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

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ABSTRACT

Background This study aims to evaluate the feasibility and effectiveness of the RinasciMENTE program, an Internet-based self-help intervention based on Cognitive Behavioral Therapy (CBT) principles and techniques in supporting individuals experiencing psychological impairments during the COVID-19 pandemic. A randomized controlled trial (RCT) design with random allocation at the level of individual will be conducted to compare the impact of the RinasciMENTE program with a waiting list control in improving the psychological functioning of the general population during the COVID-19 pandemic.

Methods A minimum sample of 128 participants experiencing mild/subthreshold levels of psychological symptoms during the COVID-19 pandemic will be recruited. After the initial screening, participants will be randomly assigned to either the experimental group or the control condition. The program will last 2 months, during which participants will receive 8 weekly CBT treatment modules. The impact of the RinasciMENTE program on selected primary and secondary psychological outcomes will be tested at the end of the intervention (2 months), 6- and 12-month follow-up.

Discussion We expect people to show an increased level of psychological functioning, and to acquire the skills and self-confidence necessary to deal with the psychological consequences of the COVID-19 outbreak and its related social isolation during and following the pandemic.

Trial registration ClinicalTrials.gov NCT0497903 Registered on 28 May 2021.

Keywords: COVID-19, Internet-based intervention, Self-help, Cognitive-behavioral therapy, Psychological distress, Randomized controlled trial, Clinical psychology.

BACKGROUND

In the hope of reducing the transmission of Coronavirus Disease 2019 (COVID-19) governments around the world have implemented unprecedentedly strict preventive measures, such as home confinement, mobility restrictions, and social distancing (1, 2). However, the COVID-19 pandemic and the resulting economic recession (3) have negatively affected the mental health of many people (4). The most common mental disorders emerging were anxiety and depression, obsessive-compulsive symptoms, insomnia, and post-traumatic stress disorder symptoms (5-9). These were not only a direct consequence of the pandemic but also largely driven by the effects of prolonged social isolation. Although necessary to limit the spread of the epidemic, social isolation resulted in increased sedentary lifestyle (2) and other COVID-19-related stressors including fears of infection, frustration and boredom, and lack of in-person contacts (10, 11). Italy was one of the most affected countries during the outbreak, initially accounting for over 223.000 infected individuals and more than 31.000 deaths (12). In May 2021, 4.111.110 people resulted having contracted the virus, and 122.833 of them died as a consequence (13, 14).

In this scenario, it is crucial to assess the level of psychological distress and to provide ad hoc psychological interventions to support the individuals' wellbeing in both the general population (15, 16) and at-risk groups (17, 18) during the COVID-19 pandemic.

Accordingly, evidence from previous epidemics highlights the risk for long-term mental health issues (19) and emphasizes the need for continued support during and after the pandemic (20).

Many health organizations have already committed resources to support the mental well-being of the individuals, adapting existing standard programs to meet evolving demands caused by COVID-19 (21). In this regard, cognitive-behavioral techniques including restructuring of cognitive bias, as well as activity planning and relaxation, have been shown particularly useful in addressing psychological distress (22-25).

Cognitive-behavioral therapy (CBT) is a time-sensitive, structured, present-oriented psychotherapy aimed at helping people identify and change thinking and behavior patterns that are harmful or ineffective, replacing them with more accurate thoughts and functional behaviors.

Still, given that face-to-face treatment is not always viable in these circumstances (26) a new way to deliver psychological treatments is urgently required, and a potentially practical solution is to deliver therapy remotely (14, 27-30).

Many systematic reviews and randomized controlled trials (RCTs) demonstrated the utility and the efficacy of Internet-based interventions in supporting people experiencing psychological problems (31-33).

Advantages include improved access for individuals (26) who have variable schedules, an important workload, or who are afraid of being contaminated through face-to-face contacts (34-36), as well as cost-effectiveness compared to face-to-face treatment.

Due to its features, CBT well-suits many aspects of distance therapy. First, it is a talking therapy, and this aspect can be relatively easily retained remotely. It also emphasizes the importance of the person making changes and working on specific tasks between sessions to bring about the change (37); this is perfectly consistent with working remotely. Moreover, with distance therapy, the patient may be less likely to attribute the progress to the therapist and more likely to have an improved sense of self-efficacy (38). One of the goals of CBT is to "become your therapist" by learning skills people can use on their own after treatment to keep feeling well.

Research shows that CBT delivered digitally (iCBT) is effective in reducing symptoms of social anxiety disorder (39, 40), generalized anxiety disorder (41, 42), panic disorder (43), major depressive disorder (44-46), obsessive-compulsive disorder (47) and insomnia (48) in both guided and unguided self-help programs. Specifically, a review of 30 studies found that CBT-based self-help interventions significantly reduced both anxiety and depression. Studies also show that people tend to maintain their progress over time, which is very encouraging (49). Furthermore, since patients can return to

the program at their convenience to access treatment information, this may facilitate learning and retention.

Despite a growing interest in the field of web-based psychological interventions, Internet-based CBT self-help programs remain underdeveloped.

To fill this important gap in the literature and to properly meet the need of the population, it is crucial to promote and investigate the impact of this Internet-based psychological intervention in increasing individuals' emotional well-being.

For this reason, the present RCT aims to explore the effectiveness of a novel Internet-based CBT self-help program specifically developed to address the immediate stress and prevent long-term psychological consequences of the COVID-19 pandemic among Italians both living in the county and abroad. To assess its impact, the effects of the RinasciMENTE program will be compared with a waiting list (WL) condition on selected self-reported measures immediately following the 8-week intervention and at 6- and 12-month follow-up.

The primary hypothesis that will be tested is that the program will be feasible and effective in increasing the psychological functioning of the person.

The secondary hypothesis will test whether participants assigned to the experimental condition will show a reduced level of stress, anxiety, depression, and fear of COVID-19, as well as improved emotion regulation strategies, self-efficacy, and psychological well-being than those in the WL condition at treatment termination.

Moreover, participants in the experimental condition will be expected to present maintained outcomes or further decreased psychological symptoms at 6 and 12-month after the end of the treatment program.

METHODS

Design

The project consists of a prospective, randomized, open, and parallel group-controlled study with two arms: an experimental arm with 8 online weekly CBT self-help sessions, and a waiting list (WL) control arm.

Ethical Statement

The study was approved by the Ethical Committee of the Catholic University of Milan, Italy (ID: 25-21). All procedures performed in the study will be run following the ethical standards of the institutional and/or national research committee and with the Helsinki Declaration and its later amendments or comparable ethical standards.

Patients and public involvement

Participants from the general population will be recruited through advertisements placed on social media platforms (i.e., Facebook, Instagram, Twitter), and online webinars on the topic.

The recruitment materials will include details about the study aim, the treatment delivered, and the conditions for participation, together with the weblink to access the program.

Inclusion criteria for the participants into the study will be: (A) being fluent in the Italian language; (B) being over 18 years old; (C) providing online informed consent; and (D) showing mild/subthreshold levels of symptoms at the 12-Item General Health Questionnaire (GHQ-12) - Italian version (50, 51) - the most extensively used screening tool assessing the severity of common mental disorders over the past few weeks using a 4-point Likert-type scale (from 0 to 3). Its total score ranges from 0 to 36, with high scores indicating worse health status. Only participants who score $\geq$ 15 on the GHQ and show moderate levels of symptoms at the clinical interview will be included in the study.

Participants will be excluded from the program if: (A) presenting visual, hearing, or cognitive impairments that will prevent them from receiving and following the intervention; (B) suffering from severe psychiatric disorders according to the Diagnostic and Statistical Manual of Mental Disorders (DSM 5) (52); (C) lacking basic computer skills or internet access.

Respondents will not be excluded if already receiving psychopharmacological therapy or psychological-psychotherapeutic support.

Sample size calculation

The minimum sample size required to conduct this study was calculated using an a priori sample size calculator (G*Power 3.1.9.2 software) for *F* tests (53-55). Participants were randomly divided into two groups: (A) iCBT self-help and (B) waiting list control. Moreover, participants will be measured in 3 moments: (1) before the intervention, (2) at the end of intervention (two months later), and (3) after 12 months from treatment termination. Due to the novelty of the study from which to derive realistic estimates of effect sizes, the partial η2 was set a priori to assume a value of 0.02 – small effect size (56, 57) – which provides a Cohen's *f* value of 0.143. Moreover, the type I error (α) rate was set at 0.05 (two-sided) and the Power (1 – β) was set at 0.95, and the a priori correlation between repeated measures was set at 0.50, according to general guidelines (56). Lastly, the non-sphericity correction was set to 1. Results showed that there is a 95% chance of correctly rejecting the null hypothesis of no significant effect of the interaction with 128 participants in total (64 for each group).

Randomization and blinding

The random randomization scheme will be generated using the Web site Randomization.com (58). Allocation concealment will be ensured by the program generating an anonymous code for each participant that will be associated with the randomization sequence. Due to the nature of the intervention, the treatment group allocation cannot be concealed from the participants, nor the research team and assessor of outcomes. Participants will be assigned to one of two conditions within 2 working days from their baseline assessment (Figure 1).

*** PLEASE INSERT Figure 1: Flow chart of the RinasciMENTE study

Measures

175 *Demographic and clinical information.* Information about age, gender, education, civil status, weight, and
176 high - used to calculate the Body Mass Index (BMI, kg/m^2) in presence of dysfunctional eating behaviors
177 - will be self-reported online at baseline. Subjects will be also asked to provide information about the
178 country where they are currently living, their work situation (before and after the COVID-19 pandemic),
179 and the personal experience they made of both COVID-19 pandemic and related preventive measures.
180 The Italian version of the following psychological measures will be also collected at baseline (T0),
181 treatment termination after 2 months (T1), at 6-month (T2), and 12-month (T3) follow-up in the
182 experimental condition only). Please see Figure 2 for a detailed project timeline.

183 *** INSERT GANTT Figure 2: Gantt of the RinasciMENTE study

184 *Primary outcome*:
185 *Outcome Questionnaire (OQ-45)* (59) composed by 45 items rated on a 5-point Likert scale (0 = Never –
186 4 = Almost always) assessing the treatment progresses across 3 different domains: Symptom Distress (SD
187 – 25 items: 2, 3, 5, 6, 8, 9, 10, 11, 13, 15, 22, 23, 24, 25, 27, 29, 31, 33, 34, 35, 36, 40, 41, 42 and 45),
188 Interpersonal Relations (IR – 11 items: 1, 7, 16, 17, 18, 19, 20, 26, 30, 37 and 43), and Social Role (SR –
189 9 items: 4, 12, 14, 21, 28, 32, 38, 39 and 44). The OQ-45 total score is calculated by summing the score of
190 the three subscales. Total score (range 0 to 180) is calculated by the sum of the items.

191 *Secondary outcomes:*
192 *Perceived stress scale* (PSS) (60), composed of 10 items rated on a 5-point Likert scale (from 0 = never to
193 4 = very often) assessing the degree to which situations in one's life are appraised as stressful. PSS scores
194 are obtained by reversing responses (i.e., 0 = 4, 1 = 3, 2 = 2, 3 = 1 and 4 = 0) to the four positively stated
195 items (items 4, 5, 7, and 8) and then summing across all scale items. The total score (range 0 to 40) is
196 calculated by the sum of the items.

197 *Emotional regulation questionnaire (*ERQ) (61), composed of 10 items rated on a 7-point Likert scale
198 (from 1 = strongly disagree to 7 = strongly agree) assessing respondents' tendency to regulate their

199 emotions in two ways: Cognitive Reappraisal (items 1, 3, 5, 7, 8, and 10) and Expressive Suppression
200 (items 2, 4, 6, and 9). The total score (range 7 to 70) is calculated by the sum of the items.

201 *Depression Anxiety Stress Scales-Short Version* (DASS-21) (62), composed by 21 statements rated on a
202 4-point Likert scale (from 0 = did not apply to me at all to 3 = applied to me very much) assessing the
203 negative emotional states of depression, anxiety, and stress. Each of the three DASS-21 scales contains 7
204 items: *Depression*: dysphoria, hopelessness, devaluation of life, self-deprecation, lack of
205 interest/involvement, anhedonia, and inertia - (Items 3, 5, 10, 13, 16, 17, and 21); *Anxiety*: autonomic
206 arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect -
207 (Items 2, 4, 7, 9, 15, 19, and 20); *Stress*: levels of chronic nonspecific arousal, difficulty relaxing,
208 nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient - (Items 1, 6, 8,
209 11, 12, 14, and 18). Sum scores are computed by adding up the scores on the items per (sub)scale and
210 multiplying them by 2. Sum scores for the total DASS-total scale thus range between 0 and 126, and
211 those for each of the subscales may range between 0 and 42. Ranges of scores correspond to levels
212 of symptoms, ranging from "normal" to "extremely serious". Notably, the DASS-21 has been recently
213 used to investigate the impact of the COVID-19 pandemic on the physical and mental health of
214 different populations worldwide (63-65).

215 *Fear of COVID-19 Scale* (FCV-19S) (66) composed by 7-item rated on a 5-point scale, ranging from 1
216 (from 1 = strongly disagree to 5 = strongly agree) reflecting cognitive, emotional, behavioral, and
217 physiological manifestations of fear related to COVID-19. The total score (range 7 to 35) is calculated by
218 the sum of the items. All items are positively worded, implying that higher scores indicate greater levels of
219 fear.

220 *General Self-efficacy Scale* (GSES) (67), composed of 10 items rated on a 4-point Likert scale (from
221 1 = Not at all true to 4 = exactly true) assessing the individuals' confidence in their ability to cope
222 with a variety of difficult or stressing situations. The total score is calculated by finding the sum of

all items. For the GSE, the total score ranges between 10 and 40, with a higher score indicating more self-efficacy.

World Health Organization Quality of Life (WHOQOL)-BREF (68), composed of 26 items rated on a 5-point Likert scale assessing four domains: physical health (7 items on mobility, daily activities, functional capacity, energy, pain, and sleep), psychological health (6 items on self-image, negative thoughts, positive attitudes, self-esteem, mentality, learning ability, memory concentration, religion, and the mental status), social relationships (3 items on personal relationships, social support, and sex life), and environmental health (8 items related to financial resources, safety, health, and social services); it also contains QOL and general health items. The scores (range 25 to 130) are transformed linearly to a 0–100-scale.

Moreover, *adherence* will be measured through indicators such as the percentage of visited pages or the number of accesses.

A*cceptability* will be assessed by registering the participants' attrition rates and – for the experimental group only - by the use of the *System Usability Scale* (SUS)(69) composed of 10 statements scored on a 5-point Likert scale (from 1 = strongly disagree to 5 = strongly agree). The final score range from 0 to 100, with a score above 68 indicating the absence of usability problems.

Procedure

Those interested in taking part in the program will be directed to the RinasciMENTE website (https://www.iterapi.se/sites/rinascimente/login) where they will find the written (online) consent, and after the acceptance of this, to each participant will be sent a document with information on the aims and requirements of the study.

They will be first asked to complete the GHQ-12 self-report questionnaires. Then, during the following 5 days, they will choose a time slot to be contacted for a clinical semi-structured interview

248 lasting about 45 minutes, led by a certified clinical psychotherapist not involved in the study who will
249 further assess the individual's eligibility to take part in the study. Additional information about the
250 study and the randomization procedure will be also given to all respondents.
251 Next, the inclusion of each participant in the study and modules comprising the program will be
252 discussed in a group by the professional who will conduct the interview and the research investigators
253 (GP and VB), and the decision will be e-mailed to each participant within a week. Reasons for
254 exclusion will be explained to the persons and – in presence of severe psychological disturbance -
255 individuals will be suggested to ask for professional help.
256 Eligible subjects will be then randomly assigned to either the experimental (iCBT self-help) or control
257 group (WL), and will receive an e-mail with a username and a customized link to create their
258 password allowing them to log into the *iterapi* platform (70, 71). The *iterapi* is a safe platform with
259 demonstrated efficacy in reducing symptoms of a wide range of disorders including somatic problems
260 - such as hearing loss (72) and tinnitus (73) - to more traditional forms of psychological suffering,
261 such as anxiety (74) and depression (75).
262 Participants in the experimental group will be required to make their first access to the platform and
263 sign an electronic informed consent form within 24 hours, while those in the control condition will
264 be able to access the online treatment once the experimental group will conclude the intervention
265 (after two months).
266 The platform will be used for communication between the mental health professionals and the
267 participants, for the delivery of the intervention, and the quantitative assessments.
268 Before entering the program, participants in the study will have to complete the self-report
269 questionnaires assessing the above selected primary and secondary outcomes (T0).
270 The treatment will consist of 8 weekly modules, for a total duration of 2 months. Seven modules
271 (*Introduction*, *Behavioral activation, Dysfunctional beliefs, Acceptance, Stress management,*
272 *Problem resolution* and *Plan of completion and maintenance*) will be maintained for all participants,
273 while one module will be selected tailored on the specific psychological needs of each participant.

between the following: (1) *Emotional school*; (2) *Anxiety and exposition*; (3) *Constant anxiety*; (4) *Social anxiety*; (5) *Panic attack*; (6) *Sleep quality*; (7) *Perfectionism*; (8) *Relaxation*; (9) *Management of difficult memories*. The description of each module is reported in Table 1.

*** INSERT Table 1: Description of the RinasciMENTE modules

For the entire duration of the intervention, every Thursday participants will receive an e-mail communicating the update of the new material on the platform. Participants who will not access the material or that will not complete the suggested tasks and exercises will receive a weekly reminder containing a brief encouraging message every Monday.

At the end of the program (after two months – T1), participants in both conditions will be asked to fill in the baseline questionnaires again. Then, the experimental group will be also assessed after 6- and 12 months from the term of the treatment (T2 and T3) (Figure 1).

Statistical analysis

Statistical analyses were performed using SPSS software ver. 24.0 (76).

First, preliminary analyses will be performed to test the assumptions of both univariate and multivariate normality: if (strong) violations will be detected, robust methods or data transformation will be applied. Dropouts will be excluded from the study.

A missing values analysis will be run to see if the values are Missing Completely at Random (MCAR), or if there is some pattern among missing data. If there are no patterns detected, then pairwise or listwise deletion will be done to deal with missing data. However, if the missing values analysis detects a pattern, then imputation will be done.

The demographic characteristics will be reported as means and standard deviations for continuous variables, and frequencies and percentages for categorical variables.

The chi-square statistic will be used to test the association between treatment groups and socio-demographic and variables (i.e., age, gender, education, civil status, job), and correlation analysis will be used to test the association between quantitative variables.

The outcomes will be compared in the two treatment conditions using an Intention-To-Treat (ITT) approach. The significance level will be set at 5%.

A repeated-measures ANOVA will be used to determine whether there are any between and within groups differences in the selected outcomes from baseline to treatment termination. , Then repeated-measures within group ANOVA will test outcome differences over time baseline, end of treatment, 6- and 12-month follow-up) in the experimental group only (. Corrected effect sizes (Cohen's *d*) and significance at 95% confidence interval (95% CI) will be calculated for both between-group and within-group differences, while for the total effect will be calculated the Cohen's *f*.

DISCUSSION

To help and mitigate the impact of the COVID-19 pandemic on selected psychological parameters, the objective of this study is to evaluate the effectiveness of an Internet-based self-help intervention based on CBT principles and techniques, in reducing the level of stress, anxiety, depression, and fear of COVID-19, while increasing emotions self-regulation and perceived self-efficacy of Italians both living in the country and abroad. .

The online modality was chosen due to the current multiple barriers for face-to-face psychological interventions (i.e., mobility), and its largely acknowledged advantages, including greater flexibility or the possibility to reach rural or low-income population (77), and Italians living outside the country who look for psychological support in their language. Also, the self-help approach to therapy will be employed to further improve access to treatments and empower users to strengthen their self-management ability, while putting less strain on therapeutic resources (78) than conventional treatments do.

Expected results

The results of this RCT will provide evidence for the feasibility and effectiveness of the RinasciMENTE program in supporting the emotional well-being of the persons. Specifically, people are expected to show reduced levels of stress, anxiety, depression, and fear of COVID-19, as well as improved emotion regulation strategies, and self-efficacy. They are also expected to acquire the skills necessary to deal with the psychological consequences of social isolation during and after the COVID-19 outbreak.

Still, among the weaknesses of this study, it must be anticipated possible lack of internet access and digital literacy skills of some people.

Non-digital natives (i.e., older people) might, indeed, experience difficulties in the use of digital tools, and social isolation can pose additional challenges to their usage (i.e., chaotic home environments, limited privacy, or unreliable internet connection) (79).

The use of online intervention might also prevent effective controlling of confounding variables (i.e. environmental factors) that might impact treatment outcomes (80).

The results from this study will help to detect and address any usability problem, as Internet-based interventions, due to their characteristics and format, might be a suitable and feasible solution to mitigate the psychological impact of the virus outbreak and its related containment measures on the mental health status of the general population across the lifespan. Moreover, the findings will contribute to the further adaption of the self-help CBT programs.

In line with previous research findings, it is possible to predict that dropout rates may be higher with web-based interventions than in traditional face-to-face therapy (80), especially when self-help programs are used. To overcome this problem, participants in the study will receive a weekly reminder and motivational messages to access the online material. A positive relationship between each respondent and their referral therapist will be also supported, and while on the one hand, the professional remains available in case of need, the subject takes responsibility over the course of the

treatment. The learning process is emphasized, so to help the person improve self-management skills and strategies to deal with their emotional problems.

Furthermore, the online format brings with it the advantage of allowing us to also support the population of Italians abroad, of which the literature does not report any in-depth analysis. RinascMENTE, therefore, represents the first attempt to provide online psychological support to the segment of the Italian population abroad.

CONCLUSION

Since the beginning of the COVID-19 pandemic, studies demonstrated a significant clinical and statistically decrease in mental health across populations worldwide. This burden is expected to continue in the aftermath making high demand for timely and pragmatic psychological interventions tailored to the unique and immediate needs of the general public. Preventive measures, fear of being infected, and financial losses give a reason for the implementation and use of digital self-help programs based on CBT principles and techniques – which might offer a range of self-management strategies to cope with emotional difficulties, besides reducing the cost of the health care system (81).

DECLARATION

Ethics approval and consent to participate

The study protocol and informed consent to participate were approved by the Research Ethics Committee of the Catholic University of Milan, Italy (25-21). All participants will sign in the online informed consent to participate before entering the study.

Consent for publication

Participants will give their consent for the anonymous publication of their data by signing the online informed consent form and information sheets

Availability of data and materials

All data will be identified only by a code, with personal details kept in a secure online platform with access only by the immediate research team.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Conceptualization, V.B, M.S., and G.P.; methodology, G.P., and G.A.; writing—original draft preparation, V.B., and M.S.; writing—review and editing, G.P., G.A., GMM, and G.C.; visualization and supervision, G.P. and G.A.; project administration, G.P., and E.M. All authors have read and agreed to the published version of the manuscript.

Authors' contributions

Not applicable

Trial status

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