Improving treatment adherence in people with diabetes mellitus (INTENSE)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21880

Source
NTR

Brief title
INTENSE

Health condition

Type 2 diabetes mellitus, medication non-adherence

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: European Foundation for the Study of Diabetes (EFSD)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary outcome measures of the study 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. Blood pressure and HbA1c level will we obtained using registry data. Data on the other secondary outcome measures will be obtained using questionnaires.

Study description

Background summary

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.

Study objective

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.

Study design

Measurements at baseline, after 3 months and after 6 months

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-07-2020
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.A.

Ethics review

Positive opinion

Date:	02-07-2020
Application type:	First submission

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
NTR-new	NL8747
Other	METC Amsterdam UMC, location VUmc : 2018.160

Study results

Summary results
N.A.