RinasciMENTE: An Internet-Based Self-Help Intervention for People with Psychological Distress Due to COVID-19: Study Protocol for A Randomized Controlled Trial.

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INFORMATIVE CONSENT FOR PARTECIPATION IN THE RESEARCH

FOR ADULTS SUBJECTS

Title of the study:

RinasciMENTE: An Internet-Based Self-Help Intervention for People with Psychological Distress Due to COVID-19: Study Protocol for A Randomized Controlled Trial.

PARTICIPANTS INSTITUTIONS:

Università Cattolica del Sacro Cuore, Milano, Italia
Bar-Ilan University, Tel-Aviv, Israel

RESEARCH TEAM

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Dr Gerhard Andersson, Department of Behavioural Science and Learning, Linköping, Sweden; Department of Clinical Neuroscience, Karolinska Institute, Sweden; gerhard.andersson@liu.se

Dear Mr/Mrs.

We inform you that we are conducting a study entitled: An Online Self-Help Intervention to Reduce Psychological Discomfort Due to COVID-19: A Randomized Controlled Study
organized by the Catholic University of the Sacred Heart in collaboration with the University of Bar-Ilan, Tel-Aviv, Israel, and the Karolinska Institute, Solna, Sweden.

For this reason, we propose you to participate in the study which will be conducted under the responsibility of Dr. Giada PIETRABISSA.
Before you decide whether to accept or renounce, we invite you to read this document carefully, if you wish to have further information and clarifications, you can contact Dr. Giada PIETRABISSA (whose contact details are indicated at the bottom of this document) who will dedicate to you all the time necessary to clarify all your doubts, it is understood that you can also contact the operators involved in the execution of the study at any time.

Are you obliged to participate in the study?

Participation is completely voluntary. Furthermore, should you change your mind at any time and wish to withdraw from the evaluation procedure, you are free to do so.

Premises and purpose of the study

- Purpose: The main objective of the project is to evaluate the effectiveness of an online self-help program based on principles and techniques of cognitive-behavioral treatment in comparison with the control condition (waiting list) in reducing the psychological impact of the pandemic and preventing the onset of psychopathological states in the general population. By "waiting list" we mean that the subjects placed in this condition will receive the intervention immediately after the experimental group.
Candidates will undergo a quantitative and qualitative assessment of the state of mental health through self-administered questionnaires and individual clinical interview, on the basis of which their inclusion / exclusion from the study will be decided. Subjects will be included in the study if: 1) over 18 years of age; 2) Italian mother

tongue; 3) They do not have high levels of psychopathology; 4) They have access to the Internet and computer skills necessary to navigate the intervention website. Individuals with neurocognitive disorders or audiovisual difficulties such as to compromise the autonomous use of the program will not be included.
The decision on the exclusion or inclusion in the study will be communicated by sending an e-mail within three days from the end of the quantitative-qualitative assessment.

What will happen if she decides to participate in the study?
The procedure involves the random assignment of subjects into two groups (experimental group vs control group - waiting list) and the use via the Internet by the experimental group of 8 self-help modules based on principles and techniques of cognitive therapy. -behavioral for the duration of two months. Participants in the study will be tested in three stages, at the beginning and at the end of the intervention and 12 months after the end of the intervention.

What are the possible benefits of participating in the study?
The intervention is aimed at improving the psychological well-being of the participants in the study

What are the possible risks / side effects of participating in the study?
No risks or side effects

Other important information
We inform you that the study will be conducted in accordance with the "Standards of Good Clinical Practice" defined internationally and in compliance with the ethical principles established in the "Declaration of Helsinki" (1964) and subsequent revisions.

Participation in the study
Your participation is completely free and voluntary.

If you agree to participate, you will be asked to sign the Informed Consent Form for Study Participation and Data Processing, attached to this document, before you begin to perform the study procedure.

The signature of the attached form is to ensure that you have received complete information and that you have freely expressed your willingness to participate; this signature does not imply any commitment on your part to continue the study, it does not constitute a contractual obligation, nor does it represent a waiver of the rights you are entitled to.

In the event that you decide to withdraw from the study, after having initially accepted, you can terminate your participation at any time by notifying the Study Manager without having to provide a justification. The choice not to participate, or to withdraw after initial acceptance, has no negative consequences and does not entail any penalties in your relationship with the staff who assist you. If you become aware of new data or results that may influence your participation in the study, you will be promptly informed; furthermore, the Head of the study may withdraw you from the study if he deems this decision to be in your best interest.

From an economic point of view, participation in the study does not entail any kind of burden or additional expense for you.

Please note that you are not required to participate in this study to receive clinical assistance, or to obtain personal diagnostic benefit.

TREATMENT OF PERSONAL DATA

The Researcher will ask you for some personal data, such as sex, date of birth and any other data. This information is important for the successful execution of the study.

All personal data acquired in the execution of this study will be processed in full compliance with the legislation provided for by Regulation (EU) 2016/679 on the subject of "Protection of individuals with regard to the processing of personal data", which entered into force on May 25 2018, and by Legislative Decree. 06/30/2003 n. 196 - Code regarding personal data, although not repealed by the entry into force of the aforementioned European regulation.

Pursuant to this legislation, the Data Controller of your personal data will remain the Catholic University of the Sacred Heart of Milan.

Nature of the data and methods of treatment

All personal information concerning you, collected during this study, is confidential and will be treated in compliance with the aforementioned current legislation.

The data you provide will be made non-identifiable, ie the collected material will be anonymized and not linked to the identity of the participant in the Study. This material will be analyzed and processed for scientific research purposes only by the staff responsible for carrying out the Study.

The data, also processed by means of electronic means, may be disseminated in a strictly anonymous form through meetings, conferences and scientific publications; in any case, your name or any other detail suitable for identifying you will not be disclosed as the data may be presented exclusively in aggregate form or in a manner that does not make the subjects participating in the study identifiable.

Data processing does not include an automated decision-making process, including profiling.

Adequate security measures will be used in order to ensure the protection, security, integrity and accessibility of personal data.

Personal data will be kept only for the time necessary to achieve the purposes for which they were collected or for any other legitimate purpose connected to them and in any case for a minimum period of 5 years (pursuant to Article 17 of the Code of Ethics of Italian psychologists).

Personal data that are no longer necessary, or for which there is no longer a legal prerequisite for its conservation, will be irreversibly anonymised or securely destroyed.

Exercise of rights

The GDPR - EU Reg. 2016/679 provides for and strengthens the protection and processing of personal data in light of the principles of correctness, lawfulness, transparency, protection of confidentiality and the rights of the data subject regarding their data.
You can exercise the rights referred to in Art. 7 of Legislative Decree 193/2003 and Articles 15-18 and Articles 20-21 of the GDPR - EU Reg. 2016/679 (access your personal data, request its integration, updating, correction, cancellation, request its limitation, request portability, oppose the processing) by contacting the Data Controller directly or through the staff appointed by it.
In the event that you withdraw from the study, no further data concerning you will be collected, without prejudice to the use of any data already acquired to determine, without altering them, the results of the study.
For any complaints or reports on the methods of data processing, it is good practice to contact the Data Controller. However, it is possible to forward one's complaints or reports to the Authority responsible for data protection, using the relevant contact details: Guarantor for the protection of personal data - piazza di Montecitorio n.121 - 00186 ROME (fax: 06 696773785; tel: 06 696771; email: garante@gpdp.it; PEC: protocol@pec.gpdp.it).

The Study Protocol in which you are proposed to participate has been approved - together with this document - by the Ethics Commission of the Department of Psychology (CERPS) of the Catholic University of the Sacred Heart.

For further information, clarifications and communications, you can contact the head of the study, Dr. Giada PIETRABISSA, at the email address giada.pietrabissa@unicatt.it

We thank you for your availability and your cooperation

INFORMED CONSENT FORM FOR PARTICIPATION IN THE STUDY AND FOR DATA PROCESSING

Title of the study:

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I, the undersigned:_____
Surname and name of the participant

born in the: _____
Place and date of birth of the participant

resident in _____, in street _____

☐ on their own

DECLARES:

1. pursuant to Legislative Decree n.196 / 2003 and the GDPR - EU Reg. 2016/679, having received specific information on the processing of personal data and in relation to what is indicated regarding the processing of such information, I express my free consent, by ticking the box indicated below, to the collection, processing and communication of personal data for all the purposes and in the manner indicated in this statement.

☐ I PROVIDE CONSENT ☐ I DON'T PROVIDE CONSENT

2. pursuant to Legislative Decree n.196 / 2003 and the GDPR - EU Reg. 2016/679, having received specific information on the processing of sensitive data relating to the state of health and in relation to what is indicated regarding the processing of such information , I express my free consent, by ticking the box indicated below, to the collection, processing and communication of sensitive data relating to the state of health for all the purposes and in the manner indicated in this information.

☐ I PROVIDE CONSENT ☐ I DON'T PROVIDE CONSENT

3. With respect to any audiovisual recordings, made in the context of the realization of the project, I express my free consent, by ticking the box indicated below, for use and publication in any form, including competitions, internet, educational and / or scientific publications , etc. .. I declare that these recordings will be registered free of charge and I forbid their use in contexts that could damage one's dignity and decorum.

☐ I AUTHORIZE ☐ I DON'T AUTHORIZE

I ALSO DECLARE THE FOLLOWING:

1. I have read and understood the information sheet of which this module is an integral part;
2. I had the opportunity to ask questions and ask for explanations to Dr. _____ from whom I received satisfactory answers;
3. I was told the nature, purpose and duration of the study, the procedures that will be followed, the treatment envisaged for the participants and the type of collaboration that will be required of them;
4. I understand that participation in the study is free and voluntary and that at any time I can decide to ithdraw my Representative from the study without being exposed in any way to negative consequences and without compromising my rights and my relationship with the staff involved;

Having said all this, by signing I accept the proposal to participate in the study described in this document.

Place and date: _____ Signature: _____