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An evidence-based stroke prevention campaign in the Netherlands

Submission date
11/02/2022

Recruitment status
No longer recruiting

Registration date
17/02/2022

Overall study status
Completed

Last Edited
21/10/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Additional identifiers

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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s)
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

Completion date
01/10/2022

Eligibility

Key inclusion criteria
Aged 18 years and older

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/02bzf1224

Organisation
Medtronic (Netherlands)

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, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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