ISRCTN41209683 https://doi.org/10.1186/ISRCTN41209683

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

Submission date
16/10/2013

Recruitment status
No longer recruiting

Registration date
30/10/2013

Overall study status
Completed

Last Edited
14/01/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/05/2010

Completion date
30/10/2012

Eligibility

Key inclusion criteria
All subjects diagnosed with IFG and motivated to change their lifestyle

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 people in each group (intervention and control)

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
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Sponsor information

Organisation
Julius Center for Health Sciences and Primary Care (Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://portal.juliuscentrum.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	02/12/2013		Yes	No
Results article	results	22/12/2015		Yes	No