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Influenza campaign: bridging the gap in vaccination inequity

Submission date	Recruitment status	[_] Prospectively registered
23/12/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/01/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2024	Respiratory	

Plain English summary of protocol

Background and study aims:
A campaign to enhance the Influenza vaccination level may help to decrease the burden of disease, not only of Influenza itself, but also of acute cardiovascular diseases.

Understanding the gaps in knowledge, attitude, and practices which may result in vaccination inequity in the Netherlands, especially in different socio-/ethnic groups, are measured using a diagnostic questionnaire at baseline. A video intervention will be shown to the participant, with the aim to improve vaccine confidence and acceptance, and subsequently may result in increasing influenza vaccine coverage. Another aim of the study is to measure the impact of racial/cultural concordance to enhance vaccination confidence and acceptance compared to racial/cultural discordance. To conclude, the aim of this study is to enhance vaccination levels in different socio-economic/ethnic groups.

Who can participate?
Participants are eligible for inclusion if aged 18 years or older.

What does the study involve?
The study consists of a questionnaire and an educational video. Participants will be shown one of four different videos. The video shown to each participant will be shown at random with an equal number of participants being shown each video. These videos are different in content and actors (different ethnicity).

What are the possible benefits and risks of participating?
Participants will help to design evidence-based health care campaigns, tailored to different socio-economic/ethnic groups. There are no anticipated risks of participating.

Where is the study run from?
This study is sponsored by Sanofi (Netherlands) and managed by Amsterdam UMC (Netherlands). The study questionnaire will be run via the internet.

When is the study starting and how long is it expected to run for?
From June 2021 to January 2022

Who is funding the study?
Sanofi (USA)

Who is the main contact?
Professor Dr. Leonard Hofstra
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
A randomised controlled influenza campaign: improvement of the influenza vaccination confidence and acceptance in different socio-economic and ethnic groups in the Netherlands by different intervention videos using cultural/racial concordance compared to cultural/racial discordance

Study objectives
1. A nationwide influenza campaign tailored to different socio-economic/ethnic groups results in improvement of vaccination confidence and tendency to vaccinate (vaccine willingness).
2. Cultural/racial concordance contributes to improvement of vaccination confidence and vaccine willingness compared to cultural/racial discordance.
3. Understanding the gaps in knowledge, attitude and practices which may result in vaccination inequity in the Netherlands, especially in different socio-economic/ethnic groups.

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; +31204443394; 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
Influenza

Interventions
This study consists of an educational intervention. The intervention video will be based on a diagnostic survey, which will be conducted in the first phase of this study, where gaps in knowledge, attitude, and practices are measured. In the second phase, participants will fill out a questionnaire, subsequently are randomised to watch one of four different intervention videos, and will then continue with the remainder of the questionnaire. These 4 different intervention videos differ in content and actors (different ethnicity).

Intervention Type
Behavioural

Primary outcome(s)
Influenza vaccine confidence and acceptance is measured using a questionnaire, before and after showing an intervention video

Key secondary outcome(s)
1. The effect of cultural/racial concordance on vaccination confidence and acceptance is measured using a questionnaire, after showing an intervention video
2. Gaps in knowledge, attitude and practices which may result in vaccination inequity in the Netherlands, especially in different socio-economic/ethnic groups are measured using a diagnostic questionnaire at baseline

Completion date
31/01/2022

Eligibility

Key inclusion criteria
Aged ≥18 years

Participant type(s)
All

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2021

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
Netherlands

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

Sponsor information

Organisation
Sanofi (Netherlands)

ROR
https://ror.org/00pgqb537

Funder(s)

Funder type

Industry

Funder Name
Sanofi

Alternative Name(s)
sanofi-aventis, Sanofi US, Sanofi-Aventis U.S. LLC, Sanofi U.S.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/02/2023	13/02/2024	Yes	No
Participant information sheet		30/03/2020	07/01/2022	No	Yes