

# A randomized controlled trial to the effectiveness of a protocol-based lifestyle intervention to prevent the development of type 2 diabetes mellitus in people with an impaired fasting glucose, part 1b: pilot implementation

Published: 28-09-2009

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The aim of the study is to investigate where the 'Routeplanner diabetespreventie' could be further improved / adjusted.

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

## Summary

### ID

NL-OMON33455

### Source

ToetsingOnline

### Brief title

Effectstudy 'Routeplanner diabetespreventie', part 1b: pilot implementation

### 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, impaired glucose tolerance, lifestyle intervention, prevention

## Outcome measures

### Primary outcome

Primary outcomes of the study are the feasibility and evaluation of the 'Routeplanner diabetespreventie'.

### Secondary outcome

Not applicable

## Study description

### Background summary

The Dutch Diabetes Federation (NDF) has developed the National Action programme Diabetes (NAD) commissioned by the ministry of health, welfare and sports (VWS). Taking care of patients with an increased risk on diabetes is one of the major topics within this action programme.

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

### Study objective

The aim of the study is to investigate where the 'Routeplanner diabetespreventie' could be further improved / adjusted.

### Study design

Ten general practices will coach 4-5 patients using the 'Routeplanner diabetespreventie\*.

The evaluation study includes both research on health care professionals and research on patients.

Research on health care professionals: Professionals in general practices will record the progress of the coaching process. In addition, a total of 40 phone interviews will take place to determine the experiences on the guidance plan (3 and 6 months after the start of the pilot implementation).

Research on patients: Patients being coached by the \*Routeplanner diabetespreventie\* will fill out a survey twice (3 and 6 months after the start of the pilot implementation) on their evaluation of the coaching and the extent of they actually changed their lifestyle.

## **Intervention**

The \*Routeplanner diabetespreventie\* is a standardized intervention for patients 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**

Nederlandse Diabetes Federatie

Stationsplein 139  
3818 LE Amersfoort  
Nederland

### **Scientific**

Nederlandse Diabetes Federatie

Stationsplein 139  
3818 LE Amersfoort  
Nederland

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Impaired Fasting Glucose (IFG) / Impaired Glucose Tolerance (IGT)
- 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

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-10-2009

Enrollment: 50

Type:

Actual

## Ethics review

Approved WMO

Date:

28-09-2009

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

NL27678.075.09