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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON56780

Source
ToetsingOnline

Brief title
Check@Home

Condition

- Cardiac arrhythmias
- Renal disorders (excl nephropathies)
- Diabetic complications

Synonym
Cardiovasular disease, kidney disease, diabetes type 2

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: NWO,Collectebussenfonds,Astra Zeneca,Happitech,Siemens,Topicus,Roche Diagnostics

Intervention

- Medical device

Keyword: Cardiovascular disease, Population screening, Renal disease

Explanation

N.a.

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

Study description

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).

Intervention

Two medical devices will be used in the home-based screening phase of this study. These devices are CE-marked and will be used according to their intended use.

- PeeSpot urine collection device: The PeeSpot urine collection device consists of a holder containing a urine absorption pad in a transport tube. The urine absorption pad is an absorption felt containing a dried hygroscopic polymer. For collecting a portion of urine with the PeeSpot, the absorbent pad is held in the urine stream for 3-5 seconds, in which approximately 1.2 ml of urine is absorbed. The holder can be placed back into the tube and can be sent to the laboratory by mail. Because of the dried preservative in the urine absorption felt, the urine has a preservation capacity of 4 days at room temperature. In the laboratory, the tube can be centrifuged and the urine will be released into the tube. In this urine, the ACR can be measured. The PeeSpots will be measured by the Star-shl laboratory (Rotterdam). The PeeSpot urine collection device is registered as medical device class I. For more details, see “D2.2 Medical device information PeeSpot”.

- Happitech SDK: With the Happitech software, participants monitor their heart rate and heart rate variability with use of photoplethysmography (PPG) and powered by AI algorithms. PPG is a non-invasive way to detect volumetric changes in blood in peripheral circulation. Blood absorbs light and each pulse from the heart increases the blood flow in the body and to the fingertips. It is possible to keep track of changes in this pulse by measuring changes in light absorption. Users are guided by voice instructions to place their fingertip on the correct part of the smartphone camera lens for 90 seconds during which time the heart rhythm is detected. The Happitech heart rhythm Software Development Kit is CE Certified and classified as a Class IIa device under the MDD (93/42/EEC). For more details, see “D2.3 Medical device information Happitech”.

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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Trial sites

Trial sites in the Netherlands

Amsterdam UMC
Target size: 320000

Universitair Medisch Centrum Groningen
Target size: 0

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

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2025
Enrollment:	320000
Duration:	3 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	Happitech Heart Rhythm SDK
Registration:	Yes - CE intended use
Product type:	Medical device
Generic name:	Peespot urine collection device
Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

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)
Notification accepted Date:	06-05-2025
Application type:	Amendment
Review commission:	METC UMCG

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
ClinicalTrials.gov	NCT06330480
CCMO	NL84419.042.23
Research portal	NL-006099