Development of a lifestyle intervention for diabetes prevention: SLIM from research to practice

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON32800

Source
ToetsingOnline

Brief title
Lifestyle intervention for diabetes prevention

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulin insensitivity, insulin resistence

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Keyword: impaired glucose tolerance, implementation, intervention maintenance, lifestyle

Outcome measures

Primary outcome

The primary endpoint of this study is the change in glucose tolerance (i.e.

2-hour blood glucose as measured during the OGTT).

Secondary outcome

Secondary outcomes: body weight, body composition, HbA1c, insulin sensitivity,

blood lipid profile, blood pressure, ECG, fitness, physical activity, dietary

habits, smoking and alcohol consumption, medication, quality of life and

medical history, including development of diabetes and cardiovascular

complications.

Study description

Background summary

The Study of Lifestyle intervention and Impaired glucose tolerance Maastricht (SLIM) is a lifestyle intervention study in subjects with impaired glucose tolerance with a mean follow-up of 5.5 years. The study is unique in the Netherlands, and shows that a healthy diet and increased physical activity is effective in improving glucose tolerance, despite moderate weight loss. Also preliminary results show the cumulative diabetes incidence after 5.5 yr is significantly lower in the intervention group as compared to the control group, with a 50% reduction in risk.

Study objective

The principal goal of this proposal is to use the results of this structured intervention to identify success indicators for implementation of the lifestyle intervention in a real-life setting, in other words: to bring SLIM from research to practice.

Study design

For this purpose several sub-questions need to be answered first: - How does the effect sustain 2 yrs after discontinuation of this long-term intervention? * What is the profile of subjects that successfully completed the intervention and maintain this effect after the study? - What barriers and promoting factors for successful implementation of this structured intervention are encountered or likely? * What is the cost-effectiveness of the intervention and various other scenarios? * This will accumulate in the 5th sub-item: the preparation of an implementation protocol, to prepare the implementation in Phase II.
Therefore, in the present proposal the first aim is to re-examine all participants of the SLIM study 2 years after discontinuation of the study.

Study burden and risks

Subjects are asked to visit the hospital twice in a period of 4 weeks time, during the first visit (of maximal 4 hours) oral glucose tolerance will be tested after an overnight fast. In total 20ml of venous blood will be sampled. During the second visit an aerobic fitness test will be performed (max 2 hours). To prevent any risks, especially for the older participants, we will monitor heart function (ECG) during the test. Furthermore, a medical doctor will be available on call during the tests.
During the OGTT, a canula will be inserted in a forearm vein. Venapunctures can occasionaly cause a local bruise. Some participants report pain during venapuncture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Previous participants of the SLIM.

Exclusion criteria

Abnormal ECG during first visit and history of heart attack are exclusion criteria for the fitness test.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2009
Enrollment:	147

Type:	Actual

Ethics review

Approved WMO Date:	14-11-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL23892.068.08
Other	Protocol wordt momenteel geregistreerd bij clinicaltrials.gov. Nummer nog niet bekend.