# Personalized approach using wearable technology for early detection of Atrial Fibrillation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

### **Summary**

#### ID

NL-OMON22716

**Source** Nationaal Trial Register

**Brief title** PATCH-AF

**Health condition** 

Atrial fibrillation

### **Sponsors and support**

**Primary sponsor:** Amsterdam University Medical Center, location AMC **Source(s) of monetary or material Support:** ZonMw

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

1. Difference in detection of new AF between the intervention and control practices during the entire 3-year study period. (intention to screen analysis)

#### Secondary outcome

1. Difference in detection of new AF between the screened patients in the intervention practices and the control practices. (per protocol analysis)

2. Difference in time to diagnosis of AF between intervention and control practices.

3. Difference in other relevant cardiovascular outcomes like ischemic stroke, TIA, heart failure, dementia and the use of anticoagulation.

4. Difference in detection of new AF in control practices participating in the trial versus detection of AF in non-participating general practices in the network (i.e. the Hawthorne effect).

5. Patient experience with the monitoring device.

# **Study description**

#### **Background summary**

#### Background:

Atrial fibrillation is a cardiac arrhythmia that strongly increases a person's risk of stroke and heart failure. Anticoagulant treatment reduces the risk of a stroke by 60%. In daily practice detecting atrial fibrillation can be quite challenging, as it often occurs in a paroxysmal or asymptomatic form. Due to advances in technology, we are now able to increase the chance of detecting paroxysmal atrial fibrillation with non-obtrusive cardiac monitoring devices that allow for continuous arrhythmia detection. We therefore aim to evaluate the diagnostic yield for atrial fibrillation when using continuous cardiac monitoring in older patients deemed at high risk compared with routine practice.

#### Methods:

A general practice based, network-run, cluster-randomized controlled trial that includes 20 general practices from the 'Academic Network general practice Amsterdam'. Randomization will be performed as block randomization with a 1:1 allocation. Patients eligible for participation must be 65 years or older with a high risk of AF. We will exclude patients with previously diagnosed AF, a pacemaker or ICD. The intervention consists of a 7-day continuous ECG monitoring at baseline (t=0), after one (t=1) and two years (t=2). The control practices will continue usual care.

#### **Study objective**

Screening for AF, using intermittent continuous ecg-monitoring, in high risk primary care patients will lead to a higher incidence of AF as compared to the usual care.

#### Study design

The primary and secondary outcomes will be defined after three years.

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#### Intervention

The intervention consist of homebased ECG monitoring with the Bittium faros  $360^{\text{TM}}$  for seven days at baseline (t=0), after one year (t=1) and two years (t=2).

### Contacts

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# **Eligibility criteria**

### **Inclusion criteria**

A subject must be at least 65 years old with a CHA2DS2VASc score of  $\geq$  3 for men or  $\geq$  4 for women

### **Exclusion criteria**

Previously documented AF, patients with a pacemaker or ICD

# Study design

### Design

Study type: Intervention model: Interventional Parallel

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Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	930
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: Undecided

## **Ethics review**

Positive opinion	
Date:	10-08-2021
Application type:	First submission

# **Study registrations**

### Followed up by the following (possibly more current) registration

ID: 54154 Bron: ToetsingOnline Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register** NTR-new CCMO ID NL9656 NL76925.018.21

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Register
OMON

**ID** NL-OMON54154

# **Study results**

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