

Effectiveness of a protocol-based lifestyle program to prevent type 2 diabetes

Submission date 16/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/10/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Effective strategies for diabetes prevention can be put into daily practice without spending a large amount of money and with less manpower. The Dutch Diabetes Federation developed a protocol (method) for coaching people with impaired (abnormal) fasting glucose to a sustainable healthy lifestyle change called the road map towards diabetes prevention (abbreviated as RM for Road Map). This protocol is applied within a GP surgery by a general practitioner and a practice nurse. We aim to study the feasibility, effectiveness and cost-effectiveness of care provided according to the RM protocol.

Who can participate?

People with Impaired Fasting Glucose (IFG) and motivated to change their lifestyle can take part in this study.

What does the study involve?

GP practices were randomly allocated to one of two groups: intervention and control. After IFG is diagnosed, motivated people in the intervention practices received 3-4 consultations by the practice nurse within one year. During these consultations they were coached to increase their level of physical activity and adopt healthy dietary habits. If necessary, participants were referred to a dietician, physiotherapist, lifestyle programs and/or local sports activities. The control group received care as usual, including a yearly check on diabetes-related symptoms and blood glucose levels.

What are the possible benefits and risks of participating?

Improving the lifestyle of individuals with IFG to delay or even prevent the development of diabetes and associated heart disease-related risk factors.

Where is the study run from?

The study is run from more than 25 general practices located in the North-eastern region of the Netherlands. Only practices which employ a practice nurse are included.

When is the study starting and how long is it expected to run for?

The study started in May 2010 and ran until November 2012.

Who is funding the study?

The study is funded by the Ministry of Health, Wellbeing and Sports (VWS) (Netherlands) and the Netherlands Diabetes Federation (NDF) (Netherlands).

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A cluster-randomized controlled trial to study the effectiveness of a protocol-based lifestyle program to prevent type 2 diabetes in people with impaired fasting glucose

Study objectives

To prevent type 2 diabetes, a protocol for coaching people with impaired fasting glucose (IFG; according to WHO criteria: 6.1 to 6.9 mmol/l) to a sustainable healthy lifestyle change is developed. This protocol is applied within a primary health care setting by a general practitioner and a practice nurse. The study hypothesis is that the protocol is feasible and cost-effective.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee Isala Klinieken, METC number: NL31342.075.10

Study design

Cluster randomised clinical trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Type 2 diabetes/impaired fasting glucose

Interventions

Randomisation is at the level of the general practices and they are followed up at one and two years.

Intervention group

General practices assigned to the intervention group apply a protocol called the road map towards diabetes prevention (Road Map: RM). The first section of the protocol focuses on case finding and testing of those with impaired fasting glucose (IFG). The second section of the protocol focuses on coaching the individual person to adopt a healthy lifestyle. The practice nurse tries to get insight into the motivational situation of the participant. Based on this insight, three to four extra consultations spread over a one-year period are carried out. During these consultations the practice nurse gives advice and teaches concrete and applicable skills in order to increase the level of physical activity and healthy dietary habits. If necessary, participants are referred to a dietician, physiotherapist, lifestyle programs and/or local sports activities. After one year participants receive care as usual.

Control group

General practices assigned to the control group provide care as usual. This includes a yearly check on diabetes-related symptoms and blood glucose levels according the type 2 diabetes guideline of the Dutch College of General Practitioners.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Change in body mass index (BMI). Measurements were performed at baseline (T0) just after the diagnoses of IFG and before the start of the intervention, and after 1 (T1) and 2 (T2) years.

Key secondary outcome(s)

1. Waist circumference
2. Total and saturated fat intake
3. Physical activity
4. Systolic blood pressure
5. Blood glucose
6. Total cholesterol
7. Triglycerides
8. Behaviour determinants risk perception
9. Perceived knowledge, motivation, attitude, self efficacy and social norm

Anthropometric parameters and risk factors for developing diabetes were measured by a practice nurse. Biochemical parameters are determined in regional laboratories. Information about fat intake, physical activity, motivation and behaviour determinants were measured by questionnaires.

Completion date

30/10/2012

Eligibility

Key inclusion criteria

All subjects diagnosed with IFG and motivated to change their lifestyle

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Subjects with emotional, psychological or intellectual problems that are likely to limit the ability of the individual to comply with the protocol
2. Malignant diseases
3. Other diseases or conditions associated with a poor prognosis

Date of first enrolment

15/05/2010

Date of final enrolment

30/10/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

Kennemerplein 7

Haarlem

Netherlands

2011 MH

Sponsor information

Organisation

Julius Center for Health Sciences and Primary Care (Netherlands)

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health, Wellbeing and Sports (VWS) (Netherlands)

Funder Name

Netherlands Diabetes Federation (NDF) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/12/2015		Yes	No
Protocol article	protocol	02/12/2013		Yes	No