

Risk communication for patients with type 2 diabetes

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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...

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

Summary

ID

NL-OMON33937

Source

ToetsingOnline

Brief title

@RISK Study

Condition

- Diabetic complications

Synonym

diabetes, type 2 diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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

Intervention

Keyword: cardiovascular disease, risk communication, risk perception, type 2 diabetes

Outcome measures

Primary outcome

The primary outcome is risk perception.

Secondary outcome

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

Study description

Background summary

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.

Study objective

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.

Intervention

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)

Study burden and risks

Not applicable

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Maximum age 75 years
- Good understanding of the Dutch language
- Newly diagnosed patients with type 2 diabetes

Exclusion criteria

- Severe disease
- Mobility problems

Study design

Design

| | |
|---------------------|-----------------------------|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Health services research

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-03-2009 |
| Enrollment: | 240 |
| Type: | Actual |

Ethics review

| | |
|--------------------|--------------------|
| Approved WMO | |
| Date: | 16-02-2009 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

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 | NL25794.029.08 |