Improving treatment adherence in people with diabetes mellitus (INTENSE)

Gepubliceerd: 02-07-2020 Laatst bijgewerkt: 13-12-2022

It is hypothesised that this study leads to a personalised intervention program that improves medication adherence in people with type 2 diabetes mellitus that are non-adherent to their oral blood glucose lowering and/or antihypertensive medication.

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

Samenvatting

ID

NL-OMON21880

Bron
NTR

Verkorte titel
INTENSE

Aandoening

Type 2 diabetes mellitus, medication non-adherence

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: European Foundation for the Study of Diabetes (EFSD)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure of the study is medication adherence measured with a telephone pillcount. The pillcount will be conducted at baseline and after six months.

Toelichting onderzoek

Achtergrond van het onderzoek

Medication non-adherence is a prevalent health problem in people with type 2 diabetes mellitus. Multiple interventions have previously been developed to enhance medication adherence. However, very few studies demonstrated an improvement of treatment outcomes and even the most efficacious interventions only achieved modest effect sizes. An explanation for these moderate effects can be that interventions are not tailored to the needs and preferences of individual patients.

Therefore, the aim of this study is to develop and test a personalised intervention to improve medication adherence in people with T2DM, who are non-adherent to oral blood glucose and/or blood pressure lowering drugs. This will be tested in a parallel-group randomised controlled trial that will be conducted in 40-50 (community) pharmacies and adjoining practises in the Netherlands and the United Kingdom (UK). A total of 300 participants will be included (150 the Netherlands / 150 the UK) and the follow-up period of the trial will be six months.

The intervention condition is a personalised intervention program that is based on one or more of the participants' predefined non-adherence profile(s). The supporting program will be tailored to a participants' specific situation, needs and preferences. Participants that are assigned to the control condition will receive access to a publicly available general T2DM information platform.

The primary outcome is medication adherence measured with a telephone pillcount. Secondary outcome measures are systolic blood pressure, HbA1c, self-reported medication adherence, attitude and beliefs toward medication, satisfaction with diabetes treatment, quality of life, and medical and productivity costs.

Doel van het onderzoek

It is hypothesised that this study leads to a personalised intervention program that improves medication adherence in people with type 2 diabetes mellitus that are non-adherent to their oral blood glucose lowering and/or antihypertensive medication.

Onderzoeksopzet

Measurements at baseline, after 3 months and after 6 months

Onderzoeksproduct en/of interventie

The intervention condition is a personalised intervention program that is based on one or more of the participants' predefined non-adherence profile(s). The four non-adherence profile(s) are: (I) knowledge and perceptions, (II) practical problems, (III) side effects, and (IV)

negative mood and beliefs. The supporting program will be tailored to a participants' specific situation, needs and preferences. Participants that are assigned to the control condition will receive access to a publicly available general T2DM information platform.

Contactpersonen

Publiek

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P.J.M. Elders

020-4448354

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The main inclusion criteria are:

1) People with type 2 diabetes mellitus treated with oral blood glucose lowering drugs;
2) Non-adherent to oral blood glucose and/or blood pressure lowering drugs;
3) Aged 35-75 years;
4) Mobile phone user.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

The main exclusion criteria are:

1) Use of insulin;
2) People that use medication-intake supporting services provided by the pharmacy;

3) People that suffer from major psychiatric disorders;
4) People that are ‘starters’, meaning that they started using the medicine somewhere in the period in which the dispensing score was calculated;
5) People that are ‘stoppers’, meaning that they did not have a medicine dispatch in the last four months of the period in which the dispensing score was calculated.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	27-07-2020
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	02-07-2020
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	NL8747
Ander register	METC Amsterdam UMC, location VUmc : 2018.160

Resultaten

Samenvatting resultaten
N.A.