# Check@Home: General population screening for early detection of atrial fibrillation and chronic kidney disease

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The Check@Home consortium aims to set up a roadmap and infrastructure for a (cost-)effective program to early detect atrial fibrillation and chronic kidney disease (defined by elevated albuminuria) in the general population. Furthermore, the project...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Cardiac arrhythmias |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56780

**Source**
ToetsingOnline

**Brief title**
Check@Home

### Condition

- Cardiac arrhythmias
- Glucose metabolism disorders (incl diabetes mellitus)
- Renal disorders (excl nephropathies)

**Synonym**
Cardiovasular disease, kidney disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** NWO,Astra Zeneca,bedrijven;zie G2,Happitech,Luscii,Roche Diagnostics,Siemens Healthineers

## Intervention

**Keyword:** Cardiovascular disease, Population screening, Renal disease

## Outcome measures

### Primary outcome

Overall effectiveness of population based screening on atrial fibrillation and

chronic kidney disease (defined by elevated albuminuria) in subjects aged 50-75

years, based on:

- Participation rate of different screening strategies and phases

- Yield of the screening (number of subjects with (newly) diagnosed disease and

risk factors)

- Effectiveness of the different screening and treatment strategies on the main

(combined) endpoint (as defined in protocol section 10.1), compared to standard

care

### Secondary outcome

Overall effectiveness of population based screening on heart failure, coronary

artery disease, and diabetes type 2 in subjects aged 50-75 years, based on:

- Effectiveness of different screening and treatment strategies on other

cardiovascular events, compared to standard care

- Cost-effectiveness of different screening strategies, compared to standard

care

- Safety of the atrial fibrillation screening and treatment program, compared

to standard care

**Background summary**

Currently, in the Netherlands there is no structured national approach for the early detection of cardiovascular disease, kidney disease, and type 2 diabetes in the general population, despite the social and economic impact of these disorders. Detecting these chronic conditions at an early stage could allow for adequate and early treatment to prevent the progression of these conditions and their complications, thereby reducing the societal and economic burden caused by these chronic diseases.

**Study objective**

The Check@Home consortium aims to set up a roadmap and infrastructure for a (cost-)effective program to early detect atrial fibrillation and chronic kidney disease (defined by elevated albuminuria) in the general population. Furthermore, the project aims to examine options for treatment of these diseases, as well as options for broader screening, including the early detection of heart failure, coronary arterty disease, and diabetes type 2.

**Study design**

This will be a population-based screening with a phased implementation and an iterative design in four regions in the Netherlands (Breda, Utrecht, Arnhem, Eindhoven). The overall screening program will consist of three phases: a home-based testing phase, diagnostic screening phase, and a treatment phase. Subjects will be invited for a home-based screening (phase 1) that includes home-based testing; urine collection for detection of elevated albuminuria, and a heart rhythm measurement using a smartphone app for detection of atrial fibrillation. Both home-based tests will be performed with CE-marked medical devices used according to their intended use. In subsets of the population, alternative, more exploratory home-based screening tests will be implemented. Depending on the results on these home-based tests, subjects will be invited for further screening in a diagnostic screening facility (phase 2). During this visit, physical data (height, weight, waist circumference, blood pressure, heart rhythm) will be collected, blood will be drawn, and urine will be collected for the assessment of parameters that are indicative of a cardiovascular disease, chronic kidney disease, type 2 diabetes or their risk factors. Participants will receive a questionnaire that include questions on demographics, educational level, disease history, medication use, health literacy, and quality of life. Based on the results of the diagnostic

screening, participants may be referred to their general practitioner for appropriate treatment (lifestyle advice/medication) according to the prevailing guidelines (phase 3).

**Study burden and risks**

Physical risks of the overall screening program are minimal. As with any population screening program, there could be some physiological discomfort associated with participation: confrontation with unfavorable results, unnecessary anxiety in case of false-positive test results, and unwarranted reassurance in case of false-negative results. The benefit of participation would be that cardiovascular disease, chronic kidney disease, type 2 diabetes or their risk factors may be detected in an early phase, allowing for early treatment of these conditions and therefore a reduced risk of disease progression and complications.

# Contacts

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**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

age 50-75 years
living in one of the four participating regions in the Netherlands

## Exclusion criteria

age <50 or >75 years living outside the participating regions being institutionalized having participated in the previously conducted THOMAS Study (NL65228.042.18, METc 2018/687)

# Study design

## Design

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|---|---|
| Study type: | Observational invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2025 |
| Enrollment: | 160000 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Generic name: | Luscii Vitals |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO
Date: 24-04-2024
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 16-01-2025
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

# 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 | NL84419.042.23 |