



Medical Sciences Division



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CICERO trial
(Communication of benefit-risk information: an online randomised controlled trial)

CUREC Approval Reference: [R86270/RE001]

Introduction

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Why is this research being conducted?

This research aims to understand how health-related information should be communicated to the general population.

We know that how evidence is communicated is important to determine what is understood: it might influence how people make decisions and how confident they feel in participating in clinical shared decision-making.

Different communication tools to present available evidence have been developed to engage people in clinical shared decision-making about their health. For instance, we know that avoiding medical and statistical jargon is important. However, how well they work is not known.

The CICERO trial will compare three different communication tools providing information on interventions for social anxiety disorder (social phobia) both in terms of how well interventions work (benefit) but also what are the possible harms associated (risk). The three communication tools ("Summary of Findings table", "Kilim plot" and "Vitruvian plot") differ in how they present information: exclusively written, mostly written and partially graphical, or mixed written and graphical.

We will ask you to familiarise yourself with the tool you will be allocated to (either a plot or a table) and then answer some validated questionnaires to measure how useful and efficient the communication strategy is.

Why have I been invited to take part?

Any members of the public from the general population aged 18 to 65 years old are eligible if they are willing to participate. We are looking to enrol at least 237 participants in total.

The Primary Researcher is Dr Edoardo G. Ostinelli, who is attached to the Department of Psychiatry at the University of Oxford. This research is being completed under the supervision of Professor Andrea Cipriani (Department of Psychiatry, University of Oxford).

If you participate, you will be asked to complete a list of questions on an online form in a single study visit. This should take about 15-20 minutes. No background knowledge is required.

Do I have to take part?

No. It is up to you to decide whether to take part. You can withdraw yourself from the research, without giving a reason, by closing the browser.

What will happen to me if I take part in the research?

The study is entirely online, completed in one session with an estimated duration of about 15-20 minutes. After this you will have completed the study.

1. Informed consent will be collected by visiting the following webpage:
<https://egostinelli.shinyapps.io/CICERO/>.
2. After this, you will need to click on a tick box to confirm that you have read the PIS, are willing to participate in this study, and are aged 18 to 65 years old.
3. You will be randomised to one of the three communication tools being investigated, and the system will automatically redirect you to the relevant online form.
4. The online form includes one communication tool (based on randomisation) and a set of questions (same for all the participants). The communication tool will show information on different medications for a common medical disorder.

You will be asked to assume you are experiencing the considered medical disorder and to express how confident you would be to use the communication tool to take a health-related decision.

What are the possible disadvantages and risks of taking part?

As this is an online study focusing on how information can be communicated, we do not foresee any discomforts, disadvantages, or risks. Your data will be presented in the research outputs as

aggregated with all the other participants, so you will not be identifiable.

Are there any benefits in taking part?

There are no immediate and direct benefits for those people participating. However, it is hoped that your participation will help us to understand what we can do to ensure people are adequately informed when making health-related decisions.

What information will be collected, and why is the collection of this information relevant to achieve the research objectives?

We will not collect any information that will directly identify you. Only the CICERO research team will have access to data collected, and they will access it exclusively for research-related purposes. Your IP address will not be stored. The data collected will be stored for three years after the publication or public release of the results.

We would like to use this data in future studies and to share this with other researchers (e.g. in online databases). This data will be limited to the answers to the questionnaires and some descriptive data (for instance, age and educational level).

Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will be written up in a thesis, conference presentations and academic publications. In any of these publications, it will not be possible for you to be identified from the outputs.

A copy of the thesis/dissertation will be deposited both in print and online in the [Oxford University Research Archive](#) where it will be publicly available to facilitate its use in future research.

Who will have access to my data?

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance website at <https://compliance.admin.ox.ac.uk/individual-rights>.

The data we collect from you may be transferred to, stored and/ or processed at a destination outside the UK and the European Economic Area. By submitting your data, you agree to this transfer, storing or processing.

Who has reviewed this research?

This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: R86270/RE001).

Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact Edoardo G. Ostinelli (edoardo.ostinelli@psych.ox.ac.uk) or Andrea Cipriani (andrea.cipriani@psych.ox.ac.uk), and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

The Chair, Medical Sciences Interdivisional Research Ethics Committee;
Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB.

Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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Please note that you may only participate in this online study if you are aged 18 to 65 years old.

If you have read the information above and agree to participate with the understanding that the data you submit will be processed accordingly, please continue to the following website:

<https://egostinelli.shinyapps.io/CICERO/>