POWER2DM: Predictive model-based decision support for diabetes patient empowerment - Quantification Campaign

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON45607

Source
ToetsingOnline

Brief title
POWER2DM: Quantification Campaign

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus, type 1 diabetes, type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: European Commission Horizon 2020

Intervention

Keyword: diabetes, mHealth, model-based, self-management

Outcome measures

Primary outcome

This study is observational in nature with blood glucose levels and HbA1c as primary outcomes.

Secondary outcome

Secondary outcomes include actual and predicted frequency, timing, and magnitude of hyperglycemic episodes and hypoglycemic episodes; psychosocial measurements of affect, stress, distress, well-being, and self-management.

Study description

Background summary

Diabetes is a chronic condition that involves the inability of the body to maintain normoglycemia. A large investment of time and energy is required to properly manage diabetes. Inadequate self-management (including unhealthy dietary habits, too little self-measurement of blood glucose (SMBG) and insulin administration based on food intake, too little exercise and other daily activities in patients on insulin therapy) usually underlies problems to maintain glycemic control. Hyperglycemia is an important cause of long-term macro-and micro-vascular complications in all patients with diabetes mellitus. And in patients on insulin therapy, (fear of) hypoglycemia has an enormous impact on quality of life. Thus optimization of self-management is one of the most important treatment goals in all types of diabetes. In order to reduce the burden and increase the effectiveness of diabetes self-management patients need to be supported in their self-management using integrated technologies and personalized plans for care.

Study objective

The objective of the POWER2DM project is to develop and evaluate technologies that assist diabetes patients in their self-management using model based decision support and dynamic action plans. To this purpose we developed a three

month observational quantification campaign to occur next to the patients* standard care in which we will use traditional means of data collection with integrated technologies as data input for new glucose simulation models in patients with diabetes. The predictive models of diabetes will be evaluated in their ability to predict specific glucose levels.

Study design

Observational study divided into two phases. Phase 1 involves one month of data collection using mobile health devices to monitor glucose levels, physical activity/sleep tracking, stress, eating behavior, and insulin and medication usage. In addition patient reported outcomes of quality of life, diabetes distress, emotional state and stress will be collected via questionnaire. Information gathered during this phase will be used to create an initial patient specific glucose metabolic model. Phase 2 is a follow-up phase of two weeks occurring in month 3 in order to assess whether the original glucose metabolic model is still accurate.

Study burden and risks

There is a limited burden to the patients in this observational study. This burden includes additional visits compared to usual care, becoming acquainted with e-health care device and filling out of questionnaires. In addition, blood samples need to be drawn and (more) frequent self-monitoring of glucose by finger-pricks is necessary on a number of days and a flash glucose monitoring device (FreeStyle Libre) should be worn on three occasions. Potential benefits for patients during this 3-month study are more insight into their glucose levels and how specific lifestyle activities and behavior impact these glucose levels.

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

* Age 20-70
* Diagnosed type 1 diabetes mellitus or type 2 diabetes mellitus
* Able to self-monitor and work with a computer and smart phone with internet connections (as assessed by researcher)

Exclusion criteria

* Severe renal insufficiency (eGFR<30ml/min)
* Serious/severe comorbidity that interferes with diabetes outcomes or diabetes self-management including but not limited to: psychiatric diseases, chronic hepatopathy, active malignancy, COPD, diseases of the digestive tract, endocrine disorders, cerebrovascular disease with disability
* Concurrent participation in other clinical trials

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2017
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-03-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
Other	EudraCT number 2016-003945-27
CCMO	NL58708.058.16