

Screening for (pre)diabetes followed by a targeted lifestyle intervention to prevent diabetes mellitus among young and middle-aged Hindustani Surinamese: a feasibility study.

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

Summary

ID

NL-OMON30979

Source

ToetsingOnline

Brief title

Diabetes intervention study in Hindustani Surinamese

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetes mellitus, high blood sugar

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Zonmw

Intervention

Keyword: Lifestyle intervention, Population screening, Prevention, Type 2 diabetes

Outcome measures

Primary outcome

Screening:

- Normal blood glucose values
- Prediabetes (impaired fasting glucose and impaired glucose tolerance)
- Diabetes

Secondary outcome

Views on the screening (from participants and professionals)

Views on the intervention (from participants and professionals)

Study description

Background summary

Diabetes mellitus type 2 (DM) is a commonly occurring chronic condition, that is particularly prevalent among certain ethnic minorities. For example, the prevalence of DM among Hindustani Surinamese is 40% among the age group 45-60 years. In addition, the Hindustani Surinamese appear to already have a higher prevalence of DM at young age (20% in the age group 35-45 years). Moreover, the Hindustani have a higher risk of developing cardiovascular disease, while early detection, e.g. by screening, and adequate treatment of DM may decrease the risk of these complications such as cardiovascular disease.

Previous studies have shown that the period between onset of DM and diagnosis of DM is on average 10 years. Lifestyle intervention programs have been shown to be effective in delaying or preventing DM with impaired glucose tolerance. However, the effectiveness of these interventions has just been assessed among (elderly) white populations. Given the different risk profile of the Hindustani

Surinamese population and differences in the lifestyle, it is to be expected that existing programs have to be adjusted to suit the needs of that population.

Study objective

The first objective of this study is to develop a screening program for the Hindustani Surinamese population and to test its feasibility. The second objective is to develop a lifestyle intervention aimed at preventing DM, targeted to the Hindustani Surinamese population.

In addition, the feasibility of this intervention will be assessed. If the screening and lifestyle intervention are found to be feasible, a larger intervention study will be set up in order to determine the effectiveness of the screening followed by lifestyle intervention.

Study design

We will invite a randomly selected group of 1500 18 to 60 year old Hindustani Surinamese patients, registered in general practices in The Hague, for the study. Before recruitment, potential participants will be randomly allocated to a standard or intensive recruitment strategy. Data collection consists of a brief questionnaire followed by a physical examination (weight, length, waist circumference, blood pressure, fasting plasma glucose). In addition, an oral glucose tolerance test will be carried out.

Participants with impaired glucose tolerance or impaired fasting glucose will subsequently be invited to participate in the intervention. Those who provide informed consent will be randomly assigned to the lifestyle intervention group or the control group. The measurement for this study consists of a confirmatory OGTT and an interview.

Intervention

Participants in the intervention group will be offered a lifestyle intervention. The intended content of the intervention is:

- Participation in a physical exercise programme *Bewegen op Recept* : 20 sessions of supervised physical activity.
- Dietary counselling: individual 3-monthly dietary counseling by a trained dietician of Hindustani Surinamese origin.

The control group will receive generic lifestyle advice concerning physical activity, dietary habits and prevention of overweight.

Study burden and risks

not applicable

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Inclusion criteria screening

- Hindustani Surinamese background
- Aged between 18-60 years;Inclusion criteria intervention:
- Hindustani Surinamese background
- Aged between 18-60 years
- Persons found to have prediabetes during the screening
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Exclusion criteria

Exclusion criteria screening:

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- Known diabetes patients;Exclusion criteria intervention:
- Persons found to have diabetes during the screening
- Any chronic illness that makes participation in a lifestyle-intervention impossible
- Medication known to interfere with glucose tolerance
- Participation in a regular vigorous exercise and/or diet program

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	1500
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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

CCMO

ID

NL17628.018.07