Diabetes educatie en zelfmanagement ter verbetering van empowerment bij diabetes type 2 patiënten

No registrations found.

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

Summary

ID

NL-OMON28753

Source
Nationaal Trial Register

Brief title
DESTINE

Health condition

People diagnosed with type 2 diabetes mellitus (T2DM; recently diagnosed as well as longer known) who are treated in primary health care.

Sponsors and support

Primary sponsor: Cosponsorship of various organisations:
- Zorg Binnen Bereik
- Kenniscentrum voor Ketenzorg
- Zelfzorg ondersteund!
- NIVEL
- Lectoraat Disseminatie van Farmaceutische Innovaties

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Study the effect of offering the PRISMA training to a T2DM patient on the use of the web portal and its educational content.

Secondary outcome

a. Study the effect of the use of the web portal and its educational content by a T2DM patient on quality parameters, as tested by:
- WHO-5 scale, representing Well Being;
- PAM, representing the Degree of Self Reliance;
- HowRwe, representing Quality of Received Care;
- SDSCA, representing Diabetes Self-management Behavior;
- MARS-5, representing Self-Reported Adherence to Medication Prescriptions;
- PEPPI-5, representing Patients' Experience of Efficacy;
- Patient participation during the medical consultation (video's).

b. Study the effect of the use of the web portal and its educational content by a T2DM patient on:
- Clinical parameters, as described in the NHG / NAD core set of diabetes parameters (appendix 2);
- Amount of prescribed (used) medicine;
- Medical care utilization (number of contacts with health care representatives);
- Rates and time of refills.

Study description

Background summary

Rationale: Accounting for the growth and ageing of the Dutch population, the effect of current (high) risks of diabetes, predominantly caused by detrimental life style changes in recent decades and an expected further growth of the number of known patients with diabetes requires a decrease of the workload per patient for care providers as the growth of health care providers will not keep up with the number of patients. We set up another study that started two years ago in which we aimed to increase patient's self-management by offering remote care services, which would result in a reduction of the individual caseload. Still, as we know from other studies, this would not result in high usage numbers within the targeted population, and this proved to be the case. To improve usage of remote services supporting self-management, different strategies will need to be developed in order to try to interest and reach different types of patients.

Our current hypothesis is that implementation, supported by PRISMA training, will lead to a

better use of the offered remote care and self-management supporting services.

Objective: Primary objective is to test the hypothesis that implementing a web portal and its educational content and the possibility to review personal diabetes related data (i.e. laboratory measurements, blood pressure and weight) by a T2DM patient supported by PRISMA training will result in an increased usage of the web portal, improved participation of the patient in consultations with his health care provider and finally improved health related quality of life.

Study design: Sequential randomised controlled study.

Study population: People diagnosed with type 2 diabetes mellitus (T2DM; recently diagnosed as well as longer known) who are treated in primary health care in The Netherlands.

Intervention (if applicable): This study investigates the effects of the voluntarily use of a web portal and its educational content with or without the support of the PRISMA program on health related quality of life.

Main study parameters/endpoints: Primary endpoints of this study are number of log-ons and duration of the visit. Secondary endpoints are patients' experience of efficacy during the medical consultation, patient's participation during the medical consultation, well-being, degree of self-reliance, evaluation of general practice, diabetes self-management behavior, self-reported adherence to medication prescriptions and health related quality of life. Tertiary endpoints are a selection of clinical measurements (in accordance with kernset patiëntengegevens diabeteszorg (see appendix 1), amount of prescribed (used) medication, medical care utilization and rates of refills.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participation in this study implies that patients are being followed up during the duration of the study (= two years). At four time points (0, 6, 12 and 24 months), questionnaires have to be filled out by the patients. Other measurements are already being performed during usual care. The first two consultations with the practice nurse (PN) during the study, usually within 6 months, will be recorded by an unmanned camera and analyzed.

Study objective

T2DM patient supported by PRISMA training will result in an increased usage of a web portal (with patient's self-management goals and information needs), improved participation of the patient in consultations with his health care provider and finally improved health related quality of life.

Study design

Patient profile: 0 months
Use of portal: 6, 12, 24 months
Questionnaires: 0, 6, 12, 24 months
Laboratory/clinical measures: 0, 12, 24 months
Medication care utilization: 0, 6, 12, 24 months
Micro- and macrovascular complications: 0, 12, 24

Intervention

The intervention in case of PRISMA training will additionally consist of interdisciplinary group training that will inform him/her of the possibilities of increase their self-management. PRISMA training is expected to support patients in overcoming their barriers to successful participation in their consultation with the PN.

To test this hypothesis, all consultations between the patients and the PN will be recorded by an unmanned camera for the duration of at least 6 months. The videotaped consultations will be reviewed to analyse the level of information exchange and to make a comparison between the patients who receive routine care and the patients who receive the additional PRISMA training.

Contacts

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Eligibility criteria

Inclusion criteria

1. A diagnosis of T2DM mellitus, as 1. registered in the primary care system under the diagnosis T90.2, and where the GP is defined as the main care giver;
2. And aged ≥18 years.

Exclusion criteria

1. Mental retardation or psychiatric treatment for schizophrenia, organic mental disorder or bipolar disorder currently or in the past.
2. Insufficient knowledge of the Dutch language to understand the requirements of the study and/ or the questions posed in the questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-07-2014
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	NL4550
NTR-old	NTR4693
Other	METC Isala : 14.07.104

Study results