De ontwikkeling van een keuzehulp voor patiënten bij de behandeling van diabetes en bijkomende risico's.

No registrations found.

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

Summary

ID

NL-OMON27858

Source
NTR

Brief title
PORTDA-diab

Health condition

Diabetes Mellitus Therapy/ Diabetes Mellitus Behandeling
Computer-Assisted Decision Making/ Computer-ondersteund Beslissen
Patient Education/ Patient Informatie
Guideline Adherence/ Richtlijn Adherentie

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Patient empowerment measured with Diabetes Empowerment Scale (overall and subscale ‘Setting and Achieving Goals’).

Secondary outcome

1. Patient perceptions about benefits and risks of treatment options (BMQ);

2. Negative emotions (PAID);

3. Satisfaction with care (PEQ-D);

4. Medication treatment;

5. Control of risk factors (UKPDS predicted 10-year risks).

Study description

Background summary

A newly developed patient oriented treatment decision aid (PTDA) will be evaluated in a randomized pre-postintervention study using a 2-by-2 factorial intervention design with a control group. The PTDA offers personalized information on possible treatment options and outcomes. The information is intended to empower the patients in taking a proactive role in their disease management. It will be offered to the patients before a scheduled year visit for diabetes management, and can then be used during this visit and further follow-up visits with the general practitioner.

Based on results of (inter)national research regarding shared goal-setting and decision making among elderly and patients with diabetes, two formats of the PTDA will be developed. The first will use the traditional clinical approach for presenting risks. The second will also provide information formulated from a patient perspective, as described in several qualitative studies. Both formats can be offered in a computer-based and a paper-based version. The information will be generated automatically using routinely registered information from the electronic medical records in addition to evidence-based information on diabetes treatment and outcomes. The 4 different versions will be evaluated in a trial with 450 patients from 20 general practices. Patients will be recruited in practices that participate in the GIANTT project. Practices will be randomly allocated to use the paper or the computer version of the PTDA and receive training on how to work with the PTDA. Within the practices, patients will be randomized to receive information from the clinical perspective or also from the patient perspective. Pre- and postintervention measurements will be conducted, where patients will receive questionnaires. Data for the other (secondary) outcomes will be collected using existing automated extractions from electronic medical records. Post-intervention questions on feasibility will be collected for a sample of visits.

Study objective

The aim of this study is to develop and evaluate a patient-oriented treatment decision aid (PTDA) focussing on shared goal-setting and decision making, which is tailored to the needs and capacities of a heterogeneous group of patients with type 2 diabetes. As part of the development process, the impact of different presentation formats and methods will be evaluated. Research questions are:

1. What is the impact of providing such personalized information on patient empowerment, negative emotions, beliefs about treatment options, satisfaction with care, and on treatment decisions and outcomes?

2. To what extent are effects at patient level modified by the presentation format (using a clinical or patient perspective) and presentation medium (paper or computer-based)?

3. What is the feasibility of implementing the decision support tool in daily practice?

Study design

Questionnaires data will be collected around one month before and three months after the intervention, using the following instruments:

1. Diabetes Empowerment Scale DES, i.e. overall-DES-scale and subscale ‘Setting and Achieving Goals’;
2. Patients' Evaluation of the Quality of Diabetes Care PEQ-D;

3. Beliefs about Medication Questionnaire BMQ;

4. Problem Areas in Diabetes Scale PAID.

Preintervention and postintervention data will be collected from medical records using the GIANTT database (www.Giantt.nl) in the year before and after the intervention to assess differences in percentages of patients with (intensified) antihypertensive treatment after insufficiently controlled blood pressure levels, of patients with (intensified) glucose-lowering treatment after insufficiently controlled HbA1c-levels, of patients treated with lipid-lowering drugs, of patients with (micro)albuminuria treated with a RAAS inhibitor, and changes in predicted absolute 10-year coronary heart disease risk (UKPDS risk engine calculation).

Intervention

The patient-oriented treatment decision aid offers personalized information on possible treatment options and outcomes. The information is intended to empower the patients in taking a proactive role in their disease management. It will be offered to the patients before a scheduled year visit for diabetes management, and can then be used during this visit and further follow-up visits with the general practitioner.

Four different versions will be used, varying in presentation format (clinical/ patient perspective) and presentation medium (paper/computer-based). The four intervention groups will thus receive information presented from:

1. Clinical perspective on paper;

2. Clinical and patient perspective on paper;

3. Clinical perspective on computer;

4. Clinical and patient perspective on computer.

The control group will receive care/information as usual.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with type 2 diabetes managed by GPs.

Exclusion criteria

1. Dementia;

2. Known cognitive deficits;

3. Not able to read Dutch;

4. Terminal illness;

5. Previous stroke or heart disease;

6. Above 65 years of age at diagnosis diabetes.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	450
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-08-2009
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	NL1832
NTR-old	NTR1942
Other	ABR/ZonMW : 29042/project 300020006
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A