMO	NL83911.100.23