

Modelling fluctuations in blood glucose levels based on food intake and physical activity in patients with Diabetes Mellitus Type 2

Published: 02-05-2019

Last updated: 15-05-2024

The primary objective is to investigate if models are able to predict changes in blood glucose levels in patients with T2DM when small changes in dietary intake and/or physical activity are applied.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON48091

Source

ToetsingOnline

Brief title

REMIND * pREdictive Modelling IN Diabetes

Condition

- Diabetic complications

Synonym

Diabetes, Type 2 Diabetes Mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: Exceptional and Deep Intelligent Coach (EDIC;grant No. 628.011.021)

Intervention

Keyword: Food intake, Physical Activity, Predictive Modelling, Type 2 diabetes mellitus

Outcome measures

Primary outcome

As the outcome of the model will be the change in blood glucose levels, to assess the models* performance, subcutaneous blood glucose will be measured using a Freestyle Libre glucose sensor.

Secondary outcome

na

Study description

Background summary

Type 2 diabetes mellitus (T2DM) is a highly prevalent disease, causing significant morbidity and mortality worldwide. Poor regulation of blood glucose can lead to debilitating micro- and macrovascular complications such as nephropathy, cardiovascular disease and amputations. Therefore, preventing complications is an important treatment goal in T2DM. To aid patients with T2DM, a coaching system can be developed to e.g. stimulate them in performing certain physical activities or advise them to eat different compositions of food to keep blood glucose levels within the desired range. Before we can implement such a system, we need to have a clear understanding of the magnitude of the effect these lifestyle changes have on blood glucose levels prior to applying them. Therefore, this pilot study is designed to investigate if we can model and predict changes of blood glucose levels when small changes in dietary intake and/or physical activity are applied in patients with T2DM.

Study objective

The primary objective is to investigate if models are able to predict changes in blood glucose levels in patients with T2DM when small changes in dietary

intake and/or physical activity are applied.

Study design

This is a prospective pilot study in the outpatient setting. Patients with T2DM from the outpatient clinic of internal medicine in the ZGT hospital Almelo, will be recruited.

Intervention

During a two-week period, participants will be asked to follow a protocol during a controlled period 4h pre-prandial until 4h post-prandial of dinner in which standardized low fat and carbohydrate dinner meals are administered and on certain days with a normal amount of carbohydrates and/or fats. Furthermore, participants are requested to eat a predetermined snack and a dessert 2h pre-prandial of dinner and directly after dinner respectively. Finally, participants are also asked or not to perform a physical activity 1 hour post-prandial of dinner, which is a 30-minute normal paced walk. Each participant will receive each change in dietary intake (dinner) and physical activity (30-minute walk) in duplo. The order of administration of the meals/physical activities is random for each participant.

Study burden and risks

There are no direct benefits for the patients to be included. Participation in the pilot study is on a voluntary base. Patients will not receive any financial support or priority for treatment of other diseases in the clinic during this pilot study, besides that the meals of interest will be provided for them by the University of Twente.

Patients will be asked to keep a lifestyle diary. During their visit, weight, height, and walking speed will be assessed. The exercise is not designed to be a strenuous amount as it is a normal paced walk. The applied dietary changes are well within the normal range of intake to affect blood glucose for the patients, so hypo- and hyperglycaemic events are not expected. Furthermore, no invasive measurements will be executed and therefore risks of participation in this pilot study are minimal.

Contacts

Public

Universiteit Twente

Zilvermeeuw 1
Almelo 7609PP

NL
Scientific
Universiteit Twente

Zilvermeeuw 1
Almelo 7609PP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * Is diagnosed with diabetes mellitus type 2
- * Is aged between 25 and 70 years
- * Receives diabetic treatment based on long term medication
- * Has a BMI between 25 and 40 kg/m²
- * Is able to do 30 min of walking at a steady pace

Exclusion criteria

- * Is receiver of short term/acute diabetic medication.
- * Has any gastrointestinal disorder that is expected to have clinical relevant effect on the uptake of nutrients from the gut.
- * Has any medical condition that prevents performing the required procedures.
- * Has uncontrolled thyroid diseases.
- * Is allergic to any substance present in any of the standardized meals.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 06-09-2019

Enrollment: 5

Type: Actual

Ethics review

Approved WMO

Date: 02-05-2019

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 04-07-2019

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

ID: 27187
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	n.t.b.
CCMO	NL69297.044.19
OMON	NL-OMON27187