Risk management in patients with diabetes mellitus: development and evaluation of a patient-oriented treatment decision aid (PTDA).

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON35174

Source
ToetsingOnline

Brief title
Development of a patient-oriented treatment decision aid for diabetes.

Condition

- Diabetic complications

Synonym
diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Computer-Assisted Decision Making, Diabetes Mellitus Therapy, Guideline Adherence, Patient Education

Outcome measures

Primary outcome

Primary Outcome: patient empowerment.

Secondary outcome

Secondary outcomes: patient perceptions about benefits and risks of treatment

options, negative emotions, satisfaction with care, medication use, control of

risk factors (UKPDS predicted 10-year risks).

Study description

Background summary

The implementation of various disease management programmes has resulted in important improvements in processes of diabetes care but effects on patient outcomes have been limited. Many patients with type 2 diabetes mellitus do not achieve the recommended targets for cardiometabolic risk management, and are undertreated or insufficiently adherent to treatment. Adequate management of chronic diseases requires not only optimal performance from providers but also sufficient understanding and motivation of patients to start and sustain complicated medication and lifestyle regimens. Simple tools that can help to structure and prioritize treatment goals and plans are needed. It is not clear, however, what is the best way to inform patients regarding the benefits and risks of treatment options, and engage them in setting treatment goals. Several computer-based support systems have been developed to calculate patient specific risks and recommendations but their value in daily practice is limited. Most of these tools formulate treatment goals from the medical perspective, while patients may have trouble with the quantitative scoring of risk and the clinical focus on numerical treatment goals instead of functional goals. As the tendency is to develop more computer and web-based decision aids, there are also concerns that especially elderly patients may not be able to use

such tools.

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

The newly developed PTDA will be evaluated in randomized pre-postintervention study using a 2-by-2 factorial intervention design with a control group.

Intervention

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.

Study burden and risks

All participating patients will be asked to complete a structured questionnaire consisting of 4 commonly used instruments (Diabetes Empowerment Scale (28 items), PEQ-D (14 items), BMQ (18 items), PAID (20 items) at home around 1 month before and 3-4 months after a routine annual visit to their own general practitioner. A sample of 100 patients will get around 10 extra questions after the intervention about their experience and use of the additional information material. No discomfort is expected from filling in the questionnaire. Patients in the intervention groups will receive additional educational information on possible treatment options and outcomes. There will be no extra visits, physical examinations or other tests being conducted for this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with type 2 diabetes managed by GPs participating in the GIANTT project.

Exclusion criteria

Dementia, known cognitive deficits, not able to read Dutch, terminal illness, previous stroke or heart disease, or above 65 years of age at diagnosis diabetes.

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-03-2010
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL29042.042.09