

The association of intra-individual determinants and the physical environment with lifestyle behaviour and glucose metabolism - Follow-up Hoorn Study 2021

Published: 14-10-2021

Last updated: 19-08-2024

Primary objective:- to determine the association of the intra-individual determinants and the physical environment in regulating lifestyle behaviour and in turn the occurrence of pre-T2D and T2D in the general population. Secondary Objective(s): -...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON54208

Source

ToetsingOnline

Brief title

Hoorn study follow up 2021

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)
- Mood disorders and disturbances NEC

Synonym

Type 2 diabetes; non-insulin-dependent diabetes mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: NWO;diabetes fonds;ZonMw

Intervention

Keyword: Cardiovascular complications, Glucose metabolism, Risk factors, Type 2 diabetes

Outcome measures

Primary outcome

The primary endpoint is incident (pre)T2D, measured by using a fasting blood samples as well as blood taken during an Oral Glucose Tolerance Test.

Secondary outcome

T2D complications including:

- Medication use;
- Frailty;
- Blood pressure, hypertension;
- Psychological complications: depression, anxiety, sleep problems, fatigue, pain, physical functioning and participating social roles, aggression and emotional support;
- Dental health;
- Quality of life;
- Occurrence of cardiovascular disease;
- All-cause and cause-specific mortality.

Study description

Background summary

Although prevention programmes show that lifestyle modification is effective to prevent type 2 diabetes (T2D), the general population is largely unable to adopt a healthy lifestyle. Moreover, such prevention programs are ineffective to maintain over a longer period of time. More insight is needed in the determinants of adoption of a healthy lifestyle and their role in disturbance of glucose metabolism and T2D risk. Theoretical models such as the socio-ecological model provide insights in such upstream determinants of lifestyle behaviours, for example motivation. Despite this, very few studies have actually investigated the association of more upstream factors with disease outcomes and whether this potential association can be explained by health behaviours. More insight in these associations can provide insights for prevention programs to address these underlying factors or identify those at high risk to develop T2D. The Hoorn study is a longstanding population-based cohort study with the primary aim to investigate the prevalence and risk factors of T2D. The Hoorn study was initiated in 1989 and since then several additional follow-up rounds have been conducted, also with sampling of new participants in 2007. Therefore, the Hoorn study provides an excellent opportunity to address these research questions.

Study objective

Primary objective:

- to determine the association of the intra-individual determinants and the physical environment in regulating lifestyle behaviour and in turn the occurrence of pre-T2D and T2D in the general population.

Secondary Objective(s):

- To determine the association between the intra-individual determinants and physical environment with secondary outcomes of the individual continuous measures of glucose metabolism (glucose, insulin, insulin sensitivity) in the general population;
- To determine the association between the intra-individual determinants and physical environment with secondary outcomes of obesity in the general population;
- To determine the association between the intra-individual determinants and physical environment determinants and complications of T2D, such as cardiovascular disease and psychological problems in the general population;
- To determine the mediation effect of the lifestyle behaviours in the association between intra-individual determinants and physical environment and glucose metabolism in the general population.

Study design

Prospective cohort study.

Study burden and risks

Participants are asked to visit the research institute 1 time. This takes in total 5 hours. Several non-invasive questionnaires are taken. Anthropometry and blood pressure are determined. During the first visit (4 hours), an oral glucose tolerance test (OGTT) is administered in those without diabetes. All participants are requested to fast before they come to the research center (starting 10pm the evening before the study; and to refrain from alcohol from 5 pm the evening before the study), participants are allowed to drink water. Blood is taken. Participants are also asked to bring a urine and faeces sample. All participants are asked to wear an accelerometer for a week.

Participants with diabetes are asked to take a Walking Speed Test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

All surviving subjects who participated in the New Hoorn Study in 2006-2008 will be invited.

All participants who provided informed consent to be contacted again for additional follow up.

Exclusion criteria

Unable to give written informed consent.

Serious mental impairment i.e. preventing to understand the study protocol/aim.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 22-12-2021

Enrollment: 1800

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 14-10-2021

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 28-06-2022

Application type: Amendment

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	ID
ISRCTN	ISRCTN31493512
CCMO	NL74969.029.21