Risk communication for patients with type 2 diabetes.

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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...

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

Samenvatting

ID

NL-OMON25797

Bron
NTR

Verkorte titel
@RISK Study

Aandoening

type 2 diabetes
risk to develop cardiovasular disease
communication

Ondersteuning

Primaire sponsor: EMGO Institute, VU University Medical Center
Overige ondersteuning: Diabetes Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Risk perception

Toelichting onderzoek

Achtergrond van het onderzoek

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 concering 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.
Secundary outcomes are the attitude and intention to change behaviour and illness perception

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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 reveive 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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Maximum age 75 years

2. Informed consent

3. Able to communicate in Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe disease

2. Mobility problems

3. History of stroke or heart attack

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-11-2008
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	NL1486
NTR-old	NTR1556
Ander register	2007-13-004 (Diabetes Fonds) : WC-2008-015 (EMGO)
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A