

# Health Checks in vulnerable groups: the role of beliefs and expectations.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON35982

### Source

ToetsingOnline

### Brief title

CHECK'D Cultural Health check Evaluating Cardiometabolic & Kidney Disease.

### Condition

- Other condition

### Synonym

Cardiovascular disease, diabetes, kidney failure.

### Health condition

Hoog risico op cardiometabole aandoeningen en nierschade.

### Research involving

Human

## Sponsors and support

**Primary sponsor:** LekkerLangLeven. Diabetes Fonds, T.a.v. Afdeling Wetenschappelijk Onderzoek en Preventie

**Source(s) of monetary or material Support:** LekkerLangLeven (fondsen: Hartstichting;Diabetesfonds en Nierstichting)

## Intervention

**Keyword:** Cardiometabolic disease, Health check, Uptake, Vulnerable groups

## Outcome measures

### Primary outcome

1. Participation in HRA (part 1 of PreventieConsult) and participation in consultations at GP (part 2 of PreventieConsult).
2. (Practical and psychological) determinants of participation in HRA and (practical and psychological) determinants of participation in consultations at GP.

### Secondary outcome

1. Test results HRA (no increased risk - slightly increased risk - increased risk).
2. Final risk profile after consultations at GP (no increased risk - slightly increased risk - increased risk) and newly diagnosed conditions.

## Study description

### Background summary

To compensate for all the commercial, untargeted self tests and health checks, the NHG guideline 'PreventieConsult, module Cardiometabool' has been developed. This guideline offers instructions to screen 45 - 70 year olds for cardiovascular disease, diabetes mellitus type 2, and kidney failure. Therefore, the PreventieConsult is aimed at people not diagnosed with these

conditions but possibly having an increased risk.

The PreventieConsult intends to:

- Offer a structured interpretation of prevention in general practice.
- Meet the patient's wish to know more about their risk of certain conditions and the need to prevent the onset of disease.

The PreventieConsult consists of two parts:

- The Health Risk Assessment (HRA). This is a short questionnaire with which the risk of cardiometabolic disease can be estimated.
- Two consultations with the GP. These consultations are only for people with an increased risk according to the HRA. During the consultations, the GP will perform physical measurements and labwork will be done. People will receive lifestyle advice and, if necessary, medication.

Experience tells us, and research has demonstrated, that preventive screening - like the PreventieConsult - reach certain groups better than others. Groups who respond well are generally health conscious, highly educated, native Dutch. They are also called the 'worried well' because usually they do not have an increased risk of cardiometabolic disease. Groups who usually do have an increased risk and respond less are non-Western immigrants and native Dutch with a low SES, from now on called 'vulnerable groups'. Possibly, current preventive health initiatives do not match well with the expectations of these groups and their health beliefs.

## **Study objective**

The objective of this study is to develop practical tools for GPs to increase participation of vulnerable patient populations in both the HRA as well as the consultations at the GP.

To achieve this, various strategies will be tested to maximize participation in the PreventieConsult of vulnerable groups. Among these strategies are different invitation and tailoring strategies (personalized information).

Research questions:

1. What is the participation rate in a (culturally) tailored postal HRA for our target groups?
2. Can this participation rate in a (culturally) tailored postal HRA be increased by:
  - A telephone call to non-responders?
  - A personal approach for subsequent non-responders when they visit their GP?
3. What are (practical and psychological) determinants of participants versus non-participants in the postal - telephone - personal HRA?
4. What are (practical and psychological) determinants of participants versus non-participants in the consultations at the GP after receiving a test result 'increased risk' from the postal - telephone - personal HRA?

## **Study design**

Non-randomized, no control intervention study.

## **Intervention**

Invitation strategies:

Currently, the HRA is provided by mail or online.

In this study, the effect of three invitation strategies will be tested:

1. The usual strategy: all patients will receive an invitation letter from their GP to participate in the HRA, either online or by mail.
2. All patients who have not responded to the postal invitation will receive a telephone call and are invited to participate in the HRA by phone.
3. All patients who have not responded to the telephone call will be approached in person when they visit their GP for an unrelated consultation and are invited to participate in the HRA.

Tailoring strategies:

Tailoring strategies are applied to provide individual persons with (parts of) an intervention. The idea behind this is that characteristics of an intervention that are individually relevant to a specific person are more attractive than a generic population-wide intervention. This way, an intervention is more effective.

Written tailoring strategies (applied during invitation strategy 1) are for example: personal letter (own name) and cultural lay-out (images / pictures people with same ethnic background, own language).

Oral tailoring strategies (applied during invitation strategy 2 and 3) are for example: approach by people with same ethnic background and in their own language. Also, during a personal conversation we will investigate individual reasons to participate or not in both the HRA and the consultations at the GP. We will use these reasons to abate ambivalence in non-participants and doubters and to motivate them to participate.

## **Study burden and risks**

Burden mainly consists of time needed to fill out the HRA, a questionnaire, and possibly for attending consultations at the GP (in case of increased risk).

Risk mainly consists of psychosocial consequences as a result of a disadvantageous test result of the PreventieConsult; increased risk of cardiometabolic disease. Participants with a newly found increased risk of cardiometabolic disease will have the chance to change their (unhealthy) lifestyle and thus prevent disease at a later age; health benefits.

## Contacts

### Public

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NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Turkish, Moroccan or Creole Surinamese origin and 45 - 70 years old.

Hindustani Surinamese origin and 35 - 70 years old.

Native Dutch origin with a low socioeconomic status and 45 - 70 years old.

### Exclusion criteria

Diagnosed cardiometabolic or kidney disease.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 11-06-2012

Enrollment: 1700

Type: Actual

## Ethics review

Approved WMO

Date: 17-10-2011

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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

NL37141.058.11