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In the general population, do specific forms of COVID-19 vaccine information, above simple information that they are safe and effective, increase willingness to be vaccinated?

Submission date
13/01/2021

Recruitment status
No longer recruiting

Registration date
13/01/2021

Overall study status
Completed

Last Edited
17/05/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In December 2020, the researchers created a survey to estimate how many people would agree to be vaccinated for COVID-19, whether there were parts of the population especially reluctant, and, most importantly, determine why people may not agree to take a new vaccine. The aim was to inform how best to provide vaccination information to enhance acceptance rates. 5,114 adults, representative of the UK population for age, gender, ethnicity, income, and region, took part. It was found that 72% of the population are willing to be vaccinated, 16% are very unsure, and 12% are strongly hesitant; COVID-19 vaccine hesitancy is spread over the whole of the population (it is not confined to isolated pockets); and what matters most is the way people think about a number of key issues relating to a COVID-19 vaccine, specifically: the potential collective benefit, the likelihood of COVID-19 infection, the effectiveness of a vaccine, its side-effects, and the speed of vaccine development. Those who are hesitant about a COVID-19 vaccine tend to be people who may not be so aware of the public health aspects of a vaccine, don't consider themselves at significant risk of illness, doubt the efficacy of a vaccine, worry about potential side effects, or fear that it's been developed too quickly. The researchers have also been carrying out interviews with people across the spectrum of vaccine views.
In this study they will use this learning to test the effect of different information provision on willingness to be vaccinated. The researchers assume a basic statement of safety and effectiveness (as currently on the NHS website) should occur in all information provision. They then test the effects of additional short chunks of text that address: i. the collective benefits of vaccination (arising from not getting ill or not infecting others), ii. the personal benefits of vaccination, iii. the seriousness of the virus, and iv. the speed of development and testing of the vaccinations. The researchers are focussed on testing chunks of information that can be used online or in a brief single sheet of information as part of a vaccination programme. They also test the effects of a number of combinations of these messages. All messaging is designed to be accurate and to reduce hesitancy and there is no testing of factors that may hinder vaccine uptake. The primary outcome is willingness to be vaccinated, but the researchers will also test mediation (beliefs about COVID-19 vaccination), and moderation (especially level of vaccine

hesitancy). In an additional exploratory part of the study, after the main testing, they evaluate the effects of four different reflective questions on vaccination against the provision of further information.

Who can participate?
15,000 UK adults (age 18 or above), quota sampled to be representative for age, gender, region, education level, and ethnicity. The participants will be recruited by the market research company, Lucid.

What does the study involve?
The research will take about 20 minutes. The researchers will ask a single question about COVID-19 vaccine views, followed by basic socio-demographic questions, then they will provide information about a Covid-19 vaccine (randomised to one of ten conditions), and then ask participants to complete a questionnaire. Following this participants will be re-randomised to reflective questions, and repeat the questionnaire.

What are the possible benefits and risks of participating?
The benefit of taking part is that people will engage in additional thinking about vaccination. There are few risks of taking part (the main one being any data security breaches).

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
December 2020 to February 2021

Who is funding the study?
1. NIHR Oxford Biomedical Research Centre (UK)
2. NIHR Oxford Health Biomedical Research Centre (UK)

Who is the main contact?
Prof. Daniel Freeman
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol 1.0

Study information

Scientific Title
COVID-19 vaccination views: Oxford Coronavirus Explanations, Attitudes, and Narratives Survey (OCEANS III)

Acronym
OCEANS III

Study objectives
The overarching question addressed is: is there specific content about COVID-19 vaccination, above a simple statement of safety and effectiveness, that may reduce hesitancy and/or consolidate existing positive views? The researchers are most interested in the effects on those in the general population who are very unsure (approximately 16%) or strongly hesitant (approximately 12%) about a COVID-19 vaccination.

The specific primary outcome questions are:
1. Does adding information about the collective benefit of vaccination from not getting ill, the collective benefit of vaccination from not spreading the virus, the personal benefit of getting vaccinated, the seriousness of the SARS-CoV-2, or why the speed of development is not a problem (directly and indirectly), lead to lower levels of COVID-19 vaccine hesitancy than a simple statement that vaccination is efficacious and safe? [This is a test against condition 1 (control) of conditions 2, 3, 4, 5, 6, 7, 8.]
2. Does combining collective and personal benefits or combining collective and personal benefits with the seriousness of the virus and indirectly why the speed of development is not a problem lead to lower levels of COVID-19 vaccine hesitancy than a simple statement that vaccination is efficacious and safe? [This is a test against condition 1 (control) of conditions 9 and 10.]

The specific secondary outcome questions are:
1. Is emphasising collective benefit better (i.e. leads to lower hesitancy) than emphasising personal benefit? [This is a test of conditions 2 and 3 against 5].
2. Is emphasising why the speed of development is not a problem better done directly or

indirectly? [This is a test of condition 7 against 8.]
3. Is combining personal and collective benefits better than emphasising personal or collective benefits alone? [This is a test of condition 9 against conditions 4 and 5].
4. Is combining collective and personal benefits with the seriousness of the virus and indirectly why the speed of development is not a problem better than just combining collective and personal benefits? [This is a test of condition 10 against 9.]

The primary moderation question is:
1. Is the effect of information provision on COVID-19 vaccine hesitancy moderated by the three groupings of the level of hesitancy (positive about vaccination, very unsure, strongly hesitant)?

The secondary moderation question is:
1. Is the effect of information provision on COVID-19 vaccine hesitancy moderated by age, gender, ethnicity, income, region, or level of Covid-19 health risk?

The mediation question is:
If a significant relationship exists between randomised conditions and vaccine hesitancy, can that relationship be explained by COVID-19 vaccine views (the potential collective benefit, the likelihood of COVID-19 infection and the effectiveness of a vaccine, its side-effects, and concerns about the speed of vaccine development)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2021, University of Oxford Central University Research Ethics Committee (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R74001/RE001

Study design
Single-blind parallel-group randomized controlled design with planned mediation and moderation tests

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) vaccine hesitancy

Interventions
Randomisation
Participants will be randomised equally across conditions stratified by three levels of vaccine hesitancy (positive, very doubtful, strongly hesitant).

Intervention conditions
There are ten information conditions. Each specific added section (conditions 2, 3, 5, 6, 7, 8) has a word count within 20% of the mean. Data on the time that participants take to read each condition will be collected. The conditions are:
1. Control: a basic statement of safety and effectiveness taken from https://www.nhs.uk. This control statement features at the end of all other conditions.
2. Collective benefit I: adding the collective vaccination benefit of not personally getting the virus.
3. Collective II: adding the collective vaccination benefit of not transmitting the virus to others.
4. Collective III: adding the collective vaccination benefits of not getting ill and not transmitting (i.e. adding 2 and 3 together).
5. Personal benefit: adding the personal benefit of getting vaccinated.
6. Seriousness: adding the seriousness of pandemic.
7. Safety: directly addressing concerns about vaccine safety related to the speed of development
8. Safety: indirectly addressing concerns about vaccine safety related to the speed of development
9. Collective and personal: adding the collective and personal benefits together (i.e. adding conditions 4 and 5).
10. Full combination: adding the information on the collective and personal benefits, the seriousness of the virus, & the safety information that indirectly addresses the speed of development concerns (i.e. adding 4, 5, 6, and 8).

Intervention Type
Other

Primary outcome measure
COVID-19 vaccine hesitancy is measured using the Oxford Covid-19 Vaccine Hesitancy Measure at post-randomisation

Secondary outcome measures
Beliefs about COVID-19 and vaccination are measured using the Oxford Vaccine Confidence and Complacency Scale at post-randomisation

Overall study start date
13/12/2020

Completion date
01/02/2021

Eligibility

Key inclusion criteria
1. UK adults (age 18 or above), quota sampled to be representative for age, gender, region, education level, and ethnicity

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At the mid-point of data collection, vaccine hesitancy levels (as assessed by the stratification question) in the participants were lower than anticipated, and therefore the researchers have planned to recruit approximately 3,500 additional participants who score for vaccine hesitancy (using the stratification question). The total study participant group is therefore likely to be approximately 18,500.

Total final enrolment
15014

Key exclusion criteria
1. Under 18 years of age
2. Do not give informed consent

Date of first enrolment
18/01/2021

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
NIHR Oxford Health Biomedical Research Centre

Results and Publications

Publication and dissemination plan
The researchers plan to publish the results in a peer-reviewed journal. Additional documents will be available directly from the research team.

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
Anonymised data will be available for reasonable requests. These requests can be made to Prof. Daniel Freeman (daniel.freeman@psych.ox.ac.uk) after the publication of the main report from the trial. The data will be available for a minimum of 3 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	17/05/2021	Yes	No