Towards the development of a personalised E-Health intervention for use in community pharmacies to analyse and improve medication non-adherence in people with type 2 diabetes mellitus, who are non-adherent to oral blood glucose and/or blood pressure lowering drugs.

Published: 20-06-2018
Last updated: 12-04-2024

The main objective of this study is to develop and investigate the (cost-) effectiveness of a pharmacist-led personalised intervention, with E-Health components, to analyse and improve medication adherence in people with T2DM, who are non-adherent...

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

Summary

ID

NL-OMON55758

Source
ToetsingOnline

Brief title
Improving treatment adherence in people with diabetes mellitus (INTENSE)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, Type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: European Foundation for the Study of Diabetes (EFSD)

Intervention

Keyword: Intervention, Medication adherence, Pharmacy, Type 2 diabetes mellitus

Outcome measures

Primary outcome

The primary study outcome is medication adherence (measured with change in a

telephone pill count).

Secondary outcome

The secondary study parameters are:

- Systolic blood pressure (registry data)

- HbA1c (registry data)

- Medication adherence (MARS-5 questionnaire)

- Attitude and beliefs toward medication (BMQ specific questionnaire)

- Satisfaction with diabetes treatment (DTSQs+c questionnaire)

- Quality of life (EQ-5D-5L questionnaire)

- Medical and productivity costs (iMTA costs questionnaire)

The other study parameters are:

- Barriers and facilitators that people with type 2 diabetes and pharmacists

experience in the use of the intervention.

- Refinement of the non-adherence profiling algorithm after evaluation of the

intervention.

Study description

Background summary

Medication adherence is suboptimal in 10-56% of all people with type 2 diabetes mellitus (T2DM). This non-adherence is associated with higher HbA1c levels, blood pressure and cholesterol levels. Moreover, non-adherence can lead to an increased number of hospitalisations, mortality rates and health care costs. Multiple interventions have 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.

Study objective

The main objective of this study is to develop and investigate the (cost-) effectiveness of a pharmacist-led personalised intervention, with E-Health components, to analyse and improve medication adherence in people with T2DM, who are non-adherent to oral blood glucose and/or blood pressure lowering drugs compared to an already available general T2DM information platform. In addition, the study has three secondary objectives:

1. To identify non-adherence profiles based on individual factors, barriers, needs and preferences related to medication adherence of people with T2DM who are non-adherent to oral blood glucose and/or blood pressure lowering drugs.

2. To perform a process analysis of the personalised intervention in order to assess the extent to which the intervention has been performed according to the study protocol and to gain insight into the barriers and facilitators of the intervention program.

3. To develop and refine non-adherence algorithms after evaluation of the personalised intervention in order to further improve the intervention for

future use.

Study design

A parallel-group randomised controlled trial is conducted in 40-50 (community) pharmacies and adjoining practises in the Netherlands and the United Kingdom (UK) (30-40 the Netherlands / 10 in the 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.

Intervention

The trial consists of an intervention and control condition. The intervention condition is a personalised intervention, which consists of four supporting programs. Participants will receive supporting program(s) based on a predefined non-adherence profile. The four supporting programs/non-adherence profiles are: (I) knowledge and perceptions, (II) practical problems, (III) side effects, and (IV) negative mood and beliefs. All of the supporting programs consist of one or more interventions that are theoretically grounded or have previously been shown to improve medication non-adherence. These interventions include: brief messaging, medication schedule, reminding messaging, medication review, medication dispensing systems, smart messaging, referral to a general practitioner (GP) and a Self-guided Self Help application. The supporting programs will be tailored to a participants* specific situation, needs and preferences. Participants that are assigned to the control condition will have access to an already available general T2DM information platform via their smartphone/tablet/computer.

Study burden and risks

Overall, for our participants we do not foresee any specific risks for possible damage and/or potential harm. Moreover, we do not include vulnerable participants and therefore conclude that the conduct of the research involves a negligible risk to human participants and is justified. We summarise the burden and risk per study procedure. First, participants vhave a pharmacyappointment at baseline (approximately 30 minutes per visit). In a subgroup of the pharmacy consultations researchers will be present and audio recording will be made for the proces evaluation of the study. Participants can indicate whether they do or do not want this.

Second, at baseline general practice or specialist registry data will be consulted to obtain a participants' blood pressure value and HbA1c level (with a time window of three months before and one month after the time point). Also at 6 months registry data will be consulted to obtain blood pressure and HbA1c level (with a time window of two months before and two months after the time point). By keeping the blood pressure and HbA1c measurements in line with

routine care (regular diabetes check-ups), the burden and risks for participants are reduced.

Third, participants are asked to fill in questionnaires at baseline, and after three and six months (30-45 minutes per fill-in moment and 1,5-2,25 hours in total). These questionnaires are validated instruments that are often used in health research. Participants in the intervention group will also receive a telephone call whether they are satisfied with the interventions, after one month (10 minutes). Furthermore, a double telephone pillcount will be conducted at baseline and after 6 months in all participants (20-30 minunted per measurement). The risk of the personalised intervention is minimal, since the supporting programs are all theoretically grounded or have previously been shown to improve medication non-adherence and no main risks have been identified in these studies.

Contacts

Public
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- People with type 2 diabetes mellitus that are non-adherent to oral blood glucose and/or bloodpressure lowering drugs.
- Participants aged 35-75 years.
- Mobile phone user.

Exclusion criteria

- People in which adherence data is invalid for instance due to hospital admission.
- People that use medication-intake supporting pill packaging services provided by the pharmacy.
- People that suffer from major psychiatric disorders.
- People that are *starters*, meaning that they started using the medicine somewhere in the period in which the dispensing score was calculated.
- 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
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2020
Enrollment:	150

Type:	Actual

Medical products/devices used

Generic name:	Electronic pill container (and online platform)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2021
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL65055.029.18