

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

Gepubliceerd: 18-11-2015 Laatste bijgewerkt: 18-08-2022

We hypothesize that receiving behavioural triggers, sent as text-messages via a smartphone app, results in increased diabetes self-management of type 2 diabetes patients on insulin therapy, and subsequently to improved glycaemic control, less weight...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23768

Bron

NTR

Verkorte titel

TRIGGER study

Aandoening

type 2 diabetes mellitus, eHealth, mHealth, self-management, behavioural change, insulin therapy

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Overige ondersteuning: Sanofi-Aventis, unrestricted grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Self-management is one of the cornerstones in the treatment of type 2 diabetes mellitus (T2DM) patients, especially in insulin treatment, but difficult to maintain. Health care providers aim to stimulate self-management. However, they have a limited number of patient's visits in which they can stimulate the patients. With the growing number of T2DM patients innovative and (cost-)effective interventions to promote self-management are needed. We aim to evaluate the (cost-)effectiveness of a smartphone app on self-management in T2DM patients on insulin therapy.

Methods/Design: Non-blinded randomised controlled trial with parallel groups and equal randomisation. Eligible patients are T2DM patients on insulin therapy since at least three months with a baseline HbA1c >53 mmol/mol (>7%). In total 330 patients are needed and will be recruited in general practices and hospitals in the Netherlands. The intervention group (n = 165) will receive text-messages via a smartphone app aiming to trigger diabetes self-management. These app-triggers are evidence and psychological theory based, unidirectional, messages with regard to dietary habits, physical activity, hypoglycaemia and glucose regulation. Patients choose their preferred frequency and topics of the intervention. The control group (n = 165) will receive standard care. The control group will be a 'waiting list control group'; when the study is finished they will get the opportunity to use the intervention. Randomisation takes place at patient level. Data are obtained during regular diabetes monitoring visits. The primary study

endpoints are 1) the percentage of patients who achieve an HbA1c level <53 mmol/mol ($<7\%$) without hypoglycaemia (plasma glucose 3.5 mmol/L (63 mg/dL), and 2) the HbA1c level (continuous variable) after a follow-up of six months. Secondary outcomes are body mass index, body weight, waist circumference, insulin dose, lipoprotein profile, blood pressure, number of hypoglycaemic events, glycaemic variability, self-management (SDSQ), food habits (FFQ), physical activity (IPAQ), health status (EQ-5D, SF36), diabetes-dependent quality of life (ADDQoL), patient's satisfaction (DTSQ) and satisfaction with the app; the cost-effectiveness of the intervention after six months; sustainability of the intervention (three months extra follow-up). We will use the intention-to-treat principle to analyse our data.

Doel van het onderzoek

We hypothesize that receiving behavioural triggers, sent as text-messages via a smartphone app, results in increased diabetes self-management of type 2 diabetes patients on insulin therapy, and subsequently to improved glycaemic control, less weight gain and less glucose variability with less hypoglycaemic events.

Onderzoeksopzet

Baseline, T3 (after 3 months of follow-up), T6 (after 6 months of follow-up) and T9 (after 9 months of follow-up)..

17-12-2015 recruitment of first participant.

Onderzoeksproduct en/of interventie

Text-messages via a smartphone app aiming to trigger diabetes self-management of type 2 diabetes patients on insulin therapy. These app-triggers are evidence and psychological theory based, unidirectional, messages with regard to dietary habits, physical activity, hypoglycaemia and glucose regulation. Patients choose their preferred frequency and topics of the text message (3 or 4 topics, including at least hypoglycemia)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible participants are type 2 diabetes patients on insulin treatment since at least three months, with a baseline HbA1c >53 mmol/mol ($>7\%$) with no upper limit, aged 40-70 years and treated for their diabetes in primary or secondary care. Logistic requirements are the possession of an e-mail address and a smartphone.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	23-11-2015
Aantal proefpersonen:	228
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	18-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4995
NTR-old	NTR5515
Ander register	NL53125.041.15 : ABR: 53125; METC: 15/438

Resultaten

Samenvatting resultaten

NA