

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

Source

NTR

Brief title

Diagame

Health condition

Diabetes mellitus

Sponsors and support

Primary sponsor : Prof dr H. Haak

Source(s) of monetary or material Support : NWO

Intervention

Outcome measures

Primary outcome

To collect patient gathered health data (PGHD) that is needed for the development of SugarVita. This includes glucose levels from patients with diabetes and information regarding different factors (physical activity, nutrition, medication and mental state) that can influence those levels. Also the HbA1c, C peptide and HOMA-IR index will be used as a clinical measure of glycemic control and insulin resistance and will be used as an outcome measure to determine the effect of playing SugarVita.

Secondary outcome

not applicable

Study description

Background summary

The DiaGame project applies the sciences of data learning and biomedical simulations to an existing serious diabetes gaming platform (SugarVita). We aim to make the current SugarVita, a data-driven, personalized serious game that empowers individuals with diabetes to manage the disease they are facing. In order to personalize the game, we will integrate our expertise on processing of personal data collected from health-related smartphone apps into our game platform. The information that this approach will be used to personalize the simulation that drives the game. Together, this will allow the use of patient-gathered health data to make the diabetes game a realistic representation of the condition of the gamer. This allows the gamer to play SugarVita-P4 using personal settings for improved educational value, since typically for diabetes, knowledge and skill are the key to effectively self-manage their condition. We will provide support for the notion that playing SugarVita-P4 creates reward and motivation and is therefore more effective.

We are already integrating the development of the game and the encompassing academic (data-processing and simulation) activities into the daily practice in diabetes care. Because of this, we generate the capacity to employ a lean development process that iteratively uses in-game observations to improve the approach to data-to-information-to-education flow. Collectively, DiaGame can change the approach to diabetes care by using data sciences in support of a data-driven personal diabetes game. Ultimately, this will improve the quality of life for patients and lighten the socio-economic and medical burden that diabetes has.

SugarVita aims to give people with diabetes more control over their chronic condition. Self-care is now seen as the primary approach to diabetes, which is a complex task, with many facets, where training and education are crucial. However, a "dry" explanation does not work for everyone.

Study objective

Patient gathered health data will be collected to optimize a personalized diabetes game, which we hypothesize will improve self management

Study design

2 visits (V 2 will be two weeks after visit 1)

Intervention

Registration of daily life by continu glucose monitoring with a Freestyle Libre Pro sensor (Abbott) and exercise, nutrition, medication and mental status by Gamebus app and smartwatch

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- Informed consent obtained before trial related activities
- 20 patients with type 1 diabetes mellitus and BMI < 30
- 200 patients with type 2 diabetes mellitus
- Age above 18 years
- Patient's language skills are sufficient for participation
- Subject has a smartphone and is willing to install the needed apps on it.

Exclusion criteria

- Pregnancy of breastfeeding women
- Scheduled scan or MRI at time of wearing freestyle libre pro sensor
- Malignancy excepted basal and squamous cell skin cancer

Study design

Design

Study type :	Observational non invasive
Intervention model :	Other
Allocation :	Non controlled trial
Masking :	Single blinded (masking used)
Control :	N/A , unknown

Recruitment

NL	
Recruitment status :	Pending
Start date (anticipated) :	01-03-2021
Enrollment :	220
Type :	Anticipated

IPD sharing statement

Plan to share IPD :	Yes
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Ethics review

Positive opinion	
Date :	05-02-2021
Application type :	First submission

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
NTR-new	NL9290
Other	METC Maxima Medical Centre : N20.010

Study results