# Influenza campaign: bridging the gap in vaccination inequity

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

#### 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 leonard.hofstra@gmail.com

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Leonard Hofstra

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# 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

#### Study design

Interventional randomized controlled trial

#### Primary study design

Interventional

#### 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

Αll

# 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** 

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes