

# An evidence-based stroke prevention campaign in the Netherlands

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<b>Registration date</b> 17/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/10/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A stroke is a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off. An evidence-based stroke prevention campaign study will be conducted to improve awareness and prevention of stroke to reduce the burden of stroke in the general population in the Netherlands by comparing personality-tailored health messaging strategies with a neutral health messaging strategy. In the first phase, the gaps in the population's awareness of stroke and lifestyle factors underlying the risk of stroke, especially in different personality traits, are assessed by a diagnostic survey at the start of the study. In the second phase, different video interventions will be shown to participants and questionnaires will be filled out with the aim to define the most effective health messaging strategy, tailored to personality traits, to establish better awareness of stroke risk factors, a better reduction of self-reported risk factors for stroke, and enhanced self-detection of atrial fibrillation (irregular heartbeat), compared with neutral health messaging. Another aim is to identify high-risk stroke participants and undetected atrial fibrillation in the research population.

### Who can participate?

People aged 18 years or older

### What does the study involve?

The study consists of questionnaires and an educational intervention video. Participants will fill out a questionnaire at the start of the study and multiple questionnaires after watching the intervention video. Each participant will be randomly assigned to one of these videos. These intervention videos are different in content, there will be a control (neutral) video and several videos which are tailored to specific personality traits. The intervention video with the best performance on improvement in awareness and lifestyle will be scaled-up and distributed through several media outlets focused on the elderly population in the Netherlands.

### What are the possible benefits and risks of participating?

The collective benefit of participation includes helping to design an evidence-based health care campaign with the aim to reduce the burden of stroke in the Netherlands. The individual benefit of participating in this study is improved awareness and prevention of stroke. There are no anticipated risks of participating.

Where is the study run from?  
Amsterdam UMC (Netherlands)

When is the study starting and how long is it expected to run for?  
March 2020 to October 2022

Who is funding the study?

1. Medtronic (USA)
2. Pfizer (USA)

Who is the main contact?

Prof. Dr Leonard Hofstra  
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## Contact information

### Type(s)

Scientific

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

Nil known

# Study information

## Scientific Title

An evidence-based stroke prevention campaign: improvement of awareness and prevention of stroke to reduce the burden of stroke in the general population in the Netherlands by comparing personality-tailored health messaging strategies with a neutral health messaging strategy

## Study objectives

### 1. Rationale:

Understanding the gaps in awareness related to lifestyle factors underlying the risk of stroke, especially in different personality traits

### 2. Hypothesis:

A stroke prevention campaign using a video intervention tailored to the personality traits of participants results in better awareness of stroke risk factors, a better reduction of self-reported risk factors for stroke, and enhanced self-detection of atrial fibrillation, compared with neutral health messaging

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 30/03/2020, Amsterdam UMC Medical Ethics Review Committee (METC) (De Boelelaan 1117, 1118, 1081HV, Netherlands; +31 (0)204443394; metc@vumc.nl), ref: 2020.178

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Internet/virtual

## **Study type(s)**

Prevention

## **Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Improving awareness and prevention to reduce the burden of stroke in the general population in the Netherlands

## **Interventions**

This study consists of different educational intervention videos, which will be based on the outcomes of a diagnostic survey. The diagnostic survey will be conducted in the first phase of the study, where gaps in awareness of stroke and related to lifestyle factors underlying the risk of stroke are measured. In the second phase, participants are randomised to watch one of our different intervention videos and subsequently will fill out multiple questionnaires. Randomisation will take place via qualtrics.com (questionnaire website). There will be four different intervention videos that will be evenly randomised (1:1:1:1) to the participants of the questionnaire. Thus, in the end the quantity of participants will be evenly distributed between the videos.

The intervention videos differ in content. The control (neutral) video consists of educational information to improve awareness and prevention of stroke. The other three videos, which are personality trait-tailored videos, consist of the content of the control video and segments which are focused on a specific personality (agreeableness, conscientiousness or open-mindedness). The intervention video with the best performance on improvement in awareness and lifestyle will be scaled-up and will be distributed via several media outlets focused on the elderly population in the Netherlands.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Understanding the gaps in awareness related to lifestyle factors underlying the risk of stroke, and in relation to different personality traits. This is measured using a questionnaire (diagnostic survey) at baseline.
2. Definition of the most effective health messaging strategy, tailored to personality traits, to increase awareness of stroke risk factors and to enhance self-detection of atrial fibrillation, measured using questionnaires before (at baseline) and after showing the different intervention videos.

## **Secondary outcome measures**

1. Self-reported risk factors for stroke measured using questionnaires before (at baseline) and after showing the intervention video
2. Identification of high-risk stroke participants and undetected atrial fibrillation in the research population using questionnaires before (at baseline) and after showing the intervention video

## **Overall study start date**

30/03/2020

**Completion date**

01/10/2022

## Eligibility

**Key inclusion criteria**

Aged 18 years and older

**Participant type(s)**

All

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Around 1200

**Total final enrolment**

2429

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

16/01/2022

**Date of final enrolment**

01/06/2022

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Amsterdam UMC, locatie VUMC

De Boelelaan 1117, 1118

Amsterdam

Netherlands

1081HV

# Sponsor information

## Organisation

Pfizer (Netherlands)

## Sponsor details

Rivium Westlaan 142  
Capelle aan den IJssel  
Netherlands  
2909 LD  
+31 (0)10 4064 200  
info@pfizer.nl

## Sponsor type

Industry

## Website

<http://www.pfizer.nl>

## ROR

<https://ror.org/02bzf1224>

## Organisation

Medtronic (Netherlands)

## Sponsor details

Larixplein 4  
Eindhoven  
Netherlands  
5616 VB  
+31 (0)40 711 7555  
netherlandscs@medtronic.com

## Sponsor type

Industry

## Website

<https://www.medtronic.nl>

## ROR

<https://ror.org/02hmjce72>

# Funder(s)

## Funder type

Industry

**Funder Name**

Medtronic

**Alternative Name(s)**

Medtronic Inc.

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

**Funder Name**

Pfizer

**Alternative Name(s)**

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/10/2023

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date