Self-management in type 2 diabetes patients on insulin therapy triggered by app-messages

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To investigate the effectiveness of text-messages sent via a smartphone app (app-triggers) regarding dietary habits, physical activity, prevention of hypoglycaemic events and glycaemic variability on HbA1c, body weight, diabetes self-management and...

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

Summary

ID

NL-OMON44809

Source
ToetsingOnline

Brief title
TRIGGER study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
noninsulin-dependent diabetes mellitus, type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Sanofi-Aventis BV

Intervention

Keyword: mHealth, RCT, self-management, type 2 diabetes mellitus

Outcome measures

Primary outcome

The primary study endpoints are 1) the percentage of patients who achieve an HbA1c level *7% (53 mmol/mol) without hypoglycaemia (plasma glucose <3.5 mmol/L (63 mg/dL) and 2) the HbA1c level as a continuous outcome variable after a follow-up duration of 6 months.

Secondary outcome

Change between baseline and 6 months (end of intervention period) in:

- Clinical parameters (body weight, BMI, waist circumference, lipid profile, blood pressure, insulin dose, number of hypoglycaemic events, glycaemic variability)
- Self-management (SDSQ)
- Food habits (FFQ)
- Physical activity (IPAQ)
- Health status (EQ-5D, SF36)
- Diabetes related quality of life (ADDQoL)
- Patients satisfaction (DTSQ).

The cost-effectiveness of the intervention after 6 months.

In the intervention group only: satisfaction with the app; the sustainability of the effect of the intervention with regard to the primary outcome, body weight and EQ-5D, after three months of non-use compared to three months prolonged use, both after six months of initial use of the app; determinants of

success for the primary outcome; such as gender, age, social economic status,

diabetes duration, short or prolonged intervention.

Study description

Background summary

Self-management is one of the cornerstones of diabetes treatment, especially in insulin treatment. Attainment to lifestyle interventions, e.g. dietary habits and physical activity, will help to prevent both micro- and macrovascular complications. Insulin dose adjustments to changes in physical activity and diet may prevent hypoglycaemic episodes and limit glycaemic variability. These self-management activities are necessary but difficult to maintain. Physicians, diabetes nurses and practice nurses aim to stimulate self-management.
In the Netherlands 85-90% of the 700.000 type 2 diabetes patients are treated in the primary care setting; among them, 15-20% are treated with insulin. With the growing number of diabetes patients, the expected shortage of practice nurses and the increasing workload of general practitioners, innovative and (cost-)effective solutions to promote self-management in the primary care are needed.

Study objective

To investigate the effectiveness of text-messages sent via a smartphone app (app-triggers) regarding dietary habits, physical activity, prevention of hypoglycaemic events and glycaemic variability on HbA1c, body weight, diabetes self-management and to assess determinants of success in type 2 diabetes patients treated with insulin therapy.

Study design

Non-blinded randomised controlled trial (RCT), with parallel-groups and randomisation ratio 1:1 intervention versus control.

Intervention

Receiving of app-triggers to support diabetes self-management regarding dietary habits, physical activity, hypoglycaemia, and glucose regulation (including glycaemic variability). The app-triggers are clear messages containing specific goals which can quickly be achieved (based on Health Belief Model), information or short questions to promote diabetes education and to motivate patients to adhere to lifestyle advices. Messages are positively framed (based on positive framing theory) with the content according to (inter-)national guidelines.

Messages are sent between 9.30 a.m. and 8.00 p.m.. Patient will determine their preferred frequency (2 or 6 times weekly, with a maximum of one message daily), and preferred topics (receiving messages with regard to hypoglycaemia is obligated, patients will choose 2-3 extra topics).

Study burden and risks

Participants are asked to complete questionnaires on food habits, physical activity, health status, diabetes related quality of life, diabetes self-management and patient satisfaction at baseline and follow-up (6 months later). Filling out these forms may be confronting and is time consuming (approximately half an hour). In the intervention group, participants are asked to fill out a questionnaire on health status after a follow-up duration of 9 months. Depending on regular clinical controls, an extra blood sample is taken at one to three measurement occasions. Patients are used to give blood samples in order to determine their HbA1c and lipid profile. Complications of taking a blood sample may be a hematoma or an infection. Participants in the intervention group receive app-triggers over a period of 6-9 months with a personalised frequency of twice or six times a week. We do not expect any adverse effects from receiving app-triggers. Patients in both the intervention as in the control group are familiar with self-management. In theory, stimulating healthy food choices and physical activity may result in hypoglycaemic events. However, receiving app-triggers with regard to preventing and managing hypoglycaemia is obligatory. Some patients may find receiving app-triggers at random times, e.g. at work, stigmatising. The study population does not involve minors or incapacitated. The privacy of the participants will be assured.

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

Type 2 diabetes patients who are on insulin treatment since at least 3 months, with a baseline HbA1c level >7% (53 mmol/mol) aged 40-70 years. Logistic requirements are the possession of an e-mail address and a smartphone.

Exclusion criteria

Insulin naïve type 2 diabetes patients, patients with a history of alcoholism, drug abuse, dementia or major psychiatric disorder that is likely to invalidate informed consent, or limit the ability of the individual to comply with the protocol requirements.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-12-2015
Enrollment:	228
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL53125.041.15

Study results

Date completed:	29-08-2018
Actual enrolment:	230