Understanding of glycemic response using contextual data and modeling * a pilot study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45902

Source
ToetsingOnline

Brief title
Glycemic response in real life settings

Condition

- Other condition

Synonym
health, wellbeing

Health condition

algemeen welbevinden en gezondheid

Research involving
Human

Sponsors and support

Primary sponsor: TKI Agri Food
Source(s) of monetary or material Support: Jumbo,Noldus,OME health,Philips Research,TKI Agri-Food,Wageningen Universiteit

Intervention

Keyword: Glucose, Health, Real-life, Self-monitoring

Outcome measures

Primary outcome

The primary study parameters are:

- Daily food intake

- Daily glucose levels

- Wellbeing

- Activity patterns

Secondary outcome

The secondary outcomes are:

- Lifestyle questionnaire at baseline

- Satiety questionnaire after the OGTT

- User experiences, after the study the user experience will be measured using

a questionnaire. Overall, the questionnaire includes self-constructed scales

that measure user experience with the research in general and self-monitoring

devices

Study description

Background summary

Many people in the Western world have an unhealthy lifestyle, including an unhealthy dietary pattern. Elevated postprandial blood glucose levels, as well as high variability in glucose levels are associated with major risk for prediabetes, type II diabetes and cardiovascular diseases. The use of glycemic index of food products for controlling glycemic responses has limited efficacy. Zeevi et al., have shown that the glycemic response on food is highly personal and not directly linked to the glycemic index of food products. Based on a cohort of 800 people using multiple measurements, a prediction model based on mainly the microbiome was made. Surprisingly, known factors influencing glycemic response like stress levels, quality of sleep and physical activity were not found. A problem with these big cohorts is the quality of data that is collected, the lack of contextual data and the laboratory setting in which the data is collected (which doesn*t necessarily reflect real-life).

The proposed research is part of a research program on Personalized Nutrition and Health (PNH). The ultimate goal of the program is to enhance the health and wellbeing of people by empowering consumers to choose and maintain an optimal personalized diet and lifestyle.

Study objective

The primary goal is to obtain and investigate the added value of real-life high quality contextual data (e.g. food intake, physical activity, sleep, wellbeing) to understand and predict the fluctuations in individual glucose levels.

The secondary objective is to define what metrics of glucose profiles can best be used to personalize lifestyle recommendations with respect to food intake and physical activity.

Study design

During this observational pilot study 24 volunteers will use a continuous glucose monitor (CGM) to self-monitor their glucose levels. Additionally, their activity patterns, heart rate and sleep quality and quantity are monitored using a Philips smartwatch. Furthermore, the participant is asked to register their food intake and score their wellbeing using a smartphone app.
The duration of the pilot study is 13 days. Since the continuous glucose sensor requires a 12 hour initialization period, one day before the start of the pilot, the glucose sensor will be applied on the participants upper arm. At the first day of the pilot a baseline measurement is performed by giving the participant and Oral Glucose Tolerance Test (OGTT), the participant is asked to fast 10 hours before the OGTT. Afterwards the participant is asked to fill in a satiety questionnaire regarding the OGTT in the HowAmI app. Additionally, the participant is asked to start wearing the smartwatch and using the apps to register and photograph their food intake and answer questions regarding their wellbeing. During the remaining days of the pilot the participant can consume

their normal diet, but the participant is asked to register the food intake and answer wellbeing questionnaires in the HowAmI smartphone app. Participants will be asked to maintain a varied diet, but also ensure some repetition (e.g. consume the same breakfast, lunch and snacks for three days during the measuring period). To aid subjects in this we will provide them with some snacks.
After 13 days of self-monitoring a debriefing will take place in which all the participants can ask questions about the study and their personal data observations. Furthermore, the participants will return the glucose sensor and the smartwatch and answer questions about their experiencees with participating in the study.

Intervention

The intervention consists of the OGTT. On the first day of the study the participant will consume an OGTT. The participant can consume the OGTT at home in the morning of the first day of the study. Before the OGTT is consumed the participant is asked not to eat or drink anything (besides water) for the last 10 hours. Just before the participant drinks the OGGT a picture of the OGTT should be taken with the HowAmI app which indicates the time the participant drinks the OGTT.

Study burden and risks

Disadvantes of participating in this study can be 1) There are some tasks to required, e.g. keeping track of food intake and answering the wellbeing questionnaires. 2) there is a small risk of skin irritation due to the glucose sensor, if this happens the participant is asked to contact the study leader and replacement of the sensor will be considered or participation in the study will be ended if the sensor is removed. 3) A potential risk is concern amongst participants to learn about health issues they are not familiar with.

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

* A researcher in the field of nutrition or health
* Aged between 20 - 55
* Able and willing to sign the informed consent form
* Willing to comply with all study procedures

Exclusion criteria

* Diabetes type 2 patients, and/or people with a finger-prick glucose value * 7.8 mmol/l during screening.
* BMI > 25
* Under treatment for neurological or psychiatric complaints, including eating disorders
* Specific dietary preferences, including vegan, raw food, paleo. Vegetarian, pescatarians and flexitarians can participate in the study
* Coeliac disease or gluten intolerance
* Skin allergy, eczema or known sensitivity for plasters
* Performs intensive sport activities more than 6 hours per week
* Pregnant or lactating women

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	Continuous glucose monitoring device 'FreeStyle Libre"
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-07-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL66268.028.18