

Risk communication for patients with type 2 diabetes.

No registrations found.

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

Summary

ID

NL-OMON25797

Source

NTR

Brief title

@RISK Study

Health condition

type 2 diabetes
risk to develop cardiovascular disease
communication

Sponsors and support

Primary sponsor: EMGO Institute, VU University Medical Center

Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Outcome measures

Primary outcome

- Risk perception

Secondary outcome

- Attitude and intention to change behaviour (according to the determinants of the Theory of Planned Behaviour) and illness perception

Study description

Background summary

Background of the study:

It is difficult for patients with diabetes to understand the risk to develop severe diabetes related complications. As a result, they do not recognize the seriousness of changing lifestyle and taking medication in time. The risk to develop cardiovascular disease can be estimated by means of a risk formula. However, these numbers are complicated to understand for patients.

Therefore, it is important to develop a method to improve risk communication for patients. This might improve the understanding of the patient concerning the risks that are associated with having diabetes and the motivation to change lifestyle. In addition, the patient will receive information that is needed to become a decision-maker of the treatment which is important to increase patient empowerment.

Objective of the study:

The aim of this study is to investigate the effects of an intervention focussed on the communication of the absolute 10-year risk to develop cardiovascular disease on risk perception, attitude towards a specific behaviour and the intention to change behaviour.

Study design:

A randomised controlled trial will be performed in the the Diabetes Care System West-Friesland. The patients will be randomised into a control and an intervention group.

Study population:

Newly diagnosed patients with type 2 diabetes not older than 75 years.

Intervention (if applicable):

The control group will receive standard managed care of the Diabetes Care System West-Friesland, which consists of a visit to a diabetes nurse followed by a visit to a dietician. The intervention group will receive this standard managed care and an intervention on risk communication by a diabetes nurse (part 1) and dietician (part 2)

The primary outcome is risk perception.

Secondary outcomes are the attitude and intention to change behaviour and illness perception

Study objective

The goal of diabetes care is to provide adequate care in order to decrease the risk to develop severe complications by means of medication and lifestyle advices.

However, when a patient does not have information on risks accompanying diabetes, then he/she is not motivated to take medication and change lifestyle.

We expect that by providing information on risks, we can improve the risk perception of the patients which might improve the attitude and intention towards lifestyle changes.

Study design

Baseline, 2 weeks (after visit to diabetes nurse and dietician), 3 months

Intervention

The control group will receive standard managed care in the Diabetes Care System West-Friesland, which consists of a yearly visit to a diabetes nurse (30 minutes) and a dietician (30 minutes).

The intervention group will receive standard managed care and an intervention on risk communication by a diabetes nurse and dietician. This intervention will consist of 6 steps:

- 1) introduction of risks
- 2) communication of the absolute risk according to the UKPDS risk engine
- 3) visual communication by means of a risk card
- 4) positive framing: explanation that lifestyle changes can help to reduce the risk
- 5) communication with the patient for a reaction
- 6) think aloud: patient has to explain the risk him/herself

Contacts

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Eligibility criteria

Inclusion criteria

1. Maximum age 75 years
2. Informed consent
3. Able to communicate in Dutch

Exclusion criteria

1. Severe disease
2. Mobility problems
3. History of stroke or heart attack

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-11-2008
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	NL1486

Register	ID
NTR-old	NTR1556
Other	2007-13-004 (Diabetes Fonds) : WC-2008-015 (EMGO)
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A