Development of real world digital health measurements for and by patients that are meaningful to patients and applicable by healthcare providers.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON57303

Source
ToetsingOnline

Brief title
MEaNingful DiGitAl Health Measurements for and by patiEnts (ENGAGE)

Condition

- Diabetic complications

Synonym
Diabetes, Microvascular complications

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: TNO (TKI);Corsano (in kind);Reinier de Graaf Groep (in Kind)

Intervention

Keyword: chronic diseases, digital biomarker, meaningful aspects of health, Patient engagement, value-based healthcare

Outcome measures

Primary outcome

The primary outcome measure of this study is the degree of correlation between

the parameter patterns, measured by the wearable, and the severity of the

micro- and macrovascular damage, as determined by the conventional analyses.

Secondary outcome

not applicable

Study description

Background summary

Chronic lifestyle-related diseases put an increasing burden on patients and healthcare. Taking type 2 diabetes (T2D) as an example, there are around 1M patients in the Netherlands. T2D is linked to poor quality of life and associated with a healthcare expenditure of 6B euros/yr. Diabetes is defined by glycemic dysregulation, with 40-56% suffering from micro- and macrovascular complications or co-morbidities. Microvascular complications include diabetic retinopathy, nephropathy and neuropathy because of impaired oxygen supply to the tissues. Macrovascular complications lead to heart failure, stroke and other cardiovascular complications. Co-morbidities include depression, diabetes distress and impaired psychological wellbeing in general. Especially micro- and macrovascular complications have been identified by people with diabetes as meaningful outcomes. Standardized outcome measures, captured by questionnaires, clinical observation, and clinical chemistry are an important driver of the transition towards value-based healthcare beyond managing HbA1c numbers to prevent complications and comorbidities that matter to the patient. Yet, these measures are burdensome and hamper the implementation of meaningful patient outcome measures. By applying non-invasive measurements with wearables, this

burden could be greatly reduced and these obstacles could be removed.

Study objective

The purpose of this observational pilot study is to evaluate the extent to which the combined glucose, heart rate, blood pressure, and other outcome patterns, collected from wearables, are associated with the severity of micro- and macrovascular complications. The results of this study can be used to determine whether these digital biomarkers can be used to assess the severity of these complications in a non-intrusive and non-invasive way.

Study design

This is an observational study in which physiological parameters are measured using wearables during a normal lifestyle over a period of ten days.

Study burden and risks

The subjects will have minimal burden in the form of a one-time blood draw to determine several diabetes and CVRM parameters.
Blood sampling is normally well tolerated by patients.
In addition, the subject must wear two CGM systems on the upper arm for 10 days, as well as a digital wristband.
Adverse consequences of this are nil.
The subject will also undergo a non-invasive fundoscopy and Pulse wave velocity measurement. In practice, this never causes any problems for those who undergo these tests.
The subject does not have to make any adjustments to the usual lifestyle, which therefore does not entail any additional risks

The risks of adverse effects when participating in this study are considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Prediabetic or diagnosed with diabetes type 2;
- BMI in the range of 25-35 kg/m2
- Aged in the range of 40 - 65 years
- Normal physical activity patterns
- Able and willing to sign the informed consent form
- Willing to comply with all study procedures

Exclusion criteria

- Type 1 diabetes
- Kidney diseases other than related to diabetes
- Cardiovascular diseases other than diabetes and/or hypertension related
- Skin allergy, eczema or known sensitivity for adhesives

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-02-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL87338.058.24