Evaluation of the POWER2DM Diabetes Self-Management Support System compared with usual care for patients with diabetes

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To provide proof of concept that POWER2DM is safe and effective in improving glycaemic control and analyse of the cost-effectiveness of the approach to highlight any potential issues that may impede implementation.

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

Summary

ID

NL-OMON46363

Source
ToetsingOnline

Brief title
POWER2DM Evaluation Campaign

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
'Diabetes Mellitus' 'Diabetes'

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: HORIZON 2020 subsidie

Intervention

Keyword: Diabetes, Mobile Health, Self-management

Outcome measures

Primary outcome

Change in glucose regulation as measured by HbA1c before and after the intervention compared between the intervention and control groups.

Secondary outcome

• Safety

As measured by:

o amount of hypoglycaemia measured by time spent in hypoglycaemia before and after treatment in the Power2DM group compared to the usual care control group,

o hypo unawareness as measured by Clarke*s hypo unawareness questionnaire, before and after treatment in the Power2DM group compared to the usual care control group and

o other adverse events occurring during the study period to include serious hypoglycemic events among others

• Glucose variability

As derived from continuous measurements and defined as measured by:

o Mean blood glucose (MBG)

o Standard deviation of MBG (SDBG)

o Largest amplitude of glycemic excursions (LAGE)

o Mean amplitude of glycemic excursions (MAGE)

o Absolute means of daily differences (MODD)

o Time spent in range

• Model based risk scores

o ADVANCE Cardiovascular risk

o ADVANCE Kidney disease Risk

o Major outcomes T1D

o UKPDS risk score

o MT2D-Marvel model

o KADIS-based Q score

• Behavioural change (self-management)

o Exercise

o Frequency of SMBG measurements

o Adherence to medication plan

o Amount of goals reached

o Weight (and BMI)

o Diabetes Self-Management score

• Psycho-social changes

o Quality of life

o Diabetes burden

o Mental health

o Diabetes knowledge

o Diabetes self-efficacy

• User satisfaction

o Satisfaction with diabetes care

o Communication with healthcare provider

o User feedback on SMSS

o Goal Progress

o Usage of app

• Cost-effectiveness (socio-economic impact)

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 healthy dietary habits and exercise, appropriate self-measurement of blood glucose (SMBG) and insulin administration based on food intake, exercise and other daily activities in patients on insulin therapy, usually underlies problems to maintain glycaemic control. Hyperglycaemia is an important cause of long-term macro-and microvascular complications in all patients with diabetes mellitus. And in patients on insulin therapy, (fear of) hypoglycaemia 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. Patients need to be supported in order to reduce the burden and increase the effectiveness of their diabetes self-management. One way to do this is by using integrated technologies and personalized plans for care as a cornerstone in the modern scope of therapeutic approach current strategies in chronic diseases. For this purpose, the POWER2DM support system was developed to give patients insight into their condition and support diabetes patients and their health care professionals in setting and achieveing self-management goals using predictive computer model simulations and behavioural action plans.

Study objective

To provide proof of concept that POWER2DM is safe and effective in improving glycaemic control and analyse of the cost-effectiveness of the approach to highlight any potential issues that may impede implementation.

Study design

This is a pragmatic randomised trial with 9 months follow-up in which patients will be randomised to either Power2DM support (Power2DM group) or usual care (usual care group) . There will be evaluation moments at baseline, after 11 weeks, 22 weeks and 37 weeks.

Intervention

The POWER2DM support group will receive access to the prototype 2 of the POWER2DM system. This system consists of two components: 1) the web-based Shared Decision Making Dashboard, used to set self-management goals together with a health care professional with the use of both short- and long-term predictive computer simulation models to, and 2) the POWER2DM Self-Management Support System as a mobile application and webpage, used to support behavioural change in DM self-management. The system is fed with data from an activity tracker, a glucose monitor and manual data entry.

Study burden and risks

The risks associated with participation in the intervention group are limited as any changes to the patient*s diabetes care plan will be done in cooperation with a healthcare professional. The primary potential foreseeable risk associated with participation in this study is negative feelings resulting from the increased attention to the patient*s illness. As the purpose of the system is to assist the patient in successfully managing their diabetes by drawing attention to their disease and its management, this risk is acceptable as the potential benefits associated with better diabetes and glucose control include lowered chance of developing diabetes related complications or dying. There is an additional burden of time presented to the patient connected as they will need to track their diabetes self-management and there will be an increase in communication moments with the patient*s healthcare provider. The POWER2DM Evaluation Campaign (EC) is the second stage of the POWER2DM Project, and is based on the results of the first stage POWER2DM Quantification Campaign (QC). In that stage, a very positive feedback was reported by the participants in the study in the two centers with patients reporting an average satisfaction of 8/10 for the system as a whole and 100% of participants who completed the study (18/20) reporting that they would like to participate in later stages of the study. Based on this feedback, the risk of the negative feelings seems low. There are long-term risks associated caused by Diabetes Mellitus. These

cardiovascular, renal and other metabolic systems risks associated with uncontrolled glucose levels should be reduced through participation in POWER2DM, meaning that the potential benefit of reduced long-term complications outweigh the slight risk of negative feelings and burden of time related to participation. Events occurred during the length of the study will be evaluated, and relationship with the POWER2DM will be also investigated.

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

Diabetes type 1 or Diabetes type 2
Able to self-monitor and work with computer and smart phone with internet connections (as assessed by researcher)

In possession of a smartphone that can run the POWER2DM mobile application

Exclusion criteria

Severe renal insufficiency (eGFR<30ml/min)
Serious/severe comorbidity that interferes with diabetes outcomes or diabetes self-management
Pregnant or wanting/trying to become pregnant in the coming 2 weeks

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2018
Enrollment:	115
Type:	Actual

Medical products/devices used

Generic name:	POWER2DM diabetes self-management support system
Registration:	No

Ethics review

Approved WMO Date:	25-05-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-12-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-01-2020
Application type:	Amendment
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	NL63735.058.17