ISRCTN26200758 https://doi.org/10.1186/ISRCTN26200758

Exploration of the Italian response to COVID-19 pandemic

Submission date
01/04/2021

Recruitment status
No longer recruiting

Registration date
11/05/2021

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol
Background and study aims
The COVID-19 pandemic outbreak is placing an overwhelming burden on health systems and authorities to respond with effective and appropriate interventions, policies and messages. The pandemic and its restrictions may have affected mental and physical well-being, social cohesion, economic stability as well as individual and community resilience and trust.
In this complex context, understanding how, why and the context in which humans and communities respond allows to 1) anticipate unwanted scenarios and initiate mitigating measures; and 2) implement pandemic response measures that are better informed, situated, accepted and thus more effective.
This study is part of the large project promoted by the World Health Organization (WHO) called "Monitoring knowledge, risk perceptions, preventive behaviours and trust to inform pandemic outbreak response" and conducted in over 30 countries of the WHO European Region.
This is an observational study with voluntary participation in the general population, with expected low risk for participants. In Italy, the survey is conducting administering a questionnaire online developed ad hoc by the WHO in four waves (from January to May 2021) to a national representative sample of aged 18-70, stratified for different dimensions.

Who can participate?
General population 18-70 years old

What does the study involve?
Participants complete an online questionnaire.

What are the possible benefits and risks of participating?
Potential risks identified include only the inconvenience of the time taken to respond to the survey, and given the current restrictions people face, many individuals currently have more available time. Benefits include the sense of contributing and being able to participate in shaping the country's pandemic response.

Where is the study run from?
IRCCS Istituto Centro San Giovanni di Dio, Fatebenefratelli (Italy)

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

Who is funding the study?
The italian project has been funded by Fondazione Cariplo and IRCCS Istituto Centro San Giovanni di Dio, Fatebenefratelli (Italy)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Monitoring knowledge, risk perceptions, preventive behaviours and trust to inform pandemic outbreak response - Italian study

Acronym

COVID-WHO-ITALY

Study objectives
The study aims to gain insights into risk perception, knowledge, trusted sources of information, attitudes toward pandemic response initiatives and other variables to inform COVID-19 outbreak response measures, including policies, interventions and communications.
The primary objectives are to:
- Monitor variables that are critical for population behaviour to control transmission of the novel coronavirus, including risk perceptions, knowledge, self-efficacy, confidence in institutions, behaviours, rumours, affect, worry, resilience, trust in/use of information sources and more
- Document changes over time in these factors to understand the effect of the pandemic process, new developments, events or measures taken
- Monitor possible issues, e.g. related to misinformation or distrust, as they emerge, to allow early response
- Identify relationships between variables to identify levers for effective and appropriate responses
- Explore the relationship of psychological variables (e.g. worry, resilience, trust, affect) with the epidemiological situation and the events and measures taken
- Identify gaps between perceived and actual knowledge
- Evaluate the effectiveness of pandemic response measures, and the acceptance and effectiveness of policies and restrictions implemented, including the easing of such restrictions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2020, Ethical Committee of IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli (25125 BRESCIA – Via Pilastroni, 4, Italy; +39 303501586; ceioc@fatebenefratelli.it), ref: 286/2020

Study design
Observational cross sectional study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Exploration of the Italian response to COVID-19 pandemic

Interventions
This study is part of a large project promoted by the World Health Organization (WHO) called “Monitoring knowledge, risk perceptions, preventive behaviours and trust to inform pandemic outbreak response” and conducted in over 30 countries of the WHO European Region.

In Italy, the survey is conducted through a questionnaire online developed ad hoc by WHO; the questionnaire is being administered in four waves (January-May 2021) to a national representative sample of people aged 18-70. A detailed sampling plan was adopted to obtain a representative sample of the Italian adult population.

The following variables were taken into account for the stratification of the participants: gender by age (4 age groups: 18-34 years, 35-44 years, 45-54 years, 55-70 years), geographical area (4 areas: North West, North East, Centre, South and Islands), size of living centers (2 classes: above and below 100,000 inhabitants), level of education (up to lower middle school, beyond lower middle school), and employment situation (employed, not employed). At the end of each survey' s wave, a weighting procedure is applied to accurately restore the proportionality of the total sample examined with the reference population, according to the most recent data of the Italian Statistics Institute (ISTAT). In particular, data are weighted for the main socio-demographic and geographic variables (e.g., sex, age, occupation, educational qualification, region and demographic size of the centers).

Intervention Type
Other

Primary outcome(s)
All measures have been collected in just one session (questionnaire administration), by means of a structured questionnaire developed ad hoc by WHO. Variables are measured using validated questions or adapted validated questions. The WHO questionnaire includes 21 different thematic areas noteworthy for the investigation of COVID-19 experience. The questionnaire was translated into Italian language, following the WHO's guidelines for translations of tools into other languages.
1. Socio-demography. Items developed ad hoc including age, gender, education, medical background, chronic illness, rural/urban, district, household, financial situation (risk group identified as: 70+ years and/or chronic illness)
2. COVID-19 personal experience. Items developed ad hoc including COVID-19 infection (own, someone close)
3. Health literacy. Items adapted from: Sørensen K, Van den Broucke S, Pelikan JM, et al. (2013) and Griebler, Robert; Nitsche, Michael (2020)
4. COVID-19 risk perception: Probability and Severity. Validated items adapted from Brewer, N. T., Chapman, G. B., Gibbons, F. X., Gerrard, M., McCaul, K. D., & Weinstein, N. D. (2007)
5. Preparedness and Perceived self-efficacy. Psychological construct: preparedness -validated items adapted from: Bandura, A. (2006). Psychological construct: perceived self-efficacy - validated items adapted from: Renner, B., & Schwarzer, R. (2005)
6. Prevention – own behaviours. Items adapted from: Steel Fisher GK et al (2012)
7. Affect related to COVID-19. Validated items adapted from: Bradley, M. M., & Lang, P. J. (1994)
8. Trust in sources of information: Schweitzer, M. E., Hershey, J. C., & Bradlow, E. T. (2006) and Pearson, S. D., & Raeke, L. H. (2000)
9. Use of sources of information. Items developed ad hoc including use of information sources (television, newspapers, health workers, social media, radio, Ministry of Health, Institute of Public Health, hotlines, official website, celebrities)
10. Frequency of Information. Items developed ad hoc including frequency in information for different sources (television, newspapers, health workers, social media, radio, Ministry of Health, Institute of Public Health, hotlines, official website, celebrities)
11. Trust in institutions (perceptions): Schweitzer, M. E., Hershey, J. C., & Bradlow, E. T. (2006) and Pearson, S. D., & Raeke, L. H. (2000)
12. Policies, interventions (perceptions). Items developed ad hoc including Perceptions related to possible/real government policies (COVID-19 vaccine, discrimination behaviours, testing, exaggeration in restrictions, quarantine)
13. Conspiracies (perceptions). Validated items taken from: Bruder M, Haffke P, Neave N, Nouripanah N, Imhoff R. (2013)
14. Resilience (perceptions). Validated items taken from: Smith, B. W., Dalen, J., Wiggins, K.,

Tooley, E., Christopher, P., & Bernard, J. (2008)
15. Testing and tracing. Items grounded in theory: Michie et al (2014)
16. Fairness (perceptions). Validated items taken from: Gamliel, E., & Peer, E. (2010)
17. Lifting restrictions (pandemic transition phase). Items developed ad hoc including perceptions related to lifting restrictions (adapted to country decisions made/considered
18. Unwanted behaviour. Items developed ad hoc including reported own behaviour (discrimination, physical exercise, alcohol, diet, smoking, vaccination postponed, drugs against COVID-19, postponed doctor visit)
19. Well-being. Validated items from: WHO 5-item well-being scale (WHO-5)
20. COVID-19 vaccine. Items grounded in theory: Michie et al (2014)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
21/05/2021

Eligibility

Key inclusion criteria
General population 18-70 years old

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
10013

Key exclusion criteria
Current isolation due to COVID-19 infection

Date of first enrolment
03/01/2021

Date of final enrolment

21/05/2021

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS Istituto Centro San Giovanni di Dio, Fatebenefratelli
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Study participating centre
AUSL Modena - Dipartimento Salute Mentale e Dipendenze Patologiche
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Study participating centre
Istituto Superiore di Sanità - Centro di Riferimento per le Scienze comportamentali e la Salute mentale
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Sponsor information

Organisation
Centro San Giovanni di Dio Fatebenefratelli

ROR
https://ror.org/02davtb12

Organisation
Azienda Unita' Sanitaria Locale Di Modena

ROR
https://ror.org/0018xw886

Organisation
Istituto Superiore di Sanità

ROR
https://ror.org/02hssy432

Funder(s)

Funder type
Charity

Funder Name
Fondazione Cariplo

Alternative Name(s)
Cariplo Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Italy

Funder Name
IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. (Zenodo, https://zenodo.org/); there will be a 2-year embargo, although it will always be possible to write to the coordinators to propose scientific collaborations based on this dataset. After the embargo, to obtain the dataset it will be necessary to write to the study coordinators. Raw data will be shared: all data are fully anonymised and it was obtained written permission from all study participants for the sharing of

completely anonymised data for scientific purposed. This is also stated in the permission obtained from the Ethical Committee.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/10/2022	14/06/2023	Yes	No
Results article		17/11/2022	14/06/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes