ISRCTN10280016 https://doi.org/10.1186/ISRCTN10280016

Beliefs about and confidence in new medical treatments: lessons from COVID-19 vaccines, the follow-up trial

Submission date 13/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 17/02/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/02/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Public health depends on both the technological developments of medical treatments and the public's willingness to take up the developed treatments. The public's willingness to take up new treatments depends on the public's beliefs about the costs and benefits of the treatments. By tracing updates on the public beliefs about COVID-19 vaccines before and after they began to be administered to the general public in Japan, this study investigates the relationships between the evolution of public beliefs about COVID-19 vaccines and the public willingness to take up the vaccines.

Who can participate?
A sample of 15,000 respondents in Japan recruited through a survey company, Rakuten Insight, Ltd.

What does the study involve?
The researchers ask whether respondents have taken COVID-19 vaccines, and, if so, whether they experienced side effects. They ask whether the respondents have taken a second, third, and fourth dose of COVID-19 vaccines and whether they want to take a further dose of COVID-19 vaccines. They ask the respondents to choose preferred hypothetical conditions for vaccination between two, which are fully randomly generated. Respondents are allowed to deny either condition and not to take up COVID-19 vaccines. They are also asked about their demographic and socio-economic backgrounds.

What are the possible benefits and risks of participating?
As a benefit, respondents will receive a certain amount of points to be used for shopping. Since the survey is done using the internet, respondents will face no substantial risk.

Where is the study run from?
University of Tokyo (Japan)

When is the study starting and how long is it expected to run for?
September 2022 to March 2023

Who is funding the study?
The Japan Society for the Promotion of Science (Japan)

Who is the main contact?
Prof. Masaki Nakabayashi, PhD, mn@iss.u-tokyo.ac.jp (Japan)

Contact information

Type(s)
Principal Investigator

Contact name
Prof Masaki Nakabayashi

ORCID ID
http://orcid.org/0000-0003-1096-1350

Contact details
Institute of Social Science
The University of Tokyo
Hongo 7-3-1
Bunkyo
Tokyo
Japan
1130033
+81(0)358414936
mn@iss.u-tokyo.ac.jp

Type(s)
Scientific

Contact name
Prof Keisuke Kawata

ORCID ID
http://orcid.org/0000-0002-2761-9255

Contact details
Institute of Social Science
The University of Tokyo
Hongo 7-3-1
Bunkyo
Japan
Tokyo 1130033
+81 (0)358414969
keisukekawata@iss.u-tokyo.ac.jp

Type(s)

Scientific

Contact name
Prof Taiyo Fukai

ORCID ID
http://orcid.org/0000-0002-5044-2099

Contact details
Faculty of Humanities and Social Sciences
University of Tsukuba
Tennodai 1-1-1
Tsukuba
Japan
Ibaraki 3058571
+81 (0)298534076
fukai@e.u-tokyo.ac.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Beliefs about and confidence in new medical treatments: lessons from COVID-19 vaccines, the the follow-up trial

Acronym
COVID-ARM-2

Study objectives
This study, following the study implemented in November 2022 (ISRCTN14065615 https://doi.org/10.1186/ISRCTN14065615), investigates whether belief updates about the costs and benefits of medical treatments affect confidence in medical treatments, taking an example from vaccinations against COVID-19. Testable hypotheses are:
1. Unexpected side effects, which are part of the costs, affect confidence in vaccination
2. Changes in the financial and time costs of vaccination affect willingness to take up vaccination

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/01/2023, Ethical Board, Institute of Social Science, The University of Tokyo (Ethical Review Board, Institute of Social Science, The University of Tokyo, Hongo 7-3-1, Bunkyo, Tokyo 1130033, Japan; +81 (0)358414908; kenkyu-kikaku@iss.u-tokyo.ac.jp), ref: 112

Study design
Observational internet survey and 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 trial outputs table

Health condition(s) or problem(s) studied
Beliefs about and confidence in new medical treatments

Interventions
This study, with the study implemented in November 2022 (ISRCTN14065615 https://doi.org/10.1186/ISRCTN14065615), is the final stage of a longitudinal interventional study that began in a first wave in February 2021, when vaccines for COVID-19 were not available to the general public in Japan, followed by the second wave in March 2022, when COVID-19 vaccines had become available to the general public.

The researchers asked whether respondents experienced delayed localized hypersensitivity reactions to COVID-19 vaccines, which are referred to as the “COVID arm” and were mostly unexpected to most of the public, conditional on vaccine takeup, as the vaccines were novel. They use the “COVID arm” symptoms as our first treatment that could have updated the beliefs about the costs of medical treatment.

1. In this wave, the researchers ask respondents whether they took a second, third, and fourth dose of the COVID-19 vaccine and investigate whether the probability of taking the further dose was associated with having experienced the “COVID arm” symptoms after taking up the first or second dose of a COVID-19 vaccine.

2. Additionally, a fully randomized conjoint experiment is designed to generate two hypothetical conditions of vaccination against COVID-19, where respondents are allowed to accept or decline vaccines and are asked under which conditions they might more likely take up COVID-19 vaccines.

The fully randomized conjoint design generates various conditions for taking up COVID-19 vaccines. Since attributes of the hypothetical conditions are fully randomized, the researchers can identify a change in attribute and a change in willingness to take up COVID-19 vaccines as a causal effect. Also, the researchers investigate whether the causal channel is affected by past experience of "COVID arm" symptoms.

The 15000 respondents are randomly assigned to three arms by the same probability, 1:3. In the first arm, respondents are shown a description of the efficacy of COVID-19 vaccines. In the second arm, respondents are shown the same description of the vaccine efficacy and an additional description of the positive externality of taking a vaccine to close people, i.e., if the respondent gets vaccinated, the probability that people close to the respondent get vaccinated would increase. In the third arm, respondents are shown the same description of the vaccine efficacy and an additional description of the negative externality of declining vaccination, i.e., if the respondent does not get vaccinated, the probability that people close to the respondent get vaccinated would decrease.

Intervention Type
Behavioural

Primary outcome measure
1. Self-reported subjective cost of/confidence in vaccination measured using a background characteristics survey when the participant responded to the survey between 27/02/2023 and 13/03/2023
2. Self-reported history of taking up COVID-19 vaccines measured using a background characteristics survey when the participant responded to the survey between 27/02/2023 and 13/03/2023
3. Impact of side effects on beliefs about vaccines, and through them, confidence in vaccination, and how long the change in confidence in vaccination sustains, measured using the results of this background characteristics survey and those implemented in 27/02/2023 and 13/03/2023
4. Marginal means (probability) of wanting to take the next dose of a COVID-19 vaccine, of being confident in vaccination, and of being confident in science, measured when the participant responded to the survey between 27/02/2023 and 13/03/2023

Secondary outcome measures
1. Hypothetical vaccination conditions under which the costs of taking up vaccines vary and respondents' preferred conditions measured using a fully randomized conjoint experimental design when the participant responded to the survey between 27/02/2023 and 13/03/2023
2. Experiences of "COVID-19 arm" symptoms measured using a background characteristics survey when the participant responded to the survey between 27/02/2023 and 13/03/2023

Overall study start date
28/09/2022

Completion date
13/03/2023

Eligibility

Key inclusion criteria
A non-probability sample of 15,000 respondents through a survey company, Rakuten Insight, Ltd, including participants of the past three survey waves

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
15000

Key exclusion criteria
Respondents who do not give informed consent at the top page of the internet survey

Date of first enrolment
27/02/2023

Date of final enrolment
13/03/2023

Locations

Countries of recruitment
Japan

Study participating centre
The University of Tokyo, Institute of Social Science
Hongo 7-3-1
Bunkyo
Japan
Tokyo 1130033

Sponsor information

Organisation
University of Tokyo

Sponsor details
Institute of Social Science
Hongo 7-3-1
Bunkyo
Tokyo
Japan

1130033
+81 (0)358414908
kenkyu-kikaku@iss.u-tokyo.ac.jp

Sponsor type
University/education

Website
https://www.iss.u-tokyo.ac.jp/

ROR
https://ror.org/057zh3y96

Funder(s)

Funder type
Research organisation

Funder Name
Japan Society for the Promotion of Science

Alternative Name(s)
KAKENHI, , Gakushin, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, JSPS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Japan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
13/03/2024

Individual participant data (IPD) sharing plan
The researchers plan to transfer the data to the Center for Social Research and Data Archives, Institute of Social Science, The University of Tokyo, from which the data will be publicly available to researchers. Until the transfer, data will be available upon request to Masaki Nakabayashi

(mn@iss.u-tokyo.ac.jp). When the data will become available and for how long: 15/11/2023, and will be available until the data is transferred to the Center for Social Research and Data Archives, Institute of Social Science, The University of Tokyo (https://csrda.iss.u-tokyo.ac.jp/english/). After being transferred to the center, data will be available to researchers from the center upon request. Center for Social Research and Data Archives, Institute of Social Science, The University of Tokyo: ssjda@iss.u-tokyo.ac.jp. The purpose of data usage should be for research. This is the only criteria and the researchers do not impose additional restrictions. They obtain consent from participants when they respond to our internet survey. On the top page, they describe the purpose of the survey and ask respondents whether they agree that researchers use the data for research purposes. Only if they agree with it, are they allowed to proceed to the survey questions. The data will be entirely anonymized by the survey company Rakuten Insight, Ltd. There are no additional ethical or legal restrictions.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/02/2023	No	Yes