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

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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...

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

Samenvatting

ID

NL-OMON28753

Bron
Nationaal Trial Register

Verkorte titel
DESTINE

Aandoening

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

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Lectoraat Disseminatie van Farmaceutische Innovaties
Bolognalaan 101
Postbus 85182
E. Pon, du
Utrecht 3508 AD
The Netherlands
088 481 2102

Wetenschappelijk

Lectoraat Disseminatie van Farmaceutische Innovaties
Bolognalaan 101
Postbus 85182
E. Pon, du
Utrecht 3508 AD
The Netherlands
088 481 2102

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-07-2014
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	NL4550
NTR-old	NTR4693
Ander register	METC Isala : 14.07.104

Resultaten