

# Influenza campaign: bridging the gap in vaccination inequity

<b>Submission date</b> 23/12/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/01/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English Summary

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

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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**  
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 hypothesis**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Prevention

**Participant information sheet**

See additional file

**Condition**

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 measure**

Influenza vaccine confidence and acceptance is measured using a questionnaire, before and after showing an intervention video

## **Secondary outcome measures**

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

## **Overall study start date**

22/06/2021

## **Overall study end date**

31/01/2022

# **Eligibility**

## **Participant inclusion criteria**

Aged  $\geq 18$  years

## **Participant type(s)**

All

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

4 clusters of 200 participants

## **Participant exclusion criteria**

Does not meet inclusion criteria

## **Recruitment start date**

01/11/2021

## **Recruitment end date**

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)

### Sponsor details

Paasheuvelweg 25  
Amsterdam  
Netherlands  
1100ED  
+31202454000  
info.nl@sanofi.com

### Sponsor type

Industry

### Website

<http://www.sanofi.nl/l/nl/nl/index.jsp>

### 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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/01/2023

**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

**Study outputs**

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