Diabetes intervention study in Hindustani Surinamese

No registrations found.

Ethical review Positive opinion **Status** Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON23888

Source

Nationaal Trial Register

Brief title

DHIAAN

Health condition

Population screening Type 2 diabetes Lifestyle intervention Prevention

Populatie screening Type 2 diabetes Leefstijlinterventie Preventie

Sponsors and support

Primary sponsor: Prof. dr. K. Stronks

Professor of Social Medicine Dept. of Social Medicine

Academic Medical Centre, University of Amsterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

- 1. Normal blood glucose values;
- 2. Prediabetes (impaired fasting glucose and impaired glucose tolerance);
- 3. Diabetes.

Secondary outcome

- 1. Views on the screening;
- 2. Views on the intervention.

Study description

Background summary

Background

Type 2 diabetes mellitus (DM) is highly prevalent among the Hindustani Surinamese; 30% in the group 45-60 years. This group is not only younger at presentation, but also at high risk of developing CVD. Early detection and treatment of DM may decrease the risk of complications. The objective of this study is to develop a screening program and lifestyle intervention for Hindustani Surinamese, aimed at identifying pre-diabetes and preventing DM.

Methods

Screening: 1500 Hindustani Surinamese in The Hague, aged 18 to 60 years, will be randomized to a standard or intensive recruitment strategy. Participants will be asked to donate a fasting blood sample and an oral glucose tolerance test will be carried out. Intervention: Persons found to have impaired fasting glucose (fasting plasma glucose 5.6-< 7.0mmol/l) or impaired glucose tolerance (2-hour post-load glucose ¡Ý7.8-<11.1mmol/l) will be invited to participate in the intervention; they will be randomized to the lifestyle intervention or control group.

The content of the intervention is based on previous lifestyle interventions and will be targeted to the Hindustani Surinamese. Data on physical activity and dietary habits in the Hindustani Surinamese population are available from the SUNSET-study. A process evaluation among Surinamese participants in a physical exercise programme will provide insight into determinants of physical activity. Additional focus group discussions will take place among Hindustani Surinamese to gain further insight in determinants of physical activity and healthy dietary habits.

Results

The full design of the screening will be presented. Moreover, we will discuss the content of

the the lifestyle intervention, including the results of the SUNSET data and the focus group discussions.

Conclusion

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 the intervention.

Study objective

A systematic screening and a lifestyle-intervention for pre-diabetes targeted at the Hindustani Surinamese population will prevent or postpone the onset of diabetes mellitus type 2.

Study design

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Intervention

Lifestyle intervention, which consists of dietary counseling and supervised physical activity.

Contacts

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Eligibility criteria

Inclusion criteria

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|---|-----------|----------|-------------|---|
| ı | Inclusion | criteria | screening | • |
| ı | | CITCCITA | 30100111119 | |

- 1. Hindustani Surinamese background;
- 2. Aged between 18-60 years.

Inclusion criteria intervention:

- 1. Hindustani Surinamese background;
- 2. Aged between 18-60 years;
- 3. Persons found to have prediabetes during the screening.

Exclusion criteria

Exclusion criteria screening:

1. Known diabetes patients.

Exclusion criteria intervention:

- 1. Persons found to have diabetes during the screening;
- 2. Any chronic illness that makes participation during lifestyle-intervention impossible;
- 3. Medication known to interfere with glucose tolerance;
- 4. Participation in a regular vigorous exercise and/or diet program.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Masking: Single blinded (masking used)

Control: Placebo

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Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2007

Enrollment: 878

Type: Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 04-09-2007

Application type: First submission

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

NTR-new NL1019 NTR-old NTR1050

Other Zonmw: 6130.0034

ISRCTN wordt niet meer aangevraagd

Study results