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Learning from the COVID-19 challenge: an Italian RCT study on an intervention's effectiveness in reducing mental health symptoms in hospitalized patients

Rizzi Damiano[1,2,3] · Gambini Giulia[3] · Benzi Ilaria Maria Antonietta[1] · De Silvestri Annalisa[3] · Rovati Anna[2,3] · Bigoni Francesca[2,3] · Mangiagalli Matteo[2] · Ivan Giacomel[2] · Perlini Stefano[4] · Valeria Musella[3] · Barone Lavinia[1] · Klersy Catherine[3]

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Abstract

This randomized control study assessed the effectiveness of in-person and remote psychological support interventions in reducing post-traumatic stress symptoms in post-COVID-19 patients. Two hundred twenty-five patients were randomized to control, in-person, and remote intervention groups. The severity of post-traumatic stress and psychological symptoms was assessed at baseline, at six months, and at twelve months. Our results did not reveal a significant overall difference between the control and intervention groups. However, among patients with initial higher post-traumatic stress symptoms, a more significant decrease in distress was observed in the intervention group compared to the control group. No significant difference between in-person and remote interventions was found, suggesting both modalities are applicable. Secondary psychological symptoms (depression, anxiety, and sleep problems) also decreased in the high-distress subgroup following the intervention, but benefits were not maintained at twelve months. This study underlines the potential benefits of tailored psychological interventions in COVID-19 recovery, particularly for individuals with higher levels of distress. It also underscores the need for sustained ongoing psychological support and the utility of in-person and remote support modalities. Further studies should consider these findings when designing interventions to improve post-COVID-19 patient psychological health outcomes.

Keywords COVID-19 · Patients · DBT-informed psychological intervention · RCT longitudinal study

Introduction

The COVID-19 pandemic, which the World Health Organization only recently declared over, has profoundly disrupted our society's public health and the global economy. The disease's burden, characterized by high mortality rates and numerous systemic manifestations far beyond respiratory ones, is irrefutable, evidenced by the epidemiological numbers that characterized the various pandemic waves (Li et al., 2021).

In this scenario, a substantial body of literature was developed to analyze the comorbidities related to COVID-19, particularly its consequences on people's psychological well-being. Studies have highlighted that patients with COVID-19 have had to endure high levels of stress and anxiety related to the severity of the disease, isolation during hospitalization, and uncertainty about disease outcomes

CK and LB are both considered as last authors.

✉ Rizzi Damiano
d.rizzi@smatteo.pv.it

[1] Department of Brain and Behavioral Sciences, University of Pavia, Piazza Botta Adorno Antoniotto, 11, Pavia 27100, Italy

[2] Fondazione Soleterre Strategie di Pace ONLUS, Milan, Italy

[3] Biostatistics and Clinical Trial Center, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy

[4] Emergency Department, Fondazione IRCCS Policlinico San Matteo, University of Pavia, Pavia, Italy

(Pfefferbaum & North, 2020). Indeed, the illness experience may have fostered consequences lingering beyond the course of the disease. Studies highlighted higher levels of anxiety, depression, and insomnia in patients with more severe presentations (Dong et al., 2021). A 2020 review comparing psychological morbidities among the general population, healthcare workers, and COVID-19 patients showed a significantly higher burden on the latter, again depression, anxiety, and sleep problems (Krishnamoorthy et al., 2020). Moreover, several studies have shown that the experience of COVID-19 resulted in the development of post-traumatic stress disorder (PTSD) (Hossain et al., 2020).

Emotional dysregulation as a response to traumatic experiences

PTSD entails symptoms that can occur in people who have experienced or witnessed a traumatic event, such as a natural disaster, serious accident, terrorist act, war/combat, or rape (APA, 2022). People with PTSD often relive the traumatic event through intrusive memories, flashbacks, or nightmares; they may also experience emotional numbness, sleep disturbances, irritability, difficulty concentrating, and heightened reactions to triggers reminiscent of the trauma. Although PTSD is most commonly associated with life-threatening events, research showed a high prevalence of PTSD symptoms among those affected by the COVID-19 pandemic. Studies in several countries have shown that many COVID-19 survivors, healthcare workers, and the general population exposed to pandemic stressors exhibit PTSD symptoms (Carmassi et al., 2020; Liu et al., 2020). These studies have emphasized the traumatic nature of the COVID-19 experience, resulting from factors such as fear of infection, the psychological impact of quarantine measures, distressing experiences of severe illness, and grief and bereavement related to the loss of loved ones to the virus. In addition, persistent uncertainty and threats to personal and social well-being likely contributed to the development of PTSD symptoms. Studies on COVID-19 discharged patients showed different percentages of PTSD symptoms, up to 30.2% (Janiri et al., 2021; Liyanage-Don et al., 2022). A 2021 meta-analysis on the prevalence of PTSD after infectious disease pandemics highlighted a prevalence of 23.8% among COVID-19 patients (Yuan et al., 2021). Despite literature showing lower prevalence than in previous pandemics and improvements in the following weeks, data suggested that PTSD symptoms increased after a stay in an intensive care unit (Horn et al., 2020). Emotional dysregulation, characterized by problems in managing emotional experiences, is a critical component of PTSD. This dysregulation can manifest in increased emotional reactivity, poor emotional awareness, and maladaptive coping strategies, which can exacerbate the distress and functional impairment associated with PTSD (Weis et al., 2022). The inability to effectively regulate emotions can lead to a negative cycle of increased stress and trauma-related symptoms, contributing to the chronicization of PTSD.

All in all, as psychological health plays a central role in a patient's overall recovery and quality of life after a significant illness, it is critical to address these psychological effects after hospitalization and explore potential solutions to mitigate these effects and facilitate recovery. In this regard, implementing targeted psychological interventions can be a valuable contribution.

Psychological interventions after intensive care intervention

Extensive literature has highlighted the need for implementing psychological interventions for COVID-19 patients, especially after intensive care intervention (Duan & Zhu, 2020; Tomaino et al., 2022; Xiang et al., 2020). For example, a study by Lazzaroni and colleagues (2022) describes the efficacy of a brief trauma-focused intervention for adult patients after hospitalization in reducing stress levels and trauma-related symptoms (Lazzaroni et al., 2022).

The COVID-19 pandemic fostered the rapid adoption of online mental health interventions, encouraging research on their effectiveness. Studies on online interventions for PTSD, such as those reported in the meta-analysis by Olthuis et al. (2016), have shown that online cognitive behavioral therapy (CBT) can be as effective as in-person intervention. For example, Lewis et al. (2020) found that psychological therapies, including online interventions, significantly reduced PTSD symptoms in adults. Similarly, a systematic review and meta-analysis by White et al. (White et al., 2022) (demonstrated that online psychological interventions are effective in reducing symptoms of depression, anxiety, and general distress in individuals with chronic health conditions. The review highlighted that online interventions provide a viable alternative to in-person therapy, offering flexibility and accessibility to individuals facing barriers to traditional therapy formats. Furthermore, Kangaslampi and Peltonen (2022) provided insights into the mechanisms of change in psychological interventions, suggesting that improvements in maladaptive posttraumatic cognitions and mindfulness are critical factors in the efficacy of both online and in-person interventions. Evaluating online and in-person modalities is crucial to provide insights into the feasibility and utility of online psychological support for post-COVID-19 patients, potentially expanding access to effective mental health care.

However, research on the comparative effectiveness of virtual versus in-presence interventions is still scarce.

Evaluating both modalities is crucial to providing insights into the feasibility and utility of online psychological support for post-COVID-19 patients, potentially expanding access to effective mental health care (Jericho et al., 2022; Parolin et al., 2021).

The present study

In this scenario, we designed a randomized, open-label, controlled study to assess the impact of psychological support on the traumatic effects of COVID-19 on patients discharged from the Fondazione IRCCS Policlinico San Matteo in Pavia (Italy).

The psychological intervention is a brief version of a Dialectical Behavior Therapy (DBT)-informed intervention. DBT, initially developed by Linehan et al. (1993), is a well-established intervention for borderline personality disorder and other conditions characterized by emotional dysregulation (Harvey et al., 2019; Neacsiu et al., 2014; Storebø et al., 2020). DBT's effectiveness in reducing psychiatric symptoms and enhancing emotional regulation skills makes it a suitable choice for addressing trauma-related symptoms in COVID-19 patients. The brief DBT-informed intervention consists of five 50-minute sessions centered around DBT principles and techniques, including mindfulness, distress tolerance, emotion regulation, and problem-solving techniques.

These sessions aim to foster exposure to painful events, enhance distress tolerance, and improve emotional regulation through active exercises, ultimately reducing trauma-related symptoms and behaviors. The selection of DBT for this study is based on its transdiagnostic approach to emotion regulation, which is pivotal in managing trauma-related symptoms. Previous studies have demonstrated DBT's efficacy in treating various psychological conditions, but its application in post-COVID-19 recovery remains underexplored. By focusing on emotion regulation, the intervention targets a core aspect of PTSD and related psychological distress, providing a tailored approach that addresses the unique challenges faced by COVID-19 survivors (Sloan et al., 2017).

This intervention is particularly needed because it is structured and focused on target priorities, thus allowing the setting of a session agenda suitably focused on emotional regulation enhancement. Furthermore, it addresses the immediate trauma-related symptoms by equipping patients with long-term coping strategies, "DBT skills," to manage future emotional challenges.

More specifically, the primary objective of the study is to assess the effectiveness of in-person and remote psychological support interventions in reducing post-traumatic stress symptoms in post-COVID-19 patients. In addition, the secondary comparison is between virtual vs. in-person intervention sessions. The secondary objectives and endpoints are the comparisons between control and intervention conditions on changes in PTSD symptoms over 12 months and between control and intervention conditions changes in psychological symptoms over 12 months. In line with the available evidence, we hypothesized that the intervention condition (both in-person and online) would show lower levels of trauma-related symptoms than the control condition after the psychological intervention (Carmassi et al., 2020; Yuan et al., 2021). Second, we expected both PTSD symptoms and psychological symptoms to decrease in the intervention condition after the intervention over 12 months.

Methods

The present study follows the CONSORT-SPI 2018 Explanation and Elaboration: Guidance for Reporting Social and Psychological Intervention Trials (Supplementary Table 1). This is an open-label randomized parallel groups-controlled trial to assess the impact of psychological support on the traumatic effects of COVID-19 on mental health, cognitive abilities, and emotional regulation of patients discharged from the Fondazione IRCCS Policlinico San Matteo diagnosed with COVID-19 (Rizzi et al., 2024).

Procedure

Between March 2021 and November 2021, we enrolled 225 patients discharged with a diagnosis of COVID-19 from our Institution. The median time from discharge to the signature of the informed consent was five months (interquartile range 3–6).

Participants

The clinical psychologists contacted consecutive patients discharged from the hospital at their first outpatient check-up or, failing that, by telephone. Once the required sample size was reached, no further patients were contacted. This study adhered to the Declaration of Helsinki and APA guidelines, receiving IRB approval from the Ethical Committee of the Fondazione IRCCS Policlinico San Matteo. Informed consent was obtained from all participants, ensuring they were fully aware of their rights, including the right to withdraw from the study without any consequences. Confidentiality was strictly maintained through secure data storage and anonymization. Throughout the study, participants were closely monitored for any signs of distress, and immediate psychological support and referrals to mental health services were provided as needed.

To be eligible for the study, patients had signed the informed consent form, were 18 or older, and had been discharged from the intensive care, infectious diseases, or respiratory diseases wards or from the emergency room with a diagnosis of COVID-19 between 3 and 6 months before.

Patients were randomized to a control group, a psychologist remote support group, or an in-person support group. The control group received no psychological support; they only met the psychologist at enrolment and the end of the study visit. The remote group received five sessions of psychological support, administered remotely via the web; each session lasted 50 min. Finally, the in-person group received five 50-minute sessions of psychological support administered in person at the outpatient clinic (Fig. 1). The two last groups were combined into the support group for analysis purposes. Patients in the control group could receive psychological support if the clinical need arose.

Sample size and randomization

Sample size calculations are based on the primary endpoint. With 64 subjects in the control arm and 128 subjects in the support arm (64 in-person, 64 remote), we can elicit an effect of 0.5 standard deviations with power over 90% and a 2-sided type I error of 5%. To account for dropout, 225 subjects were enrolled. The calculation was done using Stata 17 (StataCorp, College Station, TX, USA). We generated a randomization sequence of interventions randomly permuted in blocks of varying size using the Stata user-written command ralloc. Randomization was web-based using the REDCap platform at our Institution (©2019 Vanderbilt University). The randomization list was generated at our institution's biostatistics facility; patients were enrolled by the study psychologist, who also assigned participants to intervention. Due to the nature of the intervention, blinding was not possible.

Seventy-five patients were randomized to the control group and 150 to the support group (in-person $n=74$, remote $N=76$); in the support group, 103 were compliant with intervention (in-person $N=52$, remote $N=51$). Analyses of the primary endpoint included 75 patients in the control group and 148 in the support group (in-person $N=72$, remote $N=76$, Fig. 2).

Figure 2 summarizes the participants' flow graphically for the control and combined intervention arms. We report the numbers randomly assigned to each group, receiving the intended intervention and analyzing for the primary outcome.

Psychological intervention

The psychological intervention was a brief version of an informed Dialectical Behavior Therapy (DBT) intervention program. DBT, developed by Linehan (Linehan et al., 1993; Linehan & Wilks, 2015), is an intervention that utilizes various cognitive and behavioral techniques guided by a dialectical approach.

	Baseline	Treatment				Follow-up	
Visit	1	2	3	4	5	6	7
Months	0	1	2	3	4	6	12
Informed consent	x						
Randomization	x						
Demographic data	x						
Occupation data	x						
Psychological history							
Questionnaire administration	x					x	x
Treatment	x	x	x	x	x		

Fig. 1 Study's schedule

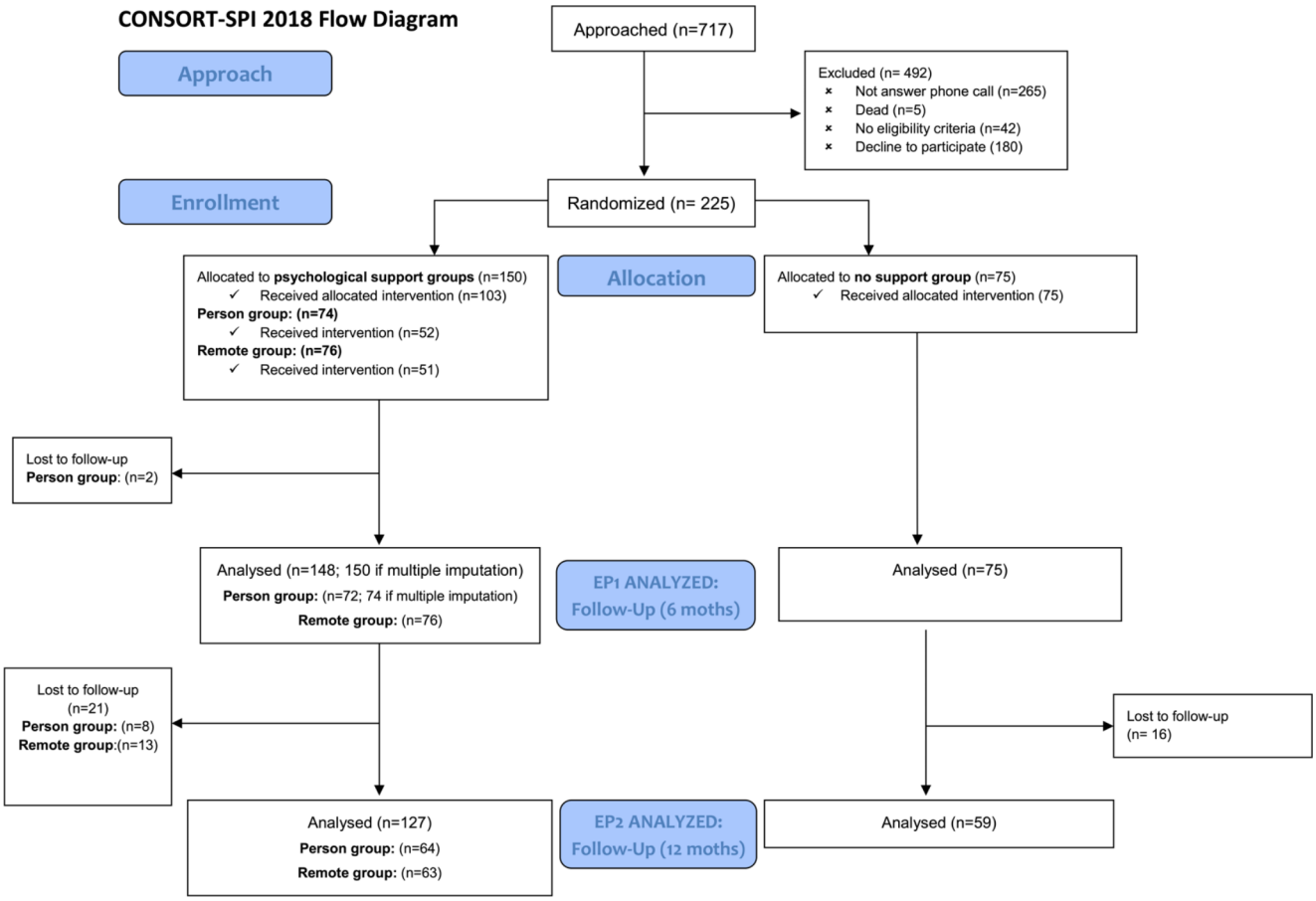

Fig. 2 Consort flow diagram

The brief DBT-informed intervention was designed by a certified DBT therapist and trainer Lavinia Barone, who trained a team of psychologists from the Soleterre Foundation in the short intervention program during a tailored 20-hour course and then monitored their clinical work with periodic supervision. The Soleterre Foundation carefully chose the psychologist responsible for the intervention. The brief intervention was designed to reduce trauma-related behaviors and symptoms in individuals: it consisted of five 50-minute individual sessions, delivered either in-person or online to the two intervention groups, each session following a structured format. The sessions were centered around Dialectical Behavior Therapy (DBT) principles and techniques and focused on fostering exposure to painful events, distress tolerance, and emotional regulation through active exercises. The exercises incorporated various DBT techniques such as mindfulness, validation, chain analysis, problem-solving, non-judgmental stance, and radical acceptance. In addition, this approach aimed to enhance participants' emotional self-compassion, awareness, and coping skills, which are crucial for mental health and well-being. A detailed illustration of the intervention is depicted in Table 1.

Measures

The study schedule (Fig. 1) shows that patients were administered psychological questionnaires exploring different dimensions at baseline and 6 and 12 months. The questionnaires lasted approximately 1.5/2 hours.

The *National Stressful Events Survey PTSD Short Scale* (NSESSS) (Kilpatrick et al., 2013) is a 9-item self-report that measures the severity of posttraumatic stress symptoms. Respondents rate how much they were bothered by each symptom during the past week on a 5-point scale from 0 (not at all) to 4 (extremely). The total score ranges from 0 to 36, and this score is used to assess the severity of PTSD symptoms. Alternatively, the average total score can be calculated by dividing the total score by the number of items, which can easily categorize the overall severity of PTSD into five levels: none (0), mild (1), moderate (2), severe (3), and extreme (4). In previous studies, Cronbach's alpha for the scale showed good internal consistency (Kim et al., 2022).

The *Level 1 Cross-Cutting Symptom Rating Scale* (APA, 2022) is a 23-item self-report measure of psychological symptoms in 13 domains: Somatic symptoms, Sleep

Table 1 Overview of the DBT-informed intervention structured format

Session	Focus of the session
Session 1	- Orientation and goals definition - Mindfulness practice: grounding (observe and describe your breath) - Defining goals and targets of the client by using validation (levels 1, 2, 3). - Closing session Mindfulness practice (paced breathing)
Session 2	- Mindfulness practice: grounding (observe and describe your breath) - Defining goals and targets of the client by using validation (levels 1, 2, 3, 4) - Teaching and observing states of mind (emotional mind, rational mind, wise mind) by discussing trauma-related events - Closing session Mindfulness practice on wise mind search
Session 3	- Mindfulness practice: observe and describe your thoughts. - Observation and validation of client's thoughts - Identification of a target trauma-related behavior - Chain analysis and problem solving - Closing session Mindfulness practice
Session 4	- Mindfulness practice: observe and describe your thoughts. - Observation and validation of client's thoughts - Behaviors that require Radical acceptance - Identification of a target behavior - Chain analysis and problem solving - Closing session Mindfulness practice
Session 5	- Mindfulness practice: observe and describe your thoughts. - Observation and validation of client's thoughts - Behaviors that require Radical acceptance - Identification of a target behavior - Chain analysis and problem solving - Commitment strategies for keeping intervention achievements and mindfulness practice over time. - Closing session mindfulness practice

The brief intervention of five 50-minute individual sessions, delivered to all subject belonging to the in-person intervention group or to the online intervention group (Linehan et al., 1993; Linehan, 2015)

problems, Memory, Depression, Anger, Mania, Anxiety, Psychosis, Personality functioning, Repetitive thoughts and behaviors, Substance use, and Suicidal ideation/suicide attempts. Items are rated on a 5-point Likert scale, with 0 indicating no symptoms and 4 indicating severe symptoms. For this study, we included the Somatic symptoms, Sleep problems, Depression, Anger, and Anxiety scores. Internal consistency was adequate in previous studies (Bastiaens & Galus, 2018).

Outcomes

The primary objective is to compare the effectiveness of the psychological intervention on post-traumatic stress at six months as assessed by the NSESSS score. The primary endpoint is the change in score from baseline. The primary comparison is between the control and the support group; the secondary is between remote vs. in-person support groups.

Secondary objectives and endpoints are (a) the comparison between control and support groups of the differences in mean NSESSS scores over the 12 months of the study; (b) the comparison between control and support groups of the differences in mean Level 1 Cross-Symptom Rating Scale (, 2013) scores over the 12 months of the study.

A subgroup analysis by score severity (NSESSS</≥2) was planned for the NSESSS primary endpoint and selected dimensions of psychological symptoms.

Statistical analysis

We used Stata 17 for computation. The confidence intervals of the estimates were calculated at the 95% level (95%CI). All statistical tests are 2-tailed; a $p < 0.05$ was considered statistically significant.

We described continuous variables with the mean and standard deviation (SD), median and quartiles, and categorical variables as counts and percentages. All analyses were conducted according to the intention-to-treat (ITT) principle: i.e., all participants are analyzed according to the group to which they were initially assigned, regardless of whether they deviated from the intervention. To analyze the primary endpoint, we used a regression model for repeated measures, including the main effects of intervention and time and their interaction; the Wald test for interaction was used to assess the difference between groups over time, as a significant interaction means that the effect of time (i.e., change from baseline at six months) depends on the intervention group and represents the mean difference between groups. We computed Huber-White robust standard errors to account for the intra-subject correlation of measures. We reported within-group changes at six months with 95%CI (corresponding to the regression coefficient of time in models stratified by type of support) and the difference between controls and support (95%CI), as stated above. If this difference is significant at the 5% level, we apply a step-down procedure and test the difference between remote and in-person support groups at the same 5% level; otherwise, the post-hoc comparison is to be considered exploratory.

To assess the robustness of our results, we refitted the same model after multiple imputations (20 runs) of the 6-month NSESSS score, using baseline NSESSS, intervention arm, age, gender, previous psychological support, and current employment as independent variables.

We also performed a predefined subgroup analysis of the primary endpoint based on the baseline severity of the NSESSS score (≤/>2); moreover, for a better understanding of the underlying mechanisms, this subgroup analysis was

Table 2 Study participants' demographics in the three randomized groups

Variables	No Support (Control) $N=75$	Support (remote + person) $N=150$	Remote $N=76$	Person $N=74$
Age (years)	62 (13)	62 (13)	60 (13)	63 (13)
Male, n(%)	51 (68%)	87 (58%)	43 (57%)	44 (59%)
Smoker, n(%)	3 (4%)	5 (4%)	4 (5%)	1 (1%)
- Yes	39 (52%)	95 (63%)	48 (63%)	47 (64%)
- No	33 (44%)	50 (33%)	24 (32%)	26 (35%)
- Ex				
Status	68 (91%)	137 (91%)	70 (92%)	67 (91%)
Lives with a partner				
Living situation/	33 (44%)	62 (41%)	32 (42%)	30 (41%)
habitual cohabitation	29 (39%)	60 (40%)	30 (39%)	30 (41%)
for the past 3 years	4 (5%)	5 (3%)	3 (4%)	2 (3%)
- with partner and	0 (0%)	3 (2%)	1 (1%)	2 (3%)
children	2 (3%)	7 (5%)	4 (5%)	2 (3%)
- with partner only	7 (9%)	13 (9%)	6 (8%)	3 (4%)
- with children only				7 (9%)
- with parents				
- with other family members				
- alone				
Education: more than 12 years	35 (66%)	80 (53%)	38 (49%)	42 (56%)
Paid employment	32 (43%)	70 (46%)	37 (49%)	33 (45%)
Psychological support before COVID-19	17 (23%)	29 (19%)	14 (19%)	15 (20%)
Psychological support during COVID-19	3 (4%)	10 (7%)	6 (8%)	4 (5%)
Number of interviews	0 (0%)	4 (40%)	3 (50%)	1 (25%)
during COVID-19	0 (0%)	1 (10%)	1 (17%)	0 (0%)
- 1	3 (100%)	5 (50%)	2 (33%)	3 (75%)
- 2–3				
- > 3				

Data are presented as mean and standard deviation or median and quartiles if continuous and as count and percent if categorical

repeated for each of the following clinically relevant psychological symptom's scores: depression, anxiety, somatic symptoms, sleep problems, and anger scores. The same regression model for repeated measures over the entire 12-month follow-up was used for the secondary endpoints. With Bonferroni correction for multiple tests, the significance was set at 0.001.

Table 3 Distributions of severity levels at baseline for PTSD symptoms in the three randomized groups

Variables	Support (remote + support)	No Support (Control)	Remote	In Person
Primary endpoint				
NSESSS	1.04 (0.85)	1.02 (0.85)	1.10 (0.94)	0.97 (0.75)
NSESSS ≥ 2	26 (17%)	11 (14%)	17 (29%)	9 (14%)
NSESSS < 2	122 (83%)	63 (86%)	59 (71%)	63 (86%)
Secondary endpoints				
depression	1.34 (1.21)	1.23 (1.30)	1.37 (1.29)	1.31 (1.12)
anger	0.86 (1.16)	1 (1.25)	1.11 (1.31)	0.60 (0.91)
anxiety	1.28 (1.31)	1.53 (1.42)	1.36 (1.46)	1.21 (1.14)
somatic symptoms	1.36 (1.43)	1.16 (1.42)	1.54 (1.46)	1.18 (1.40)
sleep problems	1.09 (1.34)	1.24 (1.43)	1.20 (1.39)	0.97 (1.30)

Data are presented as mean and standard deviation if continuous. NSESSS = National Stressful Events Survey PTSD Short Scale (Kilpatrick et al., 2013); depression, anger, anxiety, somatic symptoms, sleep problems = Level 1 Cross-Cutting Symptom Rating Scale (APA, 2022)

Results

Baseline data

Their main clinical characteristics by intervention arm are summarized in Table 2, while the results from the psychological test are summarized in Table 3. Balancing between groups was attained. The mean age was 62 years; about half of the patients were male; the vast majority lived with a partner; about half of the patients had a high school or university degree, and half were employed; 20 to 25% had received prior psychologic support either before or during the COVID-19 pandemic. The mean NSESSS score was about 1, below the threshold of 2 for severity distress. Indeed, only 16% of patients had an altered NSESSS score (≥ 2).

Outcomes and estimation

Primary endpoint

Changes at six months in the NSESSS score in the control and support arm are plotted in Fig. 3 (left panel) and detailed in Table 4. In both arms, we observed a comparable and significant mean decrease in NSESSS of 0.19 and 0.16, respectively, with no significant difference between groups ($p = 0.946$)—the sensitivity analysis after multiple imputations confirmed these results. In the predefined subgroup

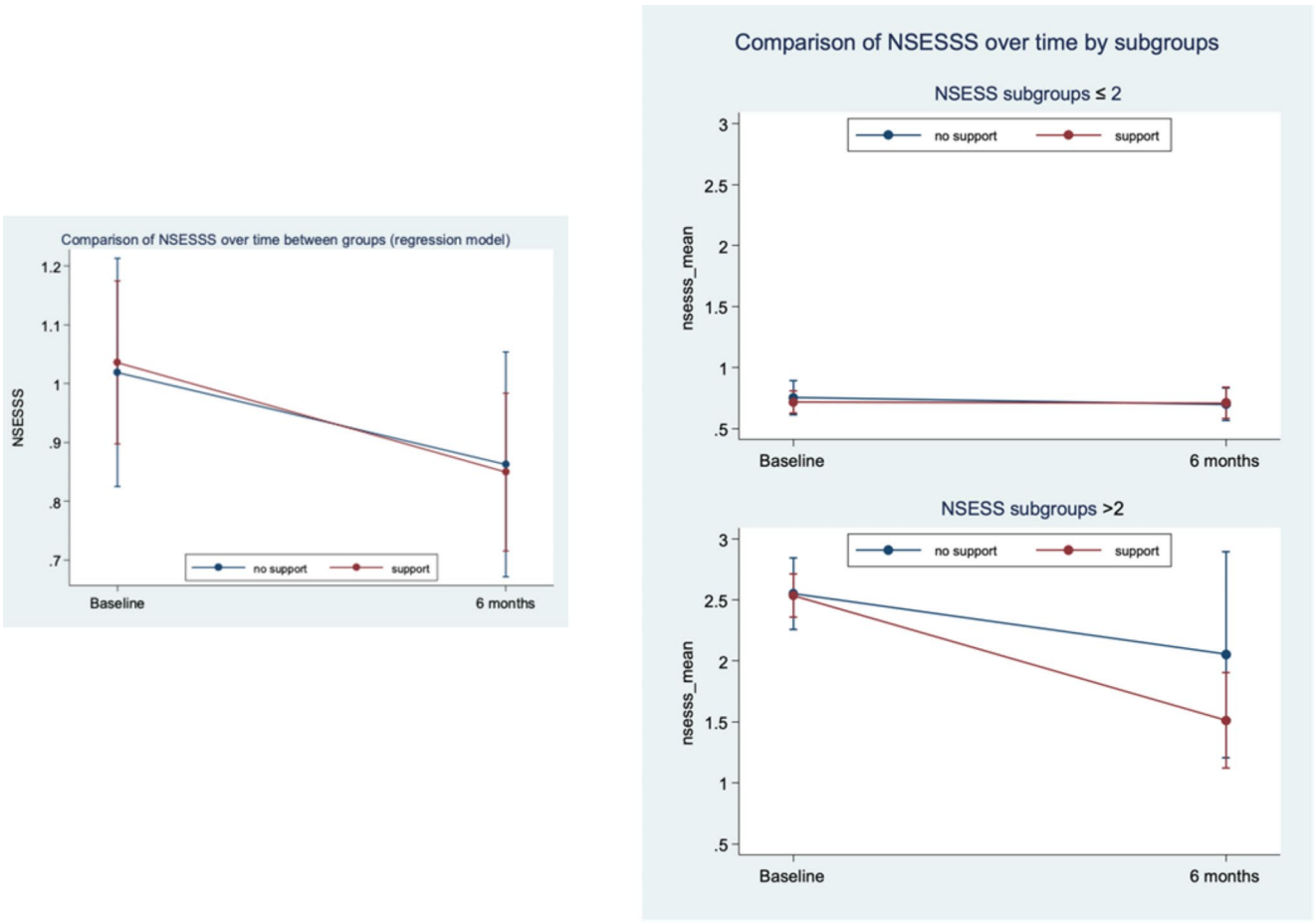

Fig. 3 Changes in the NSESSS score at 6 months (primary endpoint), overall (left panel) and by subgroups (right panel)

Table 4 Primary endpoint (6 months)

Variables	*N*	Support Mean Change from baseline (95%CI)	*N*	No Support Mean Change from baseline (95%CI)	Mean Difference between groups (95%CI)	*P* value
NSESSS	**148**	**-0.19 (-0.33; -0.05)**	**75**	**-0.16 (-0.33; -0.02)**	**-0.03 (-0.25; 0.19)**	0.946
With multiple imputation	150	-0.17 (-0.31; -0.04)	75	-0.13 (-0.30; 0.03)	-0.04 (-0.26; 0.17)	0.705
Subgroup analysis						
Baseline NSESSS ≥ 2	26	-1.02 (-1.40; -0.65)	11	-0.50 (-1.38; 0.38)	-0.53 (-1.38; 0.33)	0.220
Baseline NSESSS < 2	122	-0.01 (-0.13; 0.12)	63	-0.05 (-0.21; 0.11)	0.05 (-0.15; 0.25)	0.646

NSESSS National Stressful Events Survey PTSD Short Scale (Kilpatrick et al., 2013)

analysis by the severity of the NSESSS score (≤/>2), we observed a different dynamic behavior of the score between these subgroups (Fig. 3, right panel): in the 185 patients with normal NSESSS, no change occurred over time in neither group, while in the 37 patients with higher NSESSS, a decrease in the score was observed, that was larger and statistically significant in the support group (1.02 vs. 0.50). However, no significant difference between groups was found ($p = 0.220$, Table 4). The exploratory between treated groups mean difference was close to 0 (mean 0.01, 95%CI -0.72 to 0.73, $p = 0.983$).

Secondary endpoints

Changes in the clinically relevant psychological symptom scores (depression, anxiety, somatic symptoms, sleep problems, and anger scores) are summarized in Table 5, overall, and by subgroups. Though no significant differences arise, the exploratory subgroup analysis shows, in patients with altered NSESSS, a decrease in depression and anger scores at six months in the support group larger than in the control group. This is not confirmed at 12 months. Table 6 details the dynamic behavior of scores over the 12-month follow-up for all questionnaires in intervention and control groups.

Table 5 Overall and subgroup analysis of clinically relevant dimensions of the psychological symptoms scores significance is set at 0.001 (Bonferroni correction for multiple tests)

Variables	Months	*N*	Support Mean Change from baseline (95%CI)	Months	*N*	No Support Mean Change from baseline (95%CI)	Mean Difference between groups (95%CI)*	*p*-value
depression	6	148	-0.25 (-0.49; 0.00)	6	75	-0.07 (-0.38; 0.25)	-0.18 (-0.57; 0.22)	
	12		-0.09 (-0.36; 0.17)	12		-0.21 (-0.52; 0.10)	0.12 (-0.29; 0.52)	
Subgroup analysis								
NSESSS≥2	*6*	*26*	*-0.96 (-1.60;-0.33)*	*6*	*11*	*-0.18 (-0.87; 0.51)*	*-0.78 (-1.65; 0.09)*	
	12		*-1.07 (-1.57; -0.57)*	*12*		*-0.93 (-1.93; 0.07)*	*-0.14 (-1.14; 0.86)*	
NSESSS < 2	*6*	*122*	*-0.09 (-0.36; 0.17)*	*6*	*63*	*0.02 (-0.34; 0.37)*	*-0.11 (-0.55; 0.33)*	
	12		*0.12 (-0.18; 0.41)*	*12*		*-0.03 (-0.36; 0.29)*	*0.15 (-0.29; 0.58)*	
anxiety	6	148	-0.11 (-0.33; 0.11)	6	75	-0.33 (-0.64; -0.02)	0.22 (-0.15; 0.59)	
	12		-0.00 (-0.26; 0.26)	12		-0.31 (-0.64; 0.01)	0.31 (-0.10; 0.72)	
Subgroup analysis anxiety								
NSESSS≥2	*6*	*26*	*-0.45 (-1.00; 0.10)*	*6*	*11*	*-0.58 (-1.26; 0.10)*	*0.13 (-0.67; 0.93)*	
	12		*-1.25 (-1.89; -0.61)*	*12*		*-1.08 (-2.23; 0.07)*	*-0.17 (-1.35; 1.02)*	
NSESSS < 2	*6*	*122*	*-0.04 (-0.27; 0.20)*	*6*	*63*	*-0.24 (-0.59; 0.10)*	*0.21 (-0.20; 0.62)*	
	12		*0.27 (-0.00; 0.54)*	*12*		*-0.17 (-0.50; 0.17)*	*0.43 (0.01; 0.86)*	
somatic symptoms	6	148	-0.48 (-0.73; -0.23)	6	75	-0.26 (-0.64; 0.13)	-0.22 (-0.68; 0.23)	
	12		-0.33 (-0.60; -0.05)	12		-0.33 (-0.69; 0.03)	0.00 (-0.44; 0.45)	
Subgroup analysis somatic symptoms								
NSESSS≥2	*6*	*26*	*-0.63 (-1.31; 0.05)*	*6*	*11*	*-0.39 (-1.83; 1.06)*	*-0.24 (-1.66; 1.18)*	
	12		*-0.53 (-1.14; 0.08)*	*12*		*-1.01 (-2.28; 0.26)*	*0.48 (-0.77; 1.74)*	
NSESSS < 2	*6*	*122*	*-0.45 (-0.73; -0.17)*	*6*	*63*	*-0.20 (-0.60; 0.20)*	*-0.25 (-0.73; 0.23)*	
	12		*-0.28 (-0.59; 0.03)*	*12*		*-0.20 (-0.58; 0.17)*	*-0.08 (-0.56; 0.40)*	
sleep problems	*6*	*148*	*-0.30 (-0.54; -0.07)*	*6*	*75*	*-0.38 (-0.68; -0.09)*	*0.08 (-0.29; 0.45)*	
	12		-0.09 (-0.31; 0.13)	12		-0.21 (-0.55; 0.14)	0.12 (-0.29; 0.52)	
Subgroup analysis sleep problems								
NSESSS≥2	*6*	*26*	*-0.28 (-1.07; 0.51)*	*6*	*11*	*-0.47 (-1.95; 1.02)*	*0.19 (-1.32; 1.70)*	
	12		*-0.20 (-0.78; 0.38)*	*12*		*-0.59 (-1.81; 0.62)*	*0.39 (-0.81; 1.59)*	
NSESSS < 2	*6*	*122*	*-0.31 (-0.54; -0.07)*	*6*	*63*	*-0.33 (-0.62; -0.03)*	*0.02 (-0.36; 0.39)*	
	12		*-0.06 (-0.30; 0.18)*	*12*		*-0.14 (-0.51; 0.24)*	*0.08 (-0.36; 0.52)*	
anger	6	148	-0.19 (-0.40; 0.02)	6	75	-0.37 (-0.65; -0.08)	0.17 (-0.18; 0.52)	
	12		-0.11 (-0.35; 0.13)	12		-0.25 (-0.60; 0.09)	0.14 (-0.27; 0.56)	
Subgroup analysis anger								
NSESSS≥2	*6*	*26*	*-0.90 (-1.55; -0.25)*	*6*	*11*	*-0.52 (-1.94;0.89)*	*-0.38 (-1.77; 1.01)*	
	12		*-0.76 (-1.58; 0.06)*	*12*		*-0.90 (-2.45; 0.65)*	*0.14 (-1.43; 1.71)*	
NSESSS < 2	*6*	*122*	*-0.04 (-0.25; 0.16)*	*6*	*63*	*-0.31 (-0.60; -0.02)*	*0.27 (-0.09; 0.62)*	
	12		*0.03 (-0.20; 0.26)*	*12*		*-0.13 (-0.47; 0.21)*	*0.16 (-0.25; 0.57)*	

Difference in difference p-values for the listed endpoints are shown in the supplementary table. NSESSS = National Stressful Events Survey PTSD Short Scale (Kilpatrick et al., 2013); depression, anger, anxiety, somatic symptoms, sleep problems = Level 1 Cross-Cutting Symptom Rating Scale (APA, 2022)

No significant differences were shown (all comparisons were corrected for multiple test bias).

Discussion

This study aimed to provide findings on the effectiveness of a psychological intervention administered in-person and remotely on the levels of psychological distress in patients recovering from COVID-19.

First, we compared support vs. control groups to test the effectiveness of a short trauma-focused psychological intervention on post-traumatic stress symptoms. The brief DBT-informed intervention was particularly selected due to its established effectiveness in addressing emotional dysregulation, a core feature of PTSD and other trauma-related conditions (Harvey et al., 2019; Linehan, 1993). By focusing on DBT skills such as mindfulness, distress tolerance, and emotion regulation, this intervention aims to provide patients with robust coping mechanisms, "DBT skills," which are essential for managing the psychological aftermath of severe illnesses like COVID-19 (Storebø et al., 2020). Although our findings did not reveal a significant difference in post-traumatic stress levels (measured by the

Table 6 Secondary endpoints description significance is set at 0.001 (Bonferroni correction for multiple tests)

Test	Months	*N*	SUPPORT	*N*	NO SUPPORT	Difference between Groups over time *P* for interaction
NSESSS						0.946
	0	148	1.04 (0.85)	75	1.02 (0.85)	
	6	148	0.85 (0.78)	75	0.86 (0.77)	
	12	127	0.72 (0.73)	59	0.74 (0.78)	
depression						0.282
	0	148	1.34 (1.21)	75	1.23 (1.30)	
	6	131	1.09 (1.26)	63	1.16 (1.26)	
	12	127	1.24 (1.31)	59	1.02 (1.20)	
anger						0.628
	0	148	0.86 (1.16)	74	1.00 (1.25)	
	6	131	0.66 (0.99)	63	0.63 (1.08)	
	12	127	0.75 (1.09)	59	0.75 (1.09)	
anxiety						0.296
	0	148	1.28 (1.31)	75	1.53 (1.42)	
	6	131	1.18 (1.25)	63	1.21 (1.21)	
	12	127	1.28 (1.37)	59	1.22 (1.37)	
somatic symptoms						0.515
	0	148	1.36 (1.43)	75	1.16 (1.42)	
	6	131	0.89 (1.34)	63	0.90 (1.25)	
	12	127	1.04 (1.39)	59	0.83 (1.22)	
sleep problems						0.834
	0	148	1.09 (1.34)	75	1.24 (1.43)	
	6	131	0.79 (1.14)	63	0.86 (1.24)	
	12	127	1.00 (1.27)	59	1.03 (1.34)	

Data are presented as mean (SD). Depression, anger, anxiety, somatic symptoms, sleep problems = Level 1 Cross-Cutting Symptom Rating Scale (APA, 2022)

NSESSS score) between the control and support groups, a more detailed examination reveals the potential benefits of the interventions in specific subpopulations. Indeed, one of the key observations was the interventions' effect on patients with higher initial levels of distress, as indicated by an NSESSS score of 2 or above. This subgroup demonstrated a significant decrease in distress scores in the support group, suggesting that the interventions benefited patients suffering from greater psychological distress post-recovery from COVID-19.

This finding underscores the importance of personalized healthcare and the need for interventions to be tailored based on the individual's distress level of severity (Kongerslev et al., 2015; Norcross & Wampold, 2011). Also, as the psychological intervention was focused on emotion regulation, it aligns with the literature highlighting the importance of tackling transdiagnostic factors such as affect regulation to improve psychological symptoms and disorders (Neacsiu et al., 2014; Sloan et al., 2017). Moreover, as we conducted a secondary comparison between remote vs. in-person support groups, findings showed no differences in the two intervention modalities, suggesting the utility of resorting to online intervention when in-person is not available or difficult to implement (Jericho et al., 2022; Parolin et al., 2021).

The secondary endpoints, including depression, anxiety, and sleep problems scores, provided additional evidence supporting our discussion. For patients in the high-distress subgroup, the support interventions decreased these scores after intervention.

Interestingly, these benefits were not sustained after 12 months, suggesting the interventions' effects might diminish over time. This raises an important consideration for the future design of psychological support interventions, suggesting the potential need for sustained and ongoing support to maintain the benefits. The observed trend of diminishing effects could be attributed to several factors. Firstly, the initial level of psychological distress may play a significant role; individuals with higher baseline distress might require longer or more intensive intervention to achieve lasting benefits (Quintiliani et al., 2022). Secondly, the patient's resilience and coping mechanisms are crucial determinants of how well they sustain the benefits of the intervention. Patients with stronger resilience and better coping skills might maintain improvements longer compared to those with fewer resources. Thirdly, access to ongoing social

support can significantly influence the long-term outcomes of psychological interventions (Quintiliani et al., 2022; Traunmüller et al., 2021). Individuals with robust social support networks may experience more sustained benefits as they have additional emotional and practical resources to draw upon. Methodological considerations should also be considered, such as the length of the follow-up period and adherence to the intervention. Longer follow-up periods might reveal more about the durability of intervention effects, and ensuring high adherence rates is crucial for the validity of the outcomes. Variations in how strictly participants follow the intervention protocol could impact the results and the observed duration of benefits. A deeper dive into these factors might inform future studies' more tailored and long-lasting approach. Moreover, in future trials, it may be beneficial to include booster sessions to enhance the longevity of the intervention's impact (Nelson-Gray et al., 2006). These could be conducted at regular intervals following the conclusion of the initial intervention period. Such booster sessions could include refreshers on the main principles and strategies of the initial intervention and opportunities for discussions and reflections, helping to reinforce the skills and strategies learned. Another aspect to consider is the possible influence of patients' environmental factors, such as work or family stressors, which could counteract the effects of the interventions. Gathering information about these potential stressors could contribute to developing more comprehensive and effective intervention strategies (Moore et al., 2021; Saltzman et al., 2020). By addressing these external influences, interventions can be better tailored to support patients in managing their unique challenges.

Finally, several significant limitations must be considered when interpreting the study results. The first is the unexpectedly low rate of psychological distress (16%) in the sample population considered. This might be due to the unique characteristics of the study population and could limit the generalizability of the findings. A larger, more diverse sample could provide a more accurate representation of the broader post-COVID-19 patient population.

Further, while the study revealed noteworthy findings in the high-distress subgroup, the study was not initially powered to detect these differences. As such, it is crucial to conduct further research with larger samples specifically designed to evaluate the efficacy of support interventions in patients with higher levels of initial distress.

Adherence to the intervention was another significant challenge in this study, potentially due to the perceived burden of completing multiple questionnaires. This emphasizes the need for future studies to consider the user experience and patient burden when designing data collection methodologies.

Despite these limitations, the study contributes to the literature on psychological interventions in medical settings. Indeed, it highlights the psychological struggles patients face in their post-COVID-19 recovery and indicates a potential role for support interventions in managing these challenges. These findings serve as an essential starting point for future research and could inform the development of targeted interventions to improve psychological well-being in post-COVID-19 patients. They also shed light on the importance of continuity in providing psychological support and the need for patient-centric interventions based on the severity of distress. Through further research and patient-centered approaches, we hope to enhance the mental health outcomes for post-COVID-19 patients, ultimately contributing to their recovery process.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12144-024-06907-4.

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Data availability The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval The Ethical Committee approved all materials and procedures.

Conflict of interest The authors have no conflicts of interest to declare.

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