

Exhibit 280

COVID-19 Vaccine Messaging, Part 1

Yale University

<https://clinicaltrials.gov/ct2/show/record/NCT04460703>

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COVID-19 Vaccine Messaging, Part 1



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04460703

Recruitment Status ⓘ : Completed

First Posted ⓘ : July 7, 2020

Last Update Posted ⓘ : May 5, 2022

[View this study on Beta.ClinicalTrials.gov](#)

Sponsor:

Yale University

Information provided by (Responsible Party):

Yale University

[Study Details](#)

[Tabular View](#)

[No Results Posted](#)

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Study Description

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Brief Summary:

This study tests different messages about vaccinating against COVID-19 once the vaccine becomes available. Participants are randomized to 1 of 12 arms, with one control arm and one baseline arm. We will compare the

reported willingness to get a COVID-19 vaccine at 3 and 6 months of it becoming available between the 10 intervention arms to the 2 control arms.

Study participants are recruited online by Lucid, which matches census based sampling in online recruitment.

<u>Condition or disease</u> ⓘ	<u>Intervention/treatment</u> ⓘ	<u>Phase</u> ⓘ
Vaccination COVID-19	Other: Control message Other: Baseline message Other: Personal freedom message Other: Economic freedom message Other: Self-interest message Other: Community interest message Other: Economic benefit message Other: Guilt message Other: Embarrassment message Other: Anger message Other: Trust in science message Other: Not bravery message	Not Applicable

Study Design

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Study Type ⓘ :

Interventional (Clinical Trial)

Actual Enrollment ⓘ :

4000 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Intervention Model Description:

In this study, 2/15 of participants will be assigned to a control message (bird feeding passage), 3/15 of sample to a baseline vaccine message, and 1/15 to each of the 10 other treatment arms.

Masking:

None (Open Label)

Primary Purpose:

Other

Official Title:

Persuasive Messages for COVID-19 Vaccine Uptake: a Randomized Controlled Trial, Part 1

Actual Study Start Date  :

July 3, 2020

Actual Primary Completion Date  :

July 8, 2020

Actual Study Completion Date  :



July 8, 2020

Resource links provided by the National Library of Medicine

[MedlinePlus](#) related topics: [COVID-19 \(Coronavirus Disease 2019\)](#) [COVID-19 Vaccines](#) [Vaccines](#)



[U.S. FDA Resources](#)

Arms and InterventionsGo to


<u>Arm </u>	<u>Intervention/treatment </u>
Sham Comparator: Control Control message about birdfeeding	Other: Control message 2/15 of the sample will be assigned to the pure control group, which is a passage on the costs and benefits of bird feeding.
Active Comparator: Baseline message These participants will be assigned a message about the benefits of vaccination. All other treatment arms include this baseline language.	Other: Baseline message 3/15 of the sample will be assigned to a control group with a message about the effectiveness and safety of vaccines.
Experimental: Personal freedom Experimental message arm.	Other: Personal freedom message 1/15 of the sample will be assigned to this intervention, which is a message about how COVID-19 is limiting people's personal freedom and by working together to get enough people vaccinated society can preserve its personal freedom.

Arm ⓘ	Intervention/treatment ⓘ
<p>Experimental: Economic freedom Experimental message arm.</p>	<p>Other: Economic freedom message 1/15 of the sample will be assigned to this intervention, which is a message about how COVID-19 is limiting peoples's economic freedom and by working together to get enough people vaccinated society can preserve its economic freedom.</p>
<p>Experimental: Social benefit, self-interest Experimental message arm.</p>	<p>Other: Self-interest message 1/15 of the sample will be assigned to this intervention, which is a message that COVID-19 presents a real danger to one's health, even if one is young and healthy. Getting vaccinated against COVID-19 is the best way to prevent oneself from getting sick.</p>
<p>Experimental: Social benefit, community interest Experimental message arm.</p>	<p>Other: Community interest message 1/15 of the sample will be assigned to this intervention, which is a message about the dangers of COVID-19 to the health of loved ones. The more people who get vaccinated against COVID-19, the lower the risk that one's loved ones will get sick. Society must work together and all get vaccinated.</p>
<p>Experimental: Economic benefit Experimental message arm.</p>	<p>Other: Economic benefit message 1/15 of the sample will be assigned to this group, which is a message about how COVID-19 is wreaking havoc on the economy and the only way to strengthen the economy is to work together to get enough people vaccinated.</p>
<p>Experimental: Social pressure- guilt Experimental message arm.</p>	<p>Other: Guilt message 1/15 of the sample will be assigned to this message. The message is about the danger that</p>

Arm ⓘ	Intervention/treatment ⓘ
	<p>COVID-19 presents to the health of one's family and community. The best way to protect them is by getting vaccinated and society must work together to get enough people vaccinated. Then it asks the participant to imagine the guilt they will feel if they don't get vaccinated and spread the disease.</p>
<p>Experimental: Social pressure- embarrassment Experimental message arm.</p>	<p>Other: Embarrassment message 1/15 of the sample will be assigned to this message. The message is about the danger that COVID-19 presents to the health of one's family and community. The best way to protect them is by getting vaccinated and by working together to make sure that enough people get vaccinated. Then it asks the participant to imagine the embarrassment they will feel if they don't get vaccinated and spread the disease.</p>
<p>Experimental: Social pressure- anger Experimental message arm.</p>	<p>Other: Anger message 1/15 of the sample will be assigned to this message. The message is about the danger that COVID-19 presents to the health of one's family and community. The best way to protect them is by getting vaccinated and by working together to make sure that enough people get vaccinated. Then it asks the participant to imagine the anger they will feel if they don't get vaccinated and spread the disease.</p>
<p>Experimental: Trust in science Experimental message arm.</p>	<p>Other: Trust in science message 1/15 of the sample will be assigned to this message about how getting vaccinated against COVID-19 is the most effective way of protecting one's community. Vaccination is backed by science. If one doesn't get vaccinated that means</p>

Arm 	Intervention/treatment 
	that one doesn't understand how infections are spread or who ignores science.
Experimental: Not bravery arm Experimental message arm.	Other: Not bravery message 1/15 of the sample will be assigned to this message which describes how firefighters, doctors, and front line medical workers are brave. Those who choose not to get vaccinated against COVID-19 are not brave.

Outcome Measures

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Primary Outcome Measures

1. Intention to get COVID-19 vaccine [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a self reported measure, immediately after the intervention message, of the likelihood of getting a COVID-19 vaccination within 3 months and then 6 months of it becoming available. During analysis, responses among those assigned to different intervention messages will be compared to those in the control group.

Secondary Outcome Measures

1. Vaccine confidence scale [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a validated scale. This scale will be used to assess the impact of the messages on vaccine confidence. (Outcome assessed only for the half of the sample that answers these items post-treatment)

2. Persuade others item [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a measure of a willingness to persuade others to take the COVID-19 vaccine.

3. Fear of those who have not been vaccinated [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a measure of a comfort with an unvaccinated individual visiting an elderly friend after a vaccine becomes available

4. Social judgment of those who do not vaccinate [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a scale composed of 4 items measuring the trustworthiness, selfishness, likeableness, and competence of those who choose not to get vaccinated after a vaccine becomes available

Eligibility Criteria

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Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- At least 18 years of age
- US resident

Exclusion Criteria:

- Younger than 18 years of age
- Non-US resident
- Do not consent

Contacts and LocationsGo to **Information from the National Library of Medicine**

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT04460703**

Locations**United States, Connecticut**

Yale University
New Haven, Connecticut, United States, 06510

Sponsors and Collaborators

Yale University

More InformationGo to **Publications of Results:**

[James EK, Bokemper SE, Gerber AS, Omer SB, Huber GA. Persuasive messaging to increase COVID-19 vaccine uptake intentions. Vaccine. 2021 Dec 3;39\(49\):7158-7165. doi: 10.1016/j.vaccine.2021.10.039. Epub 2021 Oct 22.](#)

Responsible Party:

Yale University

ClinicalTrials.gov Identifier:

[NCT04460703](#) [History of Changes](#)

Other Study ID Numbers:

2000027983

First Posted:

July 7, 2020 [Key Record Dates](#)

Last Update Posted:

May 5, 2022

Last Verified:

April 2022

Individual Participant Data (IPD) Sharing Statement:**Plan to Share IPD:**

Yes

Plan Description:

Anonymized data and analysis code will be posted in a public replication archive after publication.

Supporting Materials:

Study Protocol

Statistical Analysis Plan (SAP)

Informed Consent Form (ICF)

Analytic Code

Time Frame:

After publication

Access Criteria:

Anonymized data and analysis code will be posted in a public replication archive

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Yale University:

messaging

Additional relevant MeSH terms:

COVID-19

Respiratory Tract Infections

Infections

Pneumonia, Viral

Pneumonia

Virus Diseases

Coronavirus Infections

Coronaviridae Infections


Nidovirales Infections

RNA Virus Infections

Lung Diseases

Respiratory Tract Diseases

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Information provided by (Responsible Party):

Yale University

[Study Details](#)

[Tabular View](#)

[No Results Posted](#)

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Tracking Information

First Submitted Date [ICMJE](#)

July 2, 2020

First Posted Date ICMJE
July 7, 2020
Last Update Posted Date
May 5, 2022
Actual Study Start Date ICMJE
July 3, 2020
Actual Primary Completion Date
July 8, 2020 (Final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: July 18, 2020)
<p>Intention to get COVID-19 vaccine [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]</p> <p>This is a self reported measure, immediately after the intervention message, of the likelihood of getting a COVID-19 vaccination within 3 months and then 6 months of it becoming available. During analysis, responses among those assigned to different intervention messages will be compared to those in the control group.</p>
Original Primary Outcome Measures ICMJE (submitted: July 6, 2020)
<p>Intention to get COVID-19 vaccine [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]</p> <p>This is a self reported measure of the likelihood of getting a COVID-19 vaccination within 3 months and then 6 months of it becoming available. We will compare those in the control groups to the 10 different intervention messages.</p>
Change History
Complete list of historical versions of study NCT04460703 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: July 18, 2020)
<ul style="list-style-type: none"> • Vaccine confidence scale [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided] <p>This is a validated scale. This scale will be used to assess the impact of the messages on vaccine confidence. (Outcome assessed only for the half of the sample that answers these items post-treatment)</p>

- Persuade others item [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a measure of a willingness to persuade others to take the COVID-19 vaccine.

- Fear of those who have not been vaccinated [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a measure of a comfort with an unvaccinated individual visiting an elderly friend after a vaccine becomes available

- Social judgment of those who do not vaccinate [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a scale composed of 4 items measuring the trustworthiness, selfishness, likeableness, and competence of those who choose not to get vaccinated after a vaccine becomes available

Original Secondary Outcome Measures [ICMJE](#)
(submitted: July 6, 2020)

- Vaccine confidence scale [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a validated scale. We will use the scale to assess the impact of the messages on vaccine confidence. (Outcome assessed only for the half of the sample that answers these items post-treatment)

- Persuade others item [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a measure of a willingness to persuade others to take the COVID-19 vaccine.

- Fear of those who have not been vaccinated [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a measure of a comfort with an unvaccinated individual visiting an elderly friend after a vaccine becomes available

- Social judgment of those who do not vaccinate [Time Frame: Immediately after intervention, in the same survey in which the intervention message is provided]

This is a scale composed of 4 items measuring the trustworthiness, selfishness, likeableness, and competence of those who choose not to get vaccinated after a vaccine becomes available

Current Other Pre-specified Outcome Measures

Not Provided

Original Other Pre-specified Outcome Measures

Not Provided

Descriptive Information

Brief Title [ICMJE](#)

COVID-19 Vaccine Messaging, Part 1

Official Title [ICMJE](#)

Persuasive Messages for COVID-19 Vaccine Uptake: a Randomized Controlled Trial, Part 1

Brief Summary

This study tests different messages about vaccinating against COVID-19 once the vaccine becomes available. Participants are randomized to 1 of 12 arms, with one control arm and one baseline arm. We will compare the reported willingness to get a COVID-19 vaccine at 3 and 6 months of it becoming available between the 10 intervention arms to the 2 control arms.

Study participants are recruited online by Lucid, which matches census based sampling in online recruitment.

Detailed Description

Not Provided

Study Type [ICMJE](#)

Interventional

Study Phase [ICMJE](#)

Not Applicable

Study Design [ICMJE](#)

Allocation: Randomized

Intervention Model: Parallel Assignment

Intervention Model Description:

In this study, 2/15 of participants will be assigned to a control message (bird feeding passage), 3/15 of sample to a baseline vaccine message, and 1/15 to each of the 10 other treatment arms.

Masking: None (Open Label)

Primary Purpose: Other

Condition [ICMJE](#)

- Vaccination

- COVID-19

Intervention ICMJE

- Other: Control message
2/15 of the sample will be assigned to the pure control group, which is a passage on the costs and benefits of bird feeding.
- Other: Baseline message
3/15 of the sample will be assigned to a control group with a message about the effectiveness and safety of vaccines.
- Other: Personal freedom message
1/15 of the sample will be assigned to this intervention, which is a message about how COVID-19 is limiting people's personal freedom and by working together to get enough people vaccinated society can preserve its personal freedom.
- Other: Economic freedom message
1/15 of the sample will be assigned to this intervention, which is a message about how COVID-19 is limiting peoples's economic freedom and by working together to get enough people vaccinated society can preserve its economic freedom.
- Other: Self-interest message
1/15 of the sample will be assigned to this intervention, which is a message that COVID-19 presents a real danger to one's health, even if one is young and healthy. Getting vaccinated against COVID-19 is the best way to prevent oneself from getting sick.
- Other: Community interest message
1/15 of the sample will be assigned to this intervention, which is a message about the dangers of COVID-19 to the health of loved ones. The more people who get vaccinated against COVID-19, the lower the risk that one's loved ones will get sick. Society must work together and all get vaccinated.
- Other: Economic benefit message
1/15 of the sample will be assigned to this group, which is a message about how COVID-19 is wreaking havoc on the economy and the only way to strengthen the economy is to work together to get enough people vaccinated.
- Other: Guilt message
1/15 of the sample will be assigned to this message. The message is about the danger that COVID-19 presents to the health of one's family and community. The best way to protect them is by getting vaccinated and society must work together to get enough people vaccinated. Then it asks the participant to imagine the guilt they will feel if they don't get vaccinated and spread the disease.
- Other: Embarrassment message

1/15 of the sample will be assigned to this message. The message is about the danger that COVID-19 presents to the health of one's family and community. The best way to protect them is by getting vaccinated and by working together to make sure that enough people get vaccinated. Then it asks the participant to imagine the embarrassment they will feel if they don't get vaccinated and spread the disease.

- Other: Anger message

1/15 of the sample will be assigned to this message. The message is about the danger that COVID-19 presents to the health of one's family and community. The best way to protect them is by getting vaccinated and by working together to make sure that enough people get vaccinated. Then it asks the participant to imagine the anger they will feel if they don't get vaccinated and spread the disease.

- Other: Trust in science message

1/15 of the sample will be assigned to this message about how getting vaccinated against COVID-19 is the most effective way of protecting one's community. Vaccination is backed by science. If one doesn't get vaccinated that means that one doesn't understand how infections are spread or who ignores science.

- Other: Not bravery message

1/15 of the sample will be assigned to this message which describes how firefighters, doctors, and front line medical workers are brave. Those who choose not to get vaccinated against COVID-19 are not brave.

Study Arms [ICMJE](#)

- Sham Comparator: Control

Control message about birdfeeding

Intervention: Other: Control message

- Active Comparator: Baseline message

These participants will be assigned a message about the benefits of vaccination. All other treatment arms include this baseline language.

Intervention: Other: Baseline message

- Experimental: Personal freedom

Experimental message arm.

Intervention: Other: Personal freedom message

- Experimental: Economic freedom

Experimental message arm.

Intervention: Other: Economic freedom message

- Experimental: Social benefit, self-interest

Experimental message arm.

Intervention: Other: Self-interest message

- Experimental: Social benefit, community interest

Experimental message arm.

Intervention: Other: Community interest message

- Experimental: Economic benefit

Experimental message arm.

Intervention: Other: Economic benefit message

- Experimental: Social pressure- guilt

Experimental message arm.

Intervention: Other: Guilt message

- Experimental: Social pressure- embarrassment

Experimental message arm.

Intervention: Other: Embarrassment message

- Experimental: Social pressure- anger

Experimental message arm.

Intervention: Other: Anger message

- Experimental: Trust in science

Experimental message arm.

Intervention: Other: Trust in science message

- Experimental: Not bravery arm

Experimental message arm.

Intervention: Other: Not bravery message

Publications *

[James EK, Bokemper SE, Gerber AS, Omer SB, Huber GA. Persuasive messaging to increase COVID-19 vaccine uptake intentions. Vaccine. 2021 Dec 3;39\(49\):7158-7165. doi: 10.1016/j.vaccine.2021.10.039. Epub 2021 Oct 22.](#)

* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.

Recruitment Information

Recruitment Status [ICMJE](#)

Completed

Actual Enrollment ICMJE (submitted: July 6, 2020)
4000
Original Estimated Enrollment ICMJE
<i>Same as current</i>
Actual Study Completion Date ICMJE
July 8, 2020
Actual Primary Completion Date
July 8, 2020 (Final data collection date for primary outcome measure)
Eligibility Criteria ICMJE
<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • At least 18 years of age • US resident <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Younger than 18 years of age • Non-US resident • Do not consent
Sex/Gender ICMJE
Sexes Eligible for Study: All
Ages ICMJE
18 Years and older (Adult, Older Adult)
Accepts Healthy Volunteers ICMJE
Yes
Contacts ICMJE
<i>Contact information is only displayed when the study is recruiting subjects</i>
Listed Location Countries ICMJE
United States

Removed Location Countries
Administrative Information
NCT Number ICMJE
NCT04460703
Other Study ID Numbers ICMJE
2000027983
Has Data Monitoring Committee
No
U.S. FDA-regulated Product
Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No
IPD Sharing Statement ICMJE
Plan to Share IPD: Yes
Plan Description: Anonymized data and analysis code will be posted in a public replication archive after publication.
Supporting Materials: Study Protocol
Supporting Materials: Statistical Analysis Plan (SAP)
Supporting Materials: Informed Consent Form (ICF)
Supporting Materials: Analytic Code
Time Frame: After publication
Access Criteria: Anonymized data and analysis code will be posted in a public replication archive

Current Responsible Party
Yale University
Original Responsible Party
Gregory Huber, PhD, Yale University, Chair, Department of Political Science
Current Study Sponsor ICMJE
Yale University
Original Study Sponsor ICMJE
Gregory Huber, PhD
Collaborators ICMJE
<i>Not Provided</i>
Investigators ICMJE
<i>Not Provided</i>
PRS Account
Yale University
Verification Date
April 2022
ICMJE Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP