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History of Changes for Study: NCT04460703

COVID-19 Vaccine Messaging, Part 1

Latest version (submitted October 28, 2021) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol sectio
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in red
- Study additions are displayed in green.

Study Record Versions

Version	Α	в	Submitted Date	Changes
1	0	0	<u>July 6, 2020</u>	None (earliest Version on record)
2	0	0	<u>July 18, 2020</u>	Recruitment Status, Study Status, Sponsor/Collaborators, Outcome Measures, Study Design, Study Identification, Contacts/Locations and A Interventions
3		۲	<u>October 28, 2021</u>	Study Status and References
Comp	are]	Comparison Fo	rmat: Merged Side-by-Side

Scroll up to access the controls

Study NCT04460703

Submitted Date: October 28, 2021 (v3)

Study Identification

Unique Protocol ID: 2000027983

Brief Title: COVID-19 Vaccine Messaging, Part 1

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

Secondary IDs:

Study Status

Record Verification: October 2021 Overall Status: Completed Study Start: July 3, 2020 Primary Completion: July 8, 2020 [Actual] Study Completion: July 8, 2020 [Actual] First Submitted: July 2, 2020 First Submitted that July 6, 2020 Met QC Criteria: First Posted: July 7, 2020 [Actual]

Last Update Submitted that October 28, 2021 Met QC Criteria:

Last Update Posted: November 5, 2021 [Actual]

Sponsor/Collaborators

Sponsor: Yale University

Responsible Party: Sponsor

Collaborators:

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

Data Monitoring: No

Study Description

Brief Summary: This study tests different messages about vaccinating against COVID-19 once the vaccine becomes available. Participants ar randomized to 1 of 12 arms, with one control arm and one baseline arm. We will compare the reported willingness to get a CC 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:

Conditions

Conditions: Vaccination COVID-19 Keywords: messaging

Study Design

Study TypeInterventionalPrimary PurposeOtherStudy PhaseNot ApplicableInterventional Study ModelParallel AssignmentIn this study, 2/15 of participants will be assigned to a control message (bird feeding passage), 3/15 of sample to a baseline v
message, and 1/15 to each of the 10 other treatment arms.Number of Arms:12Masking:None (Open Label)Allocation:RandomizedEnrollment:4000 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Sham Comparator: Control Control message about birdfeeding	Control message 2/15 of the sample will be assigned to the pure of which is a passage on the costs and benefits of
Active Comparator: Baseline message These participants will be assigned a message about the benefits of vaccination. All other treatment arms include this baseline language.	Baseline message 3/15 of the sample will be assigned to a control of message about the effectiveness and safety of v
Experimental: Personal freedom Experimental message arm.	Personal freedom message 1/15 of the sample will be assigned to this interv is a message about how COVID-19 is limiting pe personal freedom and by working together to ge people vaccinated society can preserve its perso
Experimental: Economic freedom Experimental message arm.	Economic freedom message 1/15 of the sample will be assigned to this interv is a message about how COVID-19 is limiting pe economic freedom and by working together to ge people vaccinated society can preserve its econ freedom.
Experimental: Social benefit, self-interest Experimental message arm.	Self-interest message 1/15 of the sample will be assigned to this interv is a message that COVID-19 presents a real dar health, even if one is young and healthy. Getting against COVID-19 is the best way to prevent one getting sick.
Experimental: Social benefit, community interest Experimental message arm.	Community interest message 1/15 of the sample will be assigned to this interv is a message about the dangers of COVID-19 to loved ones. The more people who get vaccinate COVID-19, the lower the risk that one's loved on sick. Society must work together and all get vacc
Experimental: Economic benefit Experimental message arm.	Economic benefit message 1/15 of the sample will be assigned to this group message about how COVID-19 is wreaking have economy and the only way to strengthen the eco work together to get enough people vaccinated.
Experimental: Social pressure- guilt Experimental message arm.	Guilt message 1/15 of the sample will be assigned to this mess message is about the danger that COVID-19 pre health of one's family and community. The best them is by getting vaccinated and society must to get enough people vaccinated. Then it asks th to imagine the guilt they will feel if they don't get and spread the disease.
Experimental: Social pressure- embarrassment Experimental message arm.	Embarrassment message 1/15 of the sample will be assigned to this mess message is about the danger that COVID-19 pre health of one's family and community. The best them is by getting vaccinated and by working to make sure that enough people get vaccinated. T the participant to imagine the embarrassment th they don't get vaccinated and spread the diseas
Experimental: Social pressure- anger Experimental message arm.	Anger message 1/15 of the sample will be assigned to this mess message is about the danger that COVID-19 pro- health of one's family and community. The best them is by getting vaccinated and by working to make sure that enough people get vaccinated. The the participant to imagine the anger they will fee get vaccinated and spread the disease.

Arms	Assigned Interventions
Experimental: Trust in science Experimental message arm.	Trust in science message 1/15 of the sample will be assigned to this messa how getting vaccinated against COVID-19 is the r effective way of protecting one's community. Vacc backed by science. If one doesn't get vaccinated that one doesn't understand how infections are sp ignores science.
Experimental: Not bravery arm Experimental message arm.	Not bravery message 1/15 of the sample will be assigned to this messa describes how firefighters, doctors, and front line workers are brave. Those who choose not to get against COVID-19 are not brave.

Outcome Measures

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 vaccinal months and then 6 months of it becoming available. During analysis, responses among those assigned to different interventi 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 as 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 to get vaccinated after a vaccine becomes available

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

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/Locations

Locations: United States, Connecticut

Yale University

New Haven, Connecticut, United States, 06510

Plan to	o Share IPD: Yes
	Anonymized data and analysis code will be posted in a public replication archive after publication.
	Supporting Information:
	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
	URL:
 References 	
	Citations: [Study Results] Erin K. James, Scott E. Bokemper, Alan S. Gerber, Saad B. Omer, Gregory A. Huber, Persuasive Messaging COVID-19 Vaccine Uptake Intentions, Vaccine, 2021, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2021.10.039.
	Links:
Available IPD	ll starrastica.

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