The RinasciMENTE 2.0 Project: A Study Protocol for a Randomized Controlled Trial Evaluating the Efficacy of an Internet-Based Self-Help Program for Managing Psychological Distress Within the Broader Italian Population

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Abstract. *Objective:* The aim of this study is to assess the feasibility and effectiveness of the RinasciMENTE 2.0 initiative, an internet-based self-help intervention grounded in the principles and techniques of Cognitive Behavioral Therapy (CBT), in assisting individuals from the general population who are dealing with mild psychological difficulties.

Methods: To accomplish this objective, a randomized controlled trial (RCT) will be carried out, with random allocation occurring at the individual level. The study intends to compare the impact of the RinasciMENTE 2.0 program with that of a waiting list control group in terms of enhancing the psychological well-being of a representative sample from the community. A minimum of 128 participants experiencing mild or subthreshold levels of psychological symptoms will be recruited. Following baseline screening, participants will be randomly assigned to the experimental group or the control condition. The program will extend over a period of two months, during which participants will engage in eight weekly modules of CBT. The effects of the RinasciMENTE 2.0 program on specific primary and secondary psychological outcomes will be evaluated post-intervention (at 2 months) and during a follow-up assessment at 12 months. *Expected Results and Conclusions*: Anticipated outcomes include an improvement in individuals' psychological functioning and the acquisition of skills and self-assurance necessary to effectively address their emotional difficulties.

Keywords: Web-based intervention · Cognitive-behavioral therapy · Self-help · Randomized controlled trial · Clinical psychology

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1 Background

Recent research has highlighted a concerning decline in global mental health, as evidenced by clinical assessments and statistical data [1, 2]. This alarming trend is expected to continue, underscoring the urgent need for practical psychological interventions that can meet the specific needs of the population [3–6].

In this context, cognitive-behavioral techniques, such as cognitive bias restructuring, planning activities, and relaxation strategies, have demonstrated significant effectiveness in managing emotional problems [7, 8]. CBT is a structured form of psychotherapy designed to help individuals identify and change harmful or ineffective thought and behavior patterns, replacing them with more helpful thoughts and functional behaviors [9].

However, because traditional face-to-face therapy is not always feasible [10–14], there is a growing need for innovative methods to deliver psychological treatments, and remote therapy has emerged as a potentially viable solution.

Numerous randomized controlled trials (RCTs) and systematic reviews have shown the usefulness and effectiveness of internet-based interventions in helping individuals facing psychological issues [15–18]. CBT is particularly well-suited to remote therapy for several reasons. It is a talk-based therapy, making it relatively easy to adapt for remote delivery, and it encourages individuals to take an active role in engaging in modifications and focusing on particular assignments between sessions, which aligns seamlessly with remote therapy [19]. Furthermore, remote therapy can enhance the sense of self-efficacy [20], empowering individuals to become their therapists by equipping them with skills they can use independently to maintain their well-being after treatment.

Studies have indicated that the use of digitally administered Cognitive-Behavioral Therapy (iCBT) has proven effective in alleviating symptoms associated with a range of mental health conditions, including social anxiety disorder, generalized anxiety disorder, panic disorder, major depressive disorder, obsessive-compulsive disorder, and insomnia [21–26], whether in guided or unguided self-help programs.

Despite the increasing attention given to digital interventions, internet-based self-help programs rooted in CBT have not yet reached their full potential. To close this notable research gap, it is essential to conduct comprehensive investigations into the effects of internet-based interventions on improving personal emotional health.

2 Main Hypotheses and Objectives

This RCT aims to investigate the effectiveness of an innovative internet-based Cognitive Behavioral Therapy (CBT) self-help program designed to address mild psychological distress in both Italian residents and Italians living abroad. To evaluate its impact, we will compare the outcomes of participants in the RinasciMENTE 2.0 program with those on a waiting list (WL) using self-reported measures immediately after the 8-week intervention and at a 12-month follow-up.

The primary hypothesis we will examine is whether the program is both feasible and effective in enhancing individuals' psychological well-being.

The secondary hypothesis will assess whether individuals assigned to the experimental group experienced a reduction in levels of stress, anxiety, and depression, along

with improvements in emotion regulation skills, self-efficacy, and perceived quality of life compared to those in the WL condition at the end of the treatment.

Furthermore, we anticipate that participants in the experimental group will maintain or further decrease their psychological symptoms at the 12-month follow-up after completing the treatment program.

3 Methods

3.1 Design

This project entails a randomized, open-label, and parallel-group comparative study comprising two groups: an experimental group, which will receive 8 weekly online CBT self-help sessions, and a control group placed on a waiting list (WL).

The research received approval from the Ethical Committee at the Catholic University of Milan, Italy, under the identification number 25–21. All actions conducted as part of the study will adhere to the ethical guidelines set forth by the institutional and/or national research committee, following the principles outlined in the Helsinki Declaration and its subsequent revisions or equivalent ethical norms.

3.2 Participants

Participants will be sourced from the general populace using advertisements posted on various social media platforms such as Facebook, Instagram, and Twitter, as well as through online webinars centered around the study's subject matter. The recruitment materials will contain information regarding the study's objectives, the treatment provided, and the prerequisites for participation, along with a web link to access the program.

To be eligible for participation in the study, individuals must meet the following criteria: (A) possess fluency in the Italian language, regardless of their country of origin; (B) be at least 18 years old; (C) provide informed consent online; and (D) exhibit mild or subthreshold levels of symptoms on the Web Screening Questionnaire (WSQ) [27]. This 15-item online questionnaire was designed by Cuijpers et al. [28] to quickly (about 5 min) identify the following psychiatric conditions: depressive disorder, alcohol abuse/dependence, generalized anxiety disorder (GAD), post-traumatic stress disorder (PTSD), social phobia, panic disorder, agoraphobia, specific phobia, and obsessive-compulsive disorder (OCD). Cut-off scores are set as follow: Depression: item #1 $\geq$ 5 & item #2 = 1; GAD: item #3 $\geq$ 2; Panic: item #4 $\geq$ 1; Panic with Agoraphobia: item #4 $\geq$ 1 & item #5 = 1; Agoraphobia: item #5 = 1; Specific phobia: item #6 or item #6 $\geq$ 1; Social phobia: item #8 = 1 & item #9 = 1; PTSD: item #10 = 1 or item #11 = 1; OCD: item #12 $\geq$ 1; Alcohol Abuse/Dependence: item #13 $\geq$ 2 & item #14 $\geq$ 3; Suicide: item #5 $\geq$ 3.

Exclusion from the program will apply to individuals who: (A) have visual, hearing, or cognitive impairments that hinder their ability to receive and follow the intervention; (B) suffer from severe psychiatric disorders as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) [29]; (C) lack basic computer skills or access

to the internet. Participants will not be eliminated even if they are currently undergoing psychopharmacological treatment or receiving psychological or psychotherapeutic assistance.

3.3 Sample Size Calculation

We determined the minimum sample size required for this study using a predefined sample size calculator (specifically, G*Power 3.1.9.2 software) designed for F tests [30–32]. Subjects were randomly assigned to the iCBT self-help group and the waiting list group. Additionally, they will be assessed at three different time points: (1) before the intervention, (2) after the intervention (two months later), and (3) 12 months after treatment completion.

Given the innovative nature of the study, realistic estimates of effect sizes were derived, with a predefined partial $\eta 2$ set at 0.02, indicating a small effect size [33, 34]. This corresponds to a Cohen's f value of 0.143. Furthermore, we established a type I error rate (α) of 0.05 (two-sided), a Power ($1 - \beta$) of 0.95, and a predetermined correlation between repeated measures of 0.50, following standard guidelines [33].

The adjustment for non-sphericity was established at a factor of 1.

Results indicated that with a total of 128 participants (64 in each group), there is a 95% probability of correctly rejecting the null hypothesis, indicating a significant effect of the interaction.

3.4 Randomization Procedure

The randomization plan and allocation will be created using the Randomization.com website [35]. To maintain allocation concealment, the program will generate an anonymous code for each participant, which will correspond to the randomization sequence. However, because of the nature of the intervention, it will not be possible to conceal the treatment group allocation from the participants, the research team, or the outcome assessors. Nevertheless, the clinical psychologist conducting the sessions, as well as the participants and observers, will remain unaware of the research objectives. Subjects will be allocated to the two conditions in two days from the initial assessment (Fig. 1).

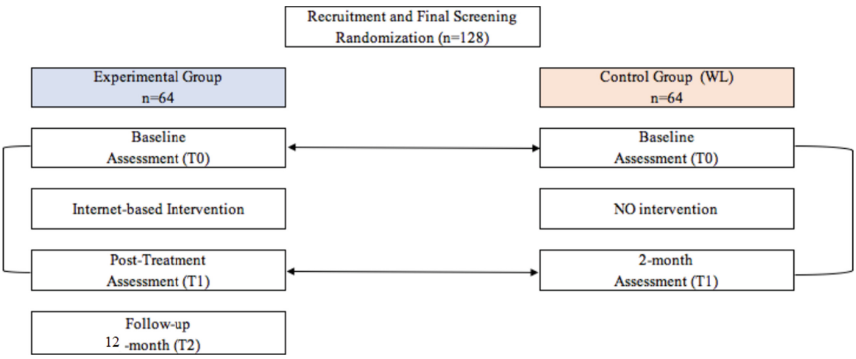

Fig. 1. Flow chart of the study

3.5 Measures

Participants will be asked to provide self-reported demographic and clinical information at the baseline assessment. This information will include age, gender, educational background, marital status, as well as their current weight, and height, which will be used to determine Body Mass Index (BMI, kg/m^2).

Furthermore, the Italian version of the following psychological measures will be administered at baseline (T0), after 2 months (T1), and at the 12-month follow-up (T2):

Primary Outcome Measure

The primary outcome will be assessed using the *Outcome Questionnaire* (OQ-45) [36], which consists of 45 items. Participants will rate these items on a 5-point Likert scale, ranging from 0 (Never) to 4 (Almost always). The OQ-45 evaluates treatment progress in three distinct domains: Symptom Distress (SD – 25 items); Interpersonal Relations (IR - 11 items), and Social Role (SR – 9 items). The total OQ-45 score is derived by summing the scores of these three subscales. The total score can range from 0 to 180. A total score equal to or greater than 63 suggests the existence of important symptoms. More specifically, a score equal to or greater than 36 in the SD subscale signifies significant symptom distress, a score equal to or greater than 15 in the IR subscale indicates dysfunctional relationships and a score equal to or greater than 12 in the SR subscale suggests an ill-defined social role.

Secondary Outcome Measure

Perceived Stress Scale (PSS) [37]: This scale consists of 10 items, and participants rate their responses on a 5-point Likert scale, ranging from 0 (Never) to 4 (Very often). It assesses the extent to which individuals perceive situations in their lives as stressful. PSS scores are calculated by reversing responses to items 4, 5, 7, and 8 and then adding up all scale items. The overall score can vary between 0 and 40.

Emotional Regulation Questionnaire (ERQ) [38]: This questionnaire consists of 10 statements that participants rate on a 7-point Likert scale, ranging from 1 (Strongly disagree) to 7 (Strongly agree). It evaluates how individuals manage their emotions in two ways: Cognitive Reappraisal and Expressive Suppression. The total score can vary between 7 and 70.

Depression Anxiety Stress Scales-Short Version (DASS-21) [39]: This scale includes 21 statements rated on a 4-point Likert scale, ranging from 0 (Did not apply to me at all) to 3 (Applied to me very much). It assesses negative emotional states, including depression, anxiety, and stress. Each scale comprises 7 items. The total scores for each subscale are obtained by summing the scores of the individual items and then doubling the result. The DASS-total score can range between 0 and 126, with each subscale score ranging between 0 and 42.

General Self-efficacy Scale (GSES) [40]: This scale comprises 10 items rated on a 4-point Likert scale, ranging from 1 (Not at all true) to 4 (Exactly true). It assesses individuals' confidence in their ability to cope with challenging or stressful events. The total score is calculated by summing all items, and it ranges from 10 to 40, with higher scores indicating greater self-efficacy.

World Health Organization Quality of Life (WHOQOL-BREF) [41]: This questionnaire includes 26 items rated on a 5-point Likert scale and assesses four domains: physical health, psychological health, social relationships, and environmental health. Scores that originally fall within the range of 25 to 130, are transformed using a conversion to fit a 0 to 100 scale.

Furthermore, adherence to the program will be assessed by examining factors like the proportion of pages visited or the frequency of access. To gauge *acceptability,* we will track participant attrition rates and, for the experimental group, by employing the *System Usability Scale* (SUS) [42]. The SUS involves responding to 10 statements using a 5-point Likert scale, with possible scores spanning from 0 to 100. A score exceeding 68 suggests there are no significant usability issues.

3.6 Procedure

Individuals interested in participating will be guided to the RinasciMENTE 2.0 website (https://www.iterapi.se/sites/rinascimente/login).

There, they will find an online consent form, and upon acceptance, each participant will receive a document outlining the study's objectives and requirements.

The initial step will involve participants completing the Web Screening Questionnaire (WSQ). Subsequently, over the following 5 days, participants will select a convenient time slot for a clinical semi-structured interview. This interview, lasting approximately 45 min, will be conducted by a certified psychotherapist who is not affiliated with the study. The purpose of this interview is to further assess each individual's eligibility for participation in the study. Additional information regarding the study and the randomization process will be provided to all respondents.

The decision regarding the inclusion of participants in the study will be made collectively by the professional conducting the interview and the research investigators. Participants will be informed of the decision via email within a week. In cases where exclusion is necessary, individuals will be provided with explanations, and if there are indications of severe psychological distress, they will be encouraged to seek professional assistance.

Eligible participants will then be randomly assigned to either the experimental group (iCBT self-help) or the control group (WL). They will receive an email containing a username and a personalized link to create a password, which will grant them access to the *iterapi* platform [43, 44]. The *iterapi* platform is a secure platform with demonstrated effectiveness in alleviating symptoms of various disorders [45–48]. In the present study, the platform content and activities will be for the first time re-design to adapt to the psychological needs of the broader Italian population.

Participants assigned to the experimental group have to log in to the platform and provide electronic informed consent. In contrast, individuals in the control group will gain access to the online treatment once the experimental group has finished its two-month intervention period. The *iterapi* platform will be the main channel for communication between mental health professionals and participants, as well as for delivering the intervention and collecting quantitative assessments. Before starting the program, participants will be required to fill out self-report questionnaires evaluating primary and secondary outcomes (T0).

The treatment itself will consist of 8 weekly modules focused on: 1) setting goals; 2) anxiety management; 3) effective communication; 4) stress management; 5) anger management; 6) taking care of yourself; 7) sleep problems; 8) plan of completion and maintenance.

Throughout the intervention, participants will receive weekly email updates notifying them of new materials available on the platform. Participants who will not access the materials or fail to complete recommended tasks and exercises will receive weekly reminders, along with brief, encouraging messages.

Upon completion of the program (after two months – T1), participants in both groups will be asked to complete the baseline questionnaires once more. Additionally, the experimental group will undergo assessments at 12-month intervals following the conclusion of the treatment (T2) (Fig. 1).

We do not anticipate any adverse or unintended effects resulting from trial participation. However, if participants experience any form of psychological discomfort, they can consult with the responsible psychologist. Moreover, participants can reach out to the study's coordinator for any doubts or information needs. Once enrolled, participants retain the freedom to withdraw from the study at any point without impacting their future treatment.

3.7 Statistical Analysis

Statistical analyses will be conducted using SPSS software version 24.0 [49].

Initially, preliminary analyses will be carried out to evaluate the assumptions related to univariate and multivariate normality. In cases where significant violations of these assumptions will be detected, robust methods or data transformations will be applied. Participants who dropped out of the study will be excluded during these preliminary analyses.

To handle missing data, a missing values analysis will be conducted to determine if the missing values were Missing Completely at Random (MCAR) or if there will be a discernible pattern among them. If no patterns are identified, then either pairwise or listwise deletion will be employed to manage missing data. However, if a pattern is identified through the missing value analysis, imputation techniques will be used.

Demographic attributes will be displayed using means and standard deviations for continuous variables, while categorical variables will be presented as frequencies and percentages.

The association between treatment groups and socio-demographic variables will be examined using the chi-square statistic, and correlation analysis will be used to explore associations among quantitative variables.

To assess treatment outcomes, an Intention-To-Treat (ITT) approach will be utilized, with a significance level set at 5%. A repeated-measures ANOVA will be employed to investigate potential differences both between and within groups in the selected outcomes from baseline to the end of treatment. Subsequently, repeated measures within-group ANOVAs will be used to assess outcome differences over time, specifically at baseline, end of treatment, and 12-month follow-up. Effect sizes, corrected for bias (Cohen's d), and their significance at a 95% confidence interval will be computed for group differences. For the overall effect, Cohen's f will be computed.

The analysis will be conducted by an independent statistician blinded to the treatment allocation.

4 Expected Results and Conclusions

The outcomes of this RCT will furnish valuable insights into the feasibility and effectiveness of the RinasciMENTE 2.0 program in enhancing the emotional health of the Italian population. Specifically, we anticipate that participants will experience reductions in stress, anxiety, and depression, along with improvements in their emotional regulation strategies and self-efficacy. Furthermore, the levels of adherence to and dropout from the program will serve as important indicators of the study's feasibility.

Still, limitations of this study might be individuals' lack of internet access and digital literacy skills, particularly among non-digital natives.

Therefore, before commencing the trial, a usability analysis was conducted to identify and address any usability challenges associated with the platform, especially for older participants [50]. The results of this study not only help identify and address usability issues but also contribute to the adaptation and refinement of self-help CBT programs.

Consistent with prior studies, it is plausible that dropout rates could be more pronounced in web-based interventions than in traditional in-person therapy, particularly when self-help programs are utilized. To address this concern, subjects will receive reminders and messages aimed at stimulating their involvement with online resources.

Emphasis will also be placed on cultivating a positive relationship between each participant and their referring therapist. While the professional remains available for support when needed, the participant is encouraged to take responsibility for their treatment as successes. This approach highlights the importance of the learning process, empowering individuals to enhance their self-management skills and to develop strategies for addressing emotional challenges.

The RinasciMENTE 2.0 program has the potential to provide individuals with a range of self-help techniques to address psychological challenges while helping to reduce the financial burden on the healthcare system.

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