

A randomised controlled trial to the effectiveness of the 'Routeplanner diabetespreventie', a protocol-based lifestyle intervention to prevent the development of type 2 diabetes mellitus in people with an impaired fasting glucose, part 2: effect study.

Published: 26-04-2010

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The aim of the study is to investigate the added value of the *Routeplanner diabetespreventie*, compared to the usual care for people with an increased risk on diabetes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34647

Source

ToetsingOnline

Brief title

'Routeplanner' study part 2: effect study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

impaired glucose tolerance, pre-diabetes, raised glucose levels

Research involving

Human

Sponsors and support

Primary sponsor: Nederlandse Diabetes Federatie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: impaired fasting glucose, lifestyle intervention, prevention, type 2 diabetes mellitus

Outcome measures

Primary outcome

The primary outcome of the study is BMI.

Secondary outcome

The secondary outcomes of the study are: waist circumference, blood pressure, cholesterol, HbA1c, behavior (diet and physical activity)

Study description

Background summary

The Dutch Diabetes Federation (NDF) has developed the National Action program Diabetes (NAD) commissioned by the Ministry of Health, Welfare and Sports. The care of patients with an increased risk on diabetes is one of the major topics within this action program.

At the moment, there are no guidelines on the care for people with an increased risk on diabetes. For this reason the Dutch Diabetes Federation has developed a standardized guidance plan: the *Routeplanner diabetespreventie*.

Study objective

The aim of the study is to investigate the added value of the *Routeplanner diabetespreventie*, compared to the usual care for people with an increased risk on diabetes.

Study design

The study is a cluster randomized controlled trial. 50 general practices will coach 4 to 5 patients using the *Routeplanner diabetespreventie*. 50 other general practices give their patients care as usual. 4 to 5 patients of these practices will be followed.

Measurements (physical measurements and a survey) take place 1) after the diagnosis of an impaired fasting glucose tolerance, 2) just after the intervention and 3) one year after the intervention.

Intervention

The *Routeplanner diabetespreventie* is a standardized guidance plan for people with an impaired fasting glucose. The aim of the *Routeplanner diabetespreventie* is to promote healthy living by means of education, guidance and referral to local lifestyle activities and by that to postpone and (if possible) to prevent diabetes.

Study burden and risks

Not applicable

Contacts

Public

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NL

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

Impaired fasting glucose (nuchtere plasma glucose $\geq 6,1$ - $\leq 6,9$ mmol/l) / Impaired Glucose Tolerance (postprandiale plasma glucose $\geq 7,8$ - $\leq 11,0$ mmol/l)

Inactive lifestyle

Motivation for behavioural change

Exclusion criteria

Co-morbidity which makes participation in programs to promote an active lifestyle impossible
Cognitive dysfunction

Study design

Design

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):	01-06-2010

Enrollment:	500
Type:	Actual

Ethics review

Approved WMO	
Date:	26-04-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL31342.075.10