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A nationwide cardiovascular disease in women awareness campaign: a digital randomised controlled trial

Submission date 03/10/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 21/10/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/10/2022	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
It is well known that cardiovascular disease is the number one killer in men. In the last two decades it has become clear that cardiovascular disease is the number one killer for women as well. In the Netherlands, women have even overtaken men in the incidence of cardiovascular disease, especially stroke. However, a large survey study in the USA showed that only 56% of women are aware that cardiovascular disease is a number one killer for them. In addition, it seems that women are unaware of their cardiovascular risk factors (including women's specific risk factors like pregnancy-related hypertension). It also seems that both men and women are unrealistic optimistic about their own cardiovascular risk.
This evidence-based cardiovascular disease in women awareness campaign study will be conducted to improve awareness of cardiovascular disease in women and underlying risk factors in the Dutch population, especially among women, by comparing a specific health messaging strategy with a generic health messaging strategy.

In the observational phase, gaps in the population's awareness of cardiovascular disease in women and underlying risk factors are measured through a diagnostic survey, among the general Dutch population, and specifically in relation to sex differences and different personality traits.
In the interventional phase, different video interventions (with specific or generic health messages) will be shown to participants and subsequent questionnaires will be filled out with the aim to define the most effective health messaging strategy, specifically designed, to establish better awareness of cardiovascular disease in women and underlying risk factors, compared to a generic health messaging strategy. Another aim is to establish a better, specific compared to generic health messaging strategy, reduction of self-reported risk factors and improvement of cardiovascular health.

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 one or more questionnaires after watching the intervention video. Each participant will be randomly assigned to one of the intervention videos. There will be a control (generic) video and one or more video(s) which are specifically tailored based on the gaps in awareness. The intervention video with the best performance on improvement of awareness will contribute to the improvement and the design of subsequent campaigns.

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 cardiovascular disease in women in the Netherlands. The individual benefit of participating in this study is improved awareness and prevention of cardiovascular disease, and underlying risk factors.
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 June 2023

Who is funding the study?
Dutch Cardiovascular Alliance (DCVA)

Who is the main contact?
Prof. Dr Leonard Hofstra
l.hofstra@cardiologiecentra.nl

Contact information

Type(s)
Scientific

Contact name
Prof Leonard Hofstra

ORCID ID
http://orcid.org/0000-0003-4432-4720

Contact details
De Boelelaan 1117 / 1118
Amsterdam
Netherlands
1081HV
+31 (0)20 4442244
l.hofstra@cardiologiecentra.nl

Type(s)
Public

Contact name
Miss Gracia Habib

ORCID ID
http://orcid.org/0000-0001-6905-3870

Contact details
De Boelelaan 1117 / 1118
Amsterdam
Netherlands
1081HV
+31 (0)20 4442244
g.l.habib@amsterdamumc.nl

Type(s)
Principal Investigator

Contact name
Prof Leonard Hofstra

Contact details
De Boelelaan 1117 / 1118
Amsterdam
Netherlands
1081HV
+31 (0)20 4442244
l.hofstra@cardiologiecentra.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A nationwide cardiovascular disease in women awareness campaign, using specific compared to generic health messaging to improve awareness of cardiovascular disease in women and underlying risk factors among the Dutch population: a digital randomised controlled trial

Study objectives

1. Rationale:
Understanding the gaps in awareness of cardiovascular disease in women and underlying risk factors in the Dutch population, and in relation to difference in sex and personality traits
2. Hypothesis:
A cardiovascular disease in women awareness campaign, using specific compared to generic health messages, results in a substantial improvement of awareness of women's cardiovascular disease and underlying risk factors in the Dutch population.

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
Observational (cross-sectional study) and interventional (randomised 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Improving awareness (of underlying risk factors) and prevention of cardiovascular disease in women among the Dutch population.

Interventions
This study will consist of an observational and an interventional phase.
In the observational phase, a diagnostic survey will be conducted, where gaps in awareness of cardiovascular disease in women and underlying risk factors are measured. In the interventional phase different educational intervention videos (with specific vs. general health messages), based on the outcomes of the diagnostic survey, will be produced and shown to the study participants. Participants are randomised to watch one of our different intervention videos and will subsequently fill out multiple questionnaires. Randomisation will take place via qualtrics.com (questionnaire website). The intervention videos will be evenly randomised to the participants. Therefore, the number of participants will be evenly distributed across all intervention videos.

Intervention Type
Behavioural

Primary outcome measure
1. Understanding the gaps in awareness of cardiovascular disease in women and underlying risk factors (lifestyle factors, women specific risk factors, optimism bias, time-inconsistency), and in relation to difference in sex and different personality traits. This is measured using a questionnaire (diagnostic survey) at baseline.
2. Definition of the most effective health messaging strategy, specific compared to generic health messages, to improve awareness of cardiovascular disease in women and underlying risk factors, measured using questionnaires before (at baseline) and after showing the different intervention videos.

Secondary outcome measures
1. Improvement of self-reported risk factors for cardiovascular disease (improvement of cardiovascular health), measured using questionnaires before (at baseline) and after showing the intervention video

Overall study start date
29/03/2020

Completion date
01/06/2023

Eligibility

Key inclusion criteria
1. Provide informed consent
2. Aged 18 years or older

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2500

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
31/10/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, locatie VUMC
De Boelelaan 1117, 1118
Amsterdam
Netherlands
1081HV

Sponsor information

Organisation
Dutch Cardiovascular Alliance

Sponsor details
Moreelsepark 1
Utrecht
Netherlands
3511EP
+31 302333600
info@dcvalliance.nl

Sponsor type
Research organisation

Website
https://www.dcvalliance.nl

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Cardiovascular Alliance

Alternative Name(s)
DCVA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from G.L. Habib, g.l.habib@amsterdamumc.nl. Further data-sharing plans for the current study will be made available at a later date.

IPD sharing plan summary
Available on request