pREdictive Modelling IN Diabetes

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27187

Source
Nationaal Trial Register

Brief title
REMIND

Health condition

Diabetes Mellitus Type 2

Sponsors and support

Primary sponsor: Dr. G.D. Laverman, Internal medicine/nephrology, ZGT Hospital
Source(s) of monetary or material Support: Part of Exceptional and Deep Intelligent Coach (EDIC, grant No. 628.011.021) financed by the Netherlands Organisation for Scientific Research (NWO)

Intervention

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.

Secondary outcome

The developed model will be dependent on several parameters; these will be measured to have them available as input variable:
• Physical activity
• Food intake

Study description

Background summary

Rationale: 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.
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.
Study population: Adult male and female patients with type 2 diabetes.
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.
Main study parameters/endpoints: 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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

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

- One baseline visit at the start of the experiment to the clinic
- The experiment will last for two weeks per subject

Intervention

During a two-week period, participants will be asked to follow a protocol during a controlled period 4 hours pre-prandial until 4 hours post-prandial of dinner in which standardized low fat and carbohydrate dinner meals are administered which on certain days contains a normal amount of carbohydrates and/or fats. Furthermore, this protocol also describes whether the participant should perform a physical exercise 1 hour post-prandial of dinner, which is a 30-minute normal paced walk. During this controlled period of 8 hours, participants are asked not to eat and drink any calorie containing substances other than the standardized dinner meal, a snack 2 hours pre-prandial of dinner, and a dessert directly after dinner. Drinks which are acceptable are: coffee and tea without milk and sugar, and water. Each participant will receive each change in dietary intake (dinner) and physical activity (30-minute walk) twice. The order of administration of the meals/physical activities is random for each participant.

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-03-2019
Enrollment:	5
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48091
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7617
CCMO	NL69297.044.19
OMON	NL-OMON48091

Study results