**COVID FEEL GOOD – A SELF-HELP VIRTUAL THERAPEUTIC
EXPERIENCE FOR OVERCOMING THE PSYCHOLOGICAL DISTRESS OF THE
COVID-19 PANDEMIC: RESULTS FROM A EUROPEAN MULTICENTRIC
TRIAL**

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Abstract: Objective: The general objective of the current study was to investigate the efficacy of a novel self-help virtual therapeutic experience (namely, the COVID Feel Good intervention) for reducing the psychological burden experienced during the COVID-19 lockdowns across different European countries. **Methods:** We focused on participants recruited from June 2020 to May 2021 in the context of a European multicenter project including four university/academic sites. Primary outcome measures were depression, anxiety and stress symptoms, perceived stress level and perceived hopelessness. Secondary outcome was the experienced social connectedness. **Results:** Using separate linear mixed-effect models, the most consistent result across the different countries was an improvement of the perceived stress level after the participation in the COVID Feel Good intervention. By pooling the results of the models using a random-effect meta-analysis, we found that the COVID Feel Good intervention was associated with a decrease in the perceived general distress [mean standardized effect size for general distress in the treatment groups compared to the control conditions was -0.52 ($p = 0.008$, 95% CI: -0.89, -0.14)] and with an increase in the perceived social connection [mean standardized effect size for social connection using COVID Feel Good compared to the control conditions was 0.50 ($p = < 0.001$, 95% CI: 0.25, 0.76)]. **Conclusion:** Globally, these findings suggest the efficacy of the proposed protocol and contribute to the growing literature supporting the use of digital psychological interventions to reduce the psychological stress among the general population during the COVID-19 crisis. **Trial registration:** ISRCTN63887521

Keywords: Psychological Stress; Virtual Reality; Covid-19; Well-Being; Digital Technology; Self-Help Technology

Acronyms List

Virtual Reality= VR

Three hundred sixty-degree= 360°

Depression Anxiety Stress Scale= DASS-21

Perceived Stress Scale – 10= PSS-10

Beck Hopelessness Scale = BHS

Social Connectedness Scale = SCS

Linear mixed-effects model= LMM

Analyses of variance = ANOVA

Estimated marginal means = EMM

Standard error = SE

1. Introduction

With more than 5 million deaths worldwide, it is evident the catastrophic effect the COVID-19 pandemic is having on human health. Beyond considering the unprecedented impact of the pandemic itself on physical health, the indirect effects of COVID-19-related restrictive measures have rapidly led to a worldwide mental health crisis (1–3). During the initial phase of the COVID-19 outbreak, many countries introduced stringent public measures based on social distancing to contain the transmission of the disease (4–7). These containment measures soon proved to be effective to slow the spread of the pandemic, but resulted in negative psychological and social consequences, many of which have been outlined in recent literature (2,8–15). Social isolation, loneliness, drastic changes in family routine and work practices, and fear of being contaminated, are dramatically affecting people's quality of life and psychological well-being (16,17).

First of all, several studies suggested how a pandemic could have adverse psychological consequences in terms of an increase in anxiety, depression, and post-traumatic stress symptoms among specific groups in the population, such as COVID-19 survivors, health professionals, and vulnerable populations (9,10,18). However, there is now evidence that the COVID-19 emergency may also result in both short- and long-term negative mental health consequences in the general population (19–23). Reviewing available studies on the psychological distress associated with the COVID-19 pandemic and related social distancing measures among the general population, Luo and colleagues (14) found that the pooled prevalence of anxiety and depression levels was 32% and 27%, respectively. In the same perspective, Salari and colleagues (13) found that the pooled prevalence of stress, anxiety, and depression feelings was 29.6, 31.9, and 33.7% respectively. A meta-analysis carried out on 25 longitudinal studies and natural experiments indicated a small, but significant effect of COVID-19 lockdowns on mental health

symptoms among the general population (24). Specifically, subgroup analyses suggested that depression and anxiety levels showed a significant effect due to the lockdowns.

These emerging mental health issues, even present among the general population, require effective, innovative psychological interventions (8,9,25,26). In fact, mental health care providers have been challenged with unprecedented difficulties during the pandemic. A recent survey carried out in 130 different countries by the World Health Organisation reported severe disruptions in mental health services during the COVID-19 crisis for most countries, while the demand for mental health is highly increasing (27). In this scenario, digital devices, such as Virtual Reality (VR) or mobile platforms, may play an important role in supporting the delivery of affordable and scalable self-help interventions to a large portion of population (28–30), considering the logistic and economic barriers that can limit the access to traditional mental health providers (30,31).

The scientific and clinical community has risen to the challenge and significant effort has been devoted to the development and testing of effective digital interventions for overcoming the psychological burden associated with the COVID-19 crisis. A first, living systematic review is now collecting and analyzing evidence from randomized controlled trials carried out so far to address COVID-19 mental health challenges (32). Authors classified psychological interventions during the COVID-19 pandemic into two types: trials specifically designed to address COVID-19 mental health issues and trials that tested the efficacy of standard psychological interventions during this peculiar period, but without a significant adaptation for the pandemic. Among the first group, Wahlund and collaborators (33) tested the efficacy of a self-guided, internet-based cognitive-behavioural intervention targeting dysfunctional COVID-19 worry on 670 individuals in Sweden; they found a significant decrease in COVID-19 anxiety and depression symptoms. An interesting example of the second type of interventions was offered by Pizarro-Ruiz and colleagues (34), who tested the efficacy of a mindfulness-based intervention delivered through a mobile-based application called “Aire Fresco” (Fresh Air) for 14 days in the middle of the national lockdown implemented in Spain.

In this context, our team developed the COVID Feel Good intervention (35), a novel self-administered Virtual Reality (VR)-based intervention aimed at supporting individuals to cope with the psychological distress experience during the lockdown. The protocol consists of watching a 10-minute three hundred and sixty-degree (360°) video, titled “The Secret Garden”, each day for one week. The video immerses participants in a natural environment to promote relaxation and self-reflection, and the intervention is combined with daily social exercises with targeted goals that are designed to be experienced with another person. Moreover, the intervention is currently available (<https://www.covidfeelgood.com/>) in twelve different languages - English, Spanish, French, Brazilian/Portuguese, German, Italian, Turkish, Japanese, Korean, Farsi, Romanian and Catalan to offer participants worldwide a free and scalable instrument to cope with the psychological distress associated with the COVID-19 emergency.

We carried out a first effectiveness study on 40 individuals having experienced at least two months of strict social distancing measures in Italy between June and July 2020 (36) to preliminarily investigate the feasibility of our protocol. Findings indicated that participants showed an improvement from baseline to post-intervention for depression levels, stress symptoms, general distress, perceived stress levels and perceived social connection. Interestingly, these significant improvements were maintained from postintervention to the 2-week follow-up. Although being interesting both theoretically and clinically, these results have to be replicated in larger samples and should be generalizable to other contexts. Consequently, the primary aim of the present study was to further investigate the efficacy of the COVID Feel Good intervention in helping individuals to cope with the psychological burden related to the COVID-19 pandemic and restrictive social distancing measures across different countries. For this purpose, we focused on participants recruited from June 2020 to May 2021 in the context of a European multicenter project including four countries and their relative university/academic sites. Our primary objective was to investigate whether the participation in the VR-based self-help protocol COVID Feel Good would be associated with a reduction of depressive and anxiety symptoms, perceived levels of stress, hopelessness (primary outcome measures), and with an increase of the interpersonal closeness (secondary outcome

measure) with respect to the control conditions. To assess the efficacy of the intervention in a multicentric context, we evaluated the strength of evidence supporting the COVID Feel Good computing a single summary estimate of the effect across the different countries.

2. Material and Methods

2.1 Study design

In the present study, we collated data from longitudinal studies and randomized controlled trials conducted between June 2020 and May 2021 to evaluate the efficacy of the COVID Feel Good intervention in four different university/academic sites located in different European countries (see Supplementary Material, Table S1 for detailed information about each included study). The scientific and clinical rationale of the COVID Feel Good multicenter pragmatic trial has previously been described in detail here (37). Procedural changes and research interruptions due to COVID-19 regulations impacted data collection worldwide; therefore, each laboratory applied a suitable experimental design compatible with COVID-19 restrictions active at the time of data collection. Accordingly, this European multicentric study included both longitudinal trials and one randomized controlled trial (see Table S1). Regarding the longitudinal trials (i.e., Study 1, Study 2, and Study 3), participants received a psychological assessment survey including all the outcome measures to be completed online through an online survey and were informed that their intervention would start after a 1-week control waiting period. When the waiting period (i.e., control condition, T0) was over, participants received another survey to be completed online (i.e., the baseline psychological assessment, T1) with instructions to start the protocol and the self-help materials as an email attachment. At the end of the intervention, they received another survey with the post-intervention assessment (i.e., post-intervention assessment, T2). Regarding the randomized controlled study (Study 4), participants were randomly assigned to the experimental (COVID Feel Good Intervention) or to the control group (Control Condition). Participants in the randomized controlled study were allocated to the intervention or the control group in a proportion 1:1. Baseline measures were collected at the beginning of the intervention (namely, the baseline psychological assessment, T1) and at the end of the intervention

(namely, post-intervention assessment, T2). Participants in the control group were assessed at the same time intervals, with the baseline psychological assessment T1 and after seven days (T1). All studies included a 2-week follow-up (T3).

2.2 Participants

From June 2020 to May 2021, participants in four different countries (Italy, Switzerland, Germany and Spain) were recruited through the combined use of traditional strategies and advertisements on different social media platforms. Participants engaged in the COVID Feel Good intervention for one week. Inclusion criteria for participation across countries included the following: being at least 18 years old; 2) living in the respective country of residence during the COVID-19 pandemic; 3) having as their mother tongue the language of the country of their residence during the pandemic; 4) having experienced at least two months of strict social distancing measures; 5) availability and agreement of a partner for conducting the relational component of the treatment; 6) availability of a smartphone with Internet access, and 7) normal or corrected-to-normal vision. Exclusion criteria (all self-reported) included the presence of a diagnosis of a major mental disorder, a lack of stereoscopic vision or a balance/vestibular problem that would disrupt the VR experience. The total number of participants in the longitudinal studies was 107. Altogether 31 participants were recruited for the randomized controlled study, 16 in the intervention group and 15 in the control group. The institutional ethical review board of the coordinator site approved the study (2020_06_16_09) and the trial was registered (Trial ID: ISRCTN63887521). All participants signed an informed consent form, and the study was done in accordance with the Declaration of Helsinki.

2.3 COVID Feel Good Intervention

The COVID Feel Good intervention (36,37) is a daily self-help intervention including seven modules. Each module consists of two integrated parts: the first part consists of watching a 10-minute 360° video entitled “Secret Garden” (see Figure 1), while the second part includes specific social exercises with different goals for each day.

[FIGURE 1]

The 360° video “Secret Garden” was developed by a team of developers, psychologists, 3D artists, musicians, and storytellers to offer participants a relaxing and joyful “journey” in a beautiful natural environment¹.

Participants are immersed in a Japanese garden, while listening to a relaxation induction narrative structured following the principles of Compassion Focused Therapy (38,39). This guided narrative aims at deactivating the human threat protection system and activating the soothing system, with a mindset devoted to giving and receiving care and nurturance. To guarantee the scalability of the protocol (see Table S1), the 360° video can be accessed both in immersive (i.e., through a Head Mounted Display or low-cost cardboard connected with a smartphone) or in a non-immersive way (i.e., for instance, YouTube supports 360° video formats both in its Android app and on its website). The second part of the protocol includes a series of social exercises to be experienced each day with another person (physically present or not). These social tasks were developed following guidelines from Winch (40) to support individuals in coping with emotional experiences that can generate emotional pain, loneliness, rejection, or rumination. Participants are invited to perform these social tasks related to personal identity and interpersonal relationships. Each task has a different objective:

- Day 1: Support to cope with stress, negative intrusive thoughts and worries related to the COVID-19 pandemic.
- Day 2: Increase in self-esteem.
- Day 3: Promotion in the use of autobiographical memories to create a stable representation of themselves over time, as well as increase intimacy and connectedness by sharing personal memories.
- Day 4: Enhanced sense of community.
- Day 5: Promotion in conscious self-regulation and self-organization of life goals.
- Day 6: Increase in empathy.

¹ The 360° Secret Garden video is still investigational.

- Day 7: Support a long-term positive psychological change.

The full description of the sessions is provided in Riva et al. (36,37).

2.4 Outcome measures

The primary outcome variables were depression, anxiety and stress levels, and perceived general distress, measured with the Depression Anxiety Stress Scale (DASS-21) (41); the perceived stress level, measured with the Perceived Stress Scale - 10 (PSS-10) (42), and perceived hopelessness, assessed with the Beck Hopelessness Scale (BHS) (43). The secondary outcome variable was perceived social connectedness, assessed with the Social Connectedness Scale (SCS) (44).

2.5 Data analysis

First, separate linear mixed-effects models (LMM, estimated using REML and bobyqa optimizer) were fitted to evaluate the effectiveness of the treatment stratified for longitudinal and randomized trials. For longitudinal studies, separate models were fitted to evaluate changes for each outcome score (depressive feelings, anxiety feelings, stress feelings, general distress, perceived stress level, perceived hopelessness, perceived social connection) across four time-points from the waiting period [control condition, seven days before the start of the treatment (T0) to baseline evaluation (T1)] to the post-intervention (T2) and follow-up assessment (T3)]. For the randomized controlled study, separate models were fitted to evaluate changes for each outcome score (depressive feelings, anxiety feelings, stress feelings, general distress, perceived stress level, perceived hopelessness, and perceived social connection) across three time periods [baseline assessment (T0), post-intervention evaluation (T1), and follow-up (T2)] and two groups (intervention vs. control group). All models were run according to the following formula = Outcome ~ Time. For longitudinal trials (Study 1-Italy, Study 2- Switzerland, Study 3- Germany), all models included a multilevel random effects structure with participants nested within countries (lmer formula = (1|Country:ID). For the randomized trial (Study 4 - Spain) only ID was put as random effect with random intercept and fixed slope (lmer formula = Outcome ~ Time*Group+(1|ID). Assumptions for all models were satisfied with bobyqa optimizer. In addition, conditional (variance of both fixed and random effects)

R^2 and the intra-class correlation (ICC) of the random effects were computed to assess the goodness-of-fit. Table S2 and TableS3 (Supplementary Material) present the parameters estimated for each model (longitudinal and randomized) that was fitted. Analyses of variance (ANOVA) on selected LMM parameters were performed with Kenward-Roger approximation for degrees of freedom (45). Significant effects were examined with post-hoc comparisons (Bonferroni's adjustment) and are reported with estimated marginal means (EMM) and standard error (SE) in Table S4 (see Supplementary Information).

Then, to obtain a single summary estimate of the effect (46), delta scores for the four scales of the DASS-21 (depressive feelings, anxiety feelings, stress feelings, general distress), perceived stress scale (PSS), Beck hopelessness scale (BHS), and social connection scale (SCS) were computed. For the randomized study the delta score was calculated by subtracting T0 from T1 (T1-T0) values in the two groups. For the longitudinal trials, the delta score for the control period was calculated by subtracting T0 from T1 (T1-T0) and for the treatment period was calculated by subtracting T1 from T2 (T2-T1). Effect size estimates were calculated as standardized mean differences (SMD). SMD are interpreted according to Cohen's rule of thumb. In particular, to get an overall estimate of the treatment, we performed random effects models without moderators to pool results from different countries and experimental designs (47,48). Negative SMD for the SCS are interpreted as a protective effect of the treatment, whereas positive SMD for the other scales as a beneficial effect of the intervention. SMD are interpreted according to the direction of the scales from pre to post-test. Positive SMD for the SCS score is interpreted as a protective effect of the treatment (i.e., a positive delta score implies an improvement in SCS), whereas negative SMD for the other scales as a beneficial effect of the intervention (i.e., a negative delta score implies a reduction of symptoms). The Linear Mixed Models were run in R Studio Version 3.6.3 with the following packages Lme4 (49) with restricted maximum likelihood (50), lmerTest (51), emmeans (52) and metafor (53).

3. Results

A total number of 136 participants were included in the study (Study 1- Italy N=40, Study 2 - Germany N=38, Study 3 - Switzerland N=29, Spain N=29). The mean age of the total sample was 34.4

(SD=13.2, min=19 - max=69). The total number of female participants was 90, while the total number of male participants was 46.

3.1 LMM results

Regarding the randomized controlled trial, ANOVA on the LMM's parameters indicated a Group by Time interaction (Figure 2) for the primary outcome of the perceived stress level ($F(2,54) = 3.42$, $p = 0.04$, $\eta^2p = 0.11$). No other significant effect was found. The model had a conditional R^2 of 0.84 and 83.5% of the variance in the response variable was explained by the random participant effect. Bonferroni-corrected post-hoc comparisons indicated a significant improvement in stress levels for the COVID Feel Good Group (Experimental Group) from T0 to T2 (EMM = 3.71, SE = 1.09, $p = 0.003$). In addition, we found a significant decrease of depressive feelings as measure by DASS-21 across the three time points (Main effect of Time: $F(2,54) = 7.2$, $p = 0.002$, $\eta^2p = 0.21$). No other significant effect was found. The model had a conditional R^2 of 0.76 and 73.5% of the variance in the response variable was explained by the random participant effect. Bonferroni-corrected post-hoc comparisons showed that regardless of the Group condition, depression levels decreased from T0 to T2 (EMM = 1.57, SE = 0.45, $p = 0.003$) and from T1 to T2 (EMM = 1.35, SE = 0.45, $p = 0.012$). Again, a main effect of Time was found to be significant for the stress feelings as measured with DASS-21 ($F(2,54) = 5.81$, $p = 0.005$, $\eta^2p = 0.18$). No other significant effect was found. The model had a conditional R^2 of 0.71 and 70.1% of the variance in the response variable was explained by the random participant effect. Bonferroni-corrected post-hoc comparisons indicated that regardless of the variable Group, with stress symptoms decreasing from T0 to T2 (EMM = 1.73, SE = 0.51, $p = 0.004$). As above, a main effect of Time was found for the General Distress total score of the DASS-21 ($F(2,54) = 7.8$, $p = 0.001$, $\eta^2p = 0.22$). Bonferroni-corrected post-hoc comparisons showed that regardless of the variable Group, perceived general stress level dropped from T0 to T2 (EMM = 4.01, SE = 1.05, $p = 0.001$) and from T1 and T2 (EMM = 2.88, SE = 1.05, $p = 0.025$). Regarding the other scales, we found no other significant results (see Supplementary Material, Table S2).

[FIGURE 2]

Regarding the longitudinal trials, analysis of variance (ANOVA) on the LMM's parameters indicated a significant effect of Time for all outcome measures (see in the Supplementary Material, Table S3 and in Table S4). Interestingly, we found a significant effect of the intervention for the perceived stress level as measured with PPS ($F(3,316) = 14.78, p < 0.001, \eta^2p = 0.12$). Bonferroni-corrected post-hoc comparisons showed that perceived stress levels improved from T0 to T2 (EMM = 2.72, SE = 0.56, $p < 0.001$), from T0 to T3 (EMM = 2.7, SE = 0.56, $p < 0.001$), from T1 to T2 (EMM = 2.54, SE = 0.56, $p < 0.001$), and from T1 to T3 (EMM = 2.52, SE = 0.56, $p < 0.001$), and from T1 to T3 (EMM = 2.52, SE = 0.56, $p < 0.001$). See Figure 3 for a summary of these findings.

[FIGURE 3]

3.2 Global evaluation of the COVID Feel Good Intervention

To quantify the pooled efficacy of our intervention regardless of the type of experimental design, number of participants in the groups, and country, we performed a random effect meta-analysis using SMD as a measure of the effect size of the treatment. The greatest effects of the treatment were found for the General Distress (DASS-21) and perceived social connectedness, with a medium effect size (SMD between 0.50 and 0.79). Compared to the control conditions, the overall effect of the COVID Feel Good intervention for General Distress (see Figure 4) was -0.52 (95% CI: -0.89, -0.14, $z = -2.67, p = 0.008$) with substantial heterogeneity that however was not significant ($Q = 6.14, df = 3, p = 0.10, I^2 = 51.26\%$).

[FIGURE 4]

Again, compared to the control conditions, the overall effect of the treatment for the perceived social connectedness (see Figure 5) was 0.5 (95% CI: 0.25, 0.76, $z = -3.6, p < 0.001$) with null heterogeneity ($Q = 0.39, df = 3, p = 0.94, I^2 = 0\%$). All the other pooled results are reported in Table 1.

[FIGURE 5]

[TABLE 1]

4. Discussion

The COVID-19 pandemic and the consequent social distancing measures posed a particular challenge for individuals' psychological well-being. Serious interference with everyday life increased the psychological burden, while accessibility to traditional mental health services was limited. There is now increasing evidence regarding the efficacy of digital psychological interventions, including efficacy for mental health outcomes that are likely to be influenced by the COVID-19 mental health crisis (54,55).

In this scenario, the general objective of the current study was to investigate the efficacy of a novel self-help digital intervention (COVID Feel Good) in helping individuals to cope with the psychological burden related to the COVID-19 pandemic and related restrictive measures across different countries in the context of a European multinational, multicenter project. Thus, we collated data from three longitudinal studies and one randomized controlled trial conducted between June 2020 and May 2021 in four university/academic sites located in different European countries. The total sample consisted of 136 participants who experienced at least two months of strict social distancing measures, including a “stay-at-home” order, implemented by their respective countries. Participants engaged in the COVID Feel Good intervention for one week. Primary outcome measures were depression, anxiety, and stress levels, perceived general distress, perceived stress levels and hopelessness, while the secondary outcome was the experienced social connectedness.

Using separate linear mixed-effect models, we initially evaluated whether the Covid Feel Good Intervention would be able to ameliorate participants' psychological well-being in the different countries and contexts. The most consistent finding across the different countries was an improvement of the perceived stress level after the participation in the COVID Feel Good intervention. Regarding the randomized controlled trial, we observed an improvement in the perceived stress level from baseline to the follow-up assessment for the participants who were assigned to the experimental group (COVID Feel Good Intervention), in comparison to participants in the control group. For the longitudinal studies, results revealed a significant improvement for all outcome variables considered, including the perceived stress level. In addition, these improvements were maintained during the 2-week follow-up. Second, we investigated the efficacy of the intervention, the strength of evidence supporting the COVID Feel Good

intervention in a multicentric context by computing a single summary estimate of the effect across the different countries. By pooling the results of the models using a random-effect meta-analysis, results revealed that the COVID Feel Good intervention was associated with a decrease in the perceived general distress and with an increase in the perceived social connection as compared to the control conditions.

The results obtained in the current study are consistent with our preliminary findings showing the effectiveness of COVID Feel Good in reducing the psychological distress experienced during the lockdown in a sample of Italian participants (36). However, the current trial is the first one demonstrating the efficacy of a short, digital self-help intervention in reducing the psychological distress and enhancing perceived social connection towards other individuals across four different European countries.

The proposed protocol has several advantages to adequately support individuals in facing mental health issues associated with the COVID-19 crisis: it offers a brief, self-guided intervention, easily accessible through different digital devices (i.e., immersive and non-immersive modalities) and available in multiple languages. Self-help interventions have been demonstrated to be effective for different psychological disorders (38,57–59). However, the self-help format is particularly encouraged during the COVID-19 pandemic, as it is less expensive, does not require physical contact with the therapist and is easily scalable (60). For example, Wasil and colleagues (61) investigated the acceptability and effectiveness of a single-session intervention (from the Common Elements Toolbox, adapted for the COVID-19 crisis) in a sample of graduate and professional students. Their findings indicated that this brief digital self-help intervention was able to provide support to individuals during the pandemic, and it was also perceived as acceptable, helpful, engaging and applicable to daily contexts.

Moreover, self-help interventions offer a promising solution to the COVID-19 mental health crisis because such interventions can be delivered through different media, including VR. In developing the COVID Feel intervention we have indeed exploited the potentiality of VR to offer participants the possibility to be immersed in a naturalistic and beautiful space (62), for diffusion of daily stressors experienced during the pandemic, where they are guided to learn specific relaxation skills. The beneficial effect of VR as a safe space to increase nature exposure during the COVID-19 pandemic has been recently

demonstrated among young adults and senior citizens (63). Across both samples, they found that walking in “virtual nature” was successful in reducing negative affect and enhancing nature connectedness.

In addition, considering that stay-at-home orders and social distancing behaviors drastically reduce the possibility to gain social support against the psychological stressors related to the COVID-19 emergency (Ye et al., 2020), COVID Feel Good specifically aims at increasing social connectedness and facilitating participation in social interactions (55). Participants are asked each day to perform a social task that is developed to facilitate a process of self-reflection (37) with another significant person (present or at-distance). Our results confirmed that the intervention was associated globally with a decrease in perceived general distress and with an increase in the perceived social connectedness. Our findings are in line with recent findings indicating that higher levels of social connectedness during the lockdown period are associated with lower levels of perceived stress (64).

4.1 Conclusion

The COVID-19 pandemic is forcing the healthcare system to more adequately tackle a global emergency for both physical and mental health. The negative psychological effects exacerbated by COVID-19 may have been aggravated by the logistical challenges and economic difficulties associated with the traditional face-to-face delivery of psychological services. An important challenge in this context will be to develop and test innovative digital self-help psychological interventions that can be easily accessed without geographic and economic barriers providing a first-aid psychological support to the general population (8,25,26). Globally, our findings from a multicentric European trial suggest the efficacy of the proposed self-help VR-based protocol and contribute to the growing literature supporting the use of digital psychological interventions to reduce psychological stress among the general population during the COVID-19 crisis (8,25,26,56).

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Table

Table 1. Summary of the meta-analysis results. Negative SMD estimate indicates a reduction in the symptoms compared to the control condition, positive SMD estimate indicates an improvement in SCS for the treatment compared to the control condition. BHS: Beck Hopelessness Scale; PSS: Perceived Stress Scale, SCS: Social Connection Scale. Q: Cochran's Q p-value.

Outcome measure	Estimate	SE	z-value	p-value	lower CI	upper CI	I ²	Q (p-value)
Depression	-0.44	0.13	-3.37	0.001	-0.69	-0.18	0.00	0.50
Anxiety	-0.42	0.13	-3.27	0.001	-0.68	-0.17	0.00	0.60
Stress	-0.43	0.20	-2.14	0.032	-0.82	-0.04	54.75	0.09
Distress	-0.52	0.19	-2.67	0.008	-0.89	-0.14	51.26	0.10
PSS	-0.49	0.13	-3.72	< 0.001	-0.74	-0.23	0.00	0.50
BHS	-0.17	0.13	-1.28	0.199	-0.42	0.09	0.00	0.78
SCS	0.50	0.13	3.86	< 0.001	0.25	0.76	0.00	0.94

Figure

Figure 1: The Secret Garden 360° video

Figure 2: Regarding the randomized controlled trial, we observed an improvement in the perceived stress level from baseline to the follow-up assessment for the participants who were assigned to the experimental

group (COVID Feel Good Intervention), in comparison to participants in the control group. Mean and 95%CI are depicted in the plot. Individual data points and line represent the longitudinal trends for each participant in the two groups. ** <0.01

Figure 3: Longitudinal trials: Bonferroni adjusted-pairwise comparisons for DASS-21 Depression Subscale (DASS_21 Depression,) DASS-21 Anxiety Subscale (DASS_21 Anxiety), DASS-21 Stress Subscale (DASS_21 Stress), DASS-21 General Distress (DASS_21 General Distress, Beck Hopelessness Scale (BHS), Perceived Stress Scale (PSS), Fear of Coronavirus outcome (FCOR, F), and Social Connectedness Scale (SCS) across the different time points. Mean and 95%CI intervals are depicted in the plots. * < 0.05; ** <0.01; ***<0.001

Figure 4. Results from random effect meta-analysis- General Distress (DASS-21). C: control group; VR: VR-based self-help intervention group

Figure 5. Results from random effect meta-analysis- Social Connection Scale (SCS). C: control group; VR: VR-based self-help intervention group