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Effectiveness of Self-Help Plus in its digital version in reducing anxiety and post-traumatic symptomatology among nursing home workers during the COVID-19 pandemic: secondary analysis of randomised controlled trial data

Marianna Purgato [iD],[1] Federico Tedeschi,[1] Marianna Riello,[2] Debora Zaccoletti,[1] Roberto Mediavilla [iD],[3] Jose Luis Ayuso-Mateos [iD],[3] David MacTaggart,[4] Corrado Barbui,[1] Elena Rusconi[2]

[1]WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation, Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, Verona, Italy
[2]Department of Psychology and Cognitive Science, University of Trento, Trento, Italy
[3]Universidad Autónoma de Madrid, Madrid, Spain
[4]University of Glasgow, Glasgow, UK

Correspondence to
Prof. Marianna Purgato; marianna.purgato@univr.it
Professor Elena Rusconi; elena.rusconi@unitn.it

ABSTRACT

Background Healthcare workers (HCWs) face substantial daily work-related pressures, leading to frequent reports of depression, anxiety and post-traumatic stress disorder (PTSD) symptoms.

Objective To compare the effects of Self-Help Plus in its digital version Doing What Matters in Times of Stress (DWM) to an equally structured activity in reducing anxiety and/or PTSD symptoms among HCWs.

Methods We compared the proportion of participants with moderate-to-severe anxiety (General Anxiety Disorder Scale; GAD-7 ≥10) and/or PTSD symptoms (Impact of Event Scale-Revised (IES-R)) ≥26) between DWM and the alternative activity. We used an intention to treat analysis and performed χ^2 tests at 1 and 14 weeks. We assessed compliance (≥five logins) and conducted per-protocol analyses. We also analysed GAD-7 and IES-R scores as continuous outcomes. Possible differential effectiveness was also assessed through login frequency.

Findings At 14 weeks, 14.5% of DWM and 27.6% of control participants showed at least moderate anxiety and/or PTSD symptoms (χ^2=3.712, p=0.054). Among those with ≥five logins, DWM participants had fewer moderate symptoms (10.6% vs 31.4%, p=0.012), with reductions in anxiety (6.3% vs 19.6%, p=0.049) and PTSD symptoms (6.4% vs 27.5%, p=0.006). At 1 week, 30.6% of DWM and 28.2% of control participants reported moderate symptoms (χ^2=0.113, p=0.736). Interaction analysis suggested compliance influenced outcomes (OR 4.560, p=0.096 at 14 weeks; OR 0.266, p=0.067 at 1 week).

Conclusions DWM is a promising strategy to reduce moderate-to-severe PTSD and/or anxiety symptoms in HCWs. Compliance is crucial to ensure efficacy.

Clinical implications DWM is a scalable digital tool that could be considered as an intermediate or complementary intervention for distressed HCWs.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Self-Help Plus in its digital version Doing What Matters in Times of Stress (DWM) has been tested for effectiveness in healthcare workers. However, its effectiveness on moderate to severe symptomatology cut-offs, and the role of compliance has not been investigated.

WHAT THIS STUDY ADDS

⇒ Our results demonstrated that DWM is a promising intervention for reducing moderate-to-severe anxiety and post-traumatic stress disorder symptoms in the medium-term, with significant differences compared with a structured alternative activity. Additionally, compliance was a key factor influencing DWM's effectiveness.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our results could promote the use of digital psychological interventions, such as the WHO DWM in preventing distress and common mental health conditions in vulnerable population groups exposed to stressors.

clinical work with patients and/or their relatives, diseases, suffering and death. These stressors also include time pressure, the responsibility of making decisions, numerous organisational challenges, rigid hierarchies, staff reductions, increased administrative tasks and societal expectations.[1] These and other factors make it difficult to engage and retain HCWs across different health settings. Moreover, intense and prolonged exposure to stressors can significantly impact their mental health. Specifically, HCWs frequently report burnout symptoms and an increase in stress-related mental disorders, including depression, anxiety and post-traumatic stress disorder (PTSD).[2] The recent COVID-19 pandemic represented an additional factor that exerted a unique taxing impact that was dreadfully

BACKGROUND

Healthcare workers (HCWs) are exposed daily to substantial stressors, which are related to their

intertwined with an already complex backdrop of psychological distress. In Italy, there was a sudden and localised surge in infections during the early months of the pandemic. According to recent statistics from the Population Reference Bureau, Italy ranks among the top 10 countries in the world for the largest percentage of older adults (65+).[3] Data released by the Italian Ministry of Health[4] reported that the number of deaths for COVID-19 in Italy went from 10 to 32 007 between 25 February and 18 May 2020. This represents 13% of the individuals who tested positive for the presence of the virus.[4] At least 86% of those deaths were located in the North of Italy.[3] A national survey conducted by Istituto Superiore di Sanità on COVID-19 during the acute phase of the pandemic in 1082 Italian nursing homes (NHs) found that, as of 1 February 2020, 80 131 residents were hosted across these facilities. By 14 April 2020, 6773 residents had died, with 40.2% suspected or confirmed as COVID-19 cases. Again, this scenario predominantly refers to Northern Italy, where our study was conducted. Staff across all roles faced significant physical and psychological difficulties in relation to the public health emergency. Many healthcare and administrative workers tested positive for COVID-19, underscoring heightened exposure and concrete risk for NH workers during the pandemic. For these reasons, NHs were among the health services that experienced the most challenging circumstances during the pandemic, with psychological repercussions on HCWs. Pooled prevalence estimates indicate that at least one in three HCWs reported symptoms of common mental disorders, such as depression, anxiety and/or PTSD during the pandemic. An epidemiological study conducted in NHs in Northern Italy estimated a prevalence of 43% for the moderate-to-severe anxiety and/or PTSD symptomatology, particularly in women and those who had been in contact with COVID-19-positive individuals.[5] These figures are consistent with those from international epidemiological studies conducted in other European and non-European countries[6–9] and highlighted the need for HCWs of receiving psychological interventions. However, it would not be possible to provide traditional one-to-one or tailored psychotherapy to all the HCWs in person, and in a timely way.[10 11]

In recent years, the WHO has developed free-access psychological interventions intended to be highly scalable within emergency settings.[12] Among them, a stress management intervention named Self-Help Plus (SH+) and based on acceptance and commitment therapy (ACT).[13] SH+ is a low-intensity, guided self-help intervention for managing stress and coping with adversity. Randomised controlled trials (RCTs) testing SH+ in its digital version Doing What Matters in Times of Stress (DWM) in HCWs are scarce and present a mixed picture. For example, a randomised study conducted on workers in Italian residential NHs during the second wave of COVID-19 contagions did not report any difference between the DWM as a stand-alone intervention, when contrasted with an active control condition (reading and reflecting on a novel), in self-reported anxiety and/or PTSD symptomatology. In that study, both primary and secondary analyses focused on mild-to-severe symptomatology.[14] More recently, however, a randomised study testing a stepped-care programme of DWM and Problem Management Plus in HCWs in Spain identified a significant reduction of psychological symptoms of depression and anxiety in the experimental condition compared with care as usual.[15] Although all levels of severity contributed to primary and secondary analyses, the initial levels of anxiety are likely to be overall more severe than in Riello et al.[5 14]

Against this background, the present work aims to test whether SH+ in its digital version DWM was effective in reducing moderate-to-severe levels of anxiety and PTSD symptomatology in NH workers. A dichotomous outcome was developed using cut-offs on rating scales corresponding to moderate-to-severe anxiety and/or PTSD symptomatology. Research on the relationship between symptom severity at baseline, and the effectiveness of psychological interventions consistently suggests that individuals with more severe symptoms may experience greater benefits from psychological interventions.[16] This is a secondary analysis of Riello et al,[14] in which the cut-offs at rating scales corresponded to mild symptomatology. The focus on moderate to severe symptomatology cut-offs is also aligned with epidemiological data collected during the first phase of the pandemic.[5] Additionally, we aimed to test whether compliance could have an impact on the effect of the intervention.

METHODS
Objectives
In the present analysis, we primarily aimed to test whether DWM was effective in reducing anxiety and PTSD symptomatology defined as dichotomous outcomes according to cut-offs that correspond to moderate-to-severe anxiety symptomatology measured with the General Anxiety Disorder Scale (GAD-7 score ≥ 10[17]) and/or moderate-to-severe PTSD symptomatology measured with the Impact of Event Scale-Revised (IES-R score ≥ 26[18]). Our second aim was to test whether compliance could have an impact on the effect of the intervention. To test this hypothesis, we conducted a per-protocol (PP) analysis including participants who logged into the website of DWM or the control intervention at least five times—that was conservatively taken as a proxy of having accessed the majority of the intervention contents.[15] The primary aim of the trial of Riello et al[14] was to test the effectiveness of SH+ in its digital version DWM in reducing anxiety and/or PTSD symptomatology defined as a dichotomous outcome according to the cut-offs that correspond to mild-to-severe symptomatology in GAD-7[17] and IES-R.[18]

Study design
A protocol for this analysis was published in the Open Science Framework.[19] This study is a reanalysis of a single-blind, prospective, randomised, parallel-group study reported in Riello et al.[14] The study took place over a period of 20 weeks, from 10 March 2021 to 3 August 2021. Details of the RCT methods are found in Riello et al.[14]

Participants
Briefly, an RCT was conducted involving 238 NH workers in Northern Italian NHs during the second wave of the COVID-19 pandemic (see figure 1). Twenty-two NHs located in Northern Italy were recruited via convenience and snowball sampling. NHs were contacted simultaneously via mailing lists and informed about the intervention study, which would span 5 weeks plus an additional 3 months from the start of the intervention. We asked NH workers to complete an initial survey (including demographic information and baseline assessment). Participants were nursing and care home workers from the following groups: medical/healthcare staff, such as physicians, nurses, healthcare auxiliary staff, physiotherapists, psychiatric rehabilitation technicians, speech therapists and psychologists; technical staff, such as educators, entertainers, mediators, caseworkers, trainers, sociologists, specialised auxiliaries, technicians for the maintenance of the building and cleaning staff; administrative staff, such as directors, nursing coordinators, administrative collaborators or assistants and secretaries.
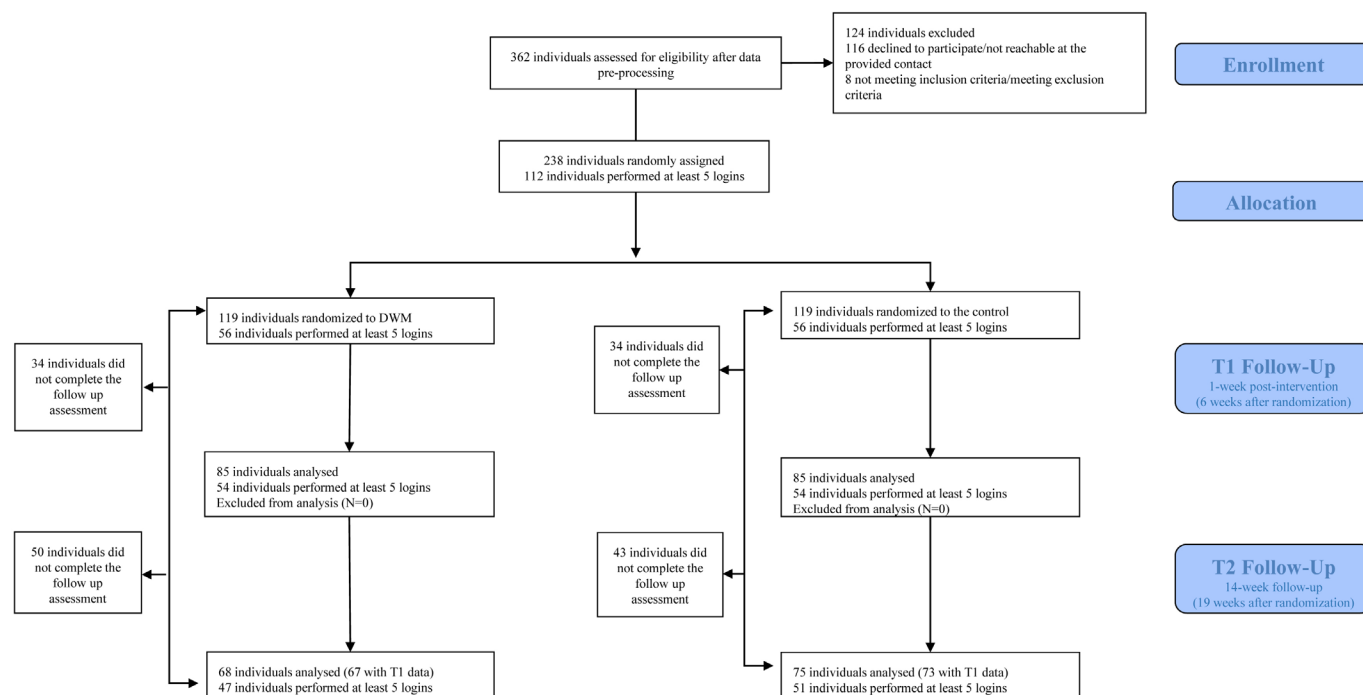
Figure 1 Consolidated Standards for Reporting Trials for Social and Psychological Interventions-SPI flow diagram. DWM, Doing What Matters in Times of Stress.

Participants were randomly allocated to DWM (n=119) or an alternative intervention strategy (n=119). For the present analysis, we considered participants with the following characteristics (as in Riello et al)[14]: (a) providing online informed consent to participate in the study; (b) aged 18 years or above; (c) able to speak, read and understand Italian fluently (self-assessed); (d) working in a Northern Italian NH as medical/healthcare, administrative or technical staff. The decision to include administrative and technical staff in our sample is related to the NH setting, in which the relationship between technical staff and NH hosts is close, as administrative staff frequently engage with hosts and their families, often daily. Most NHs in Italy host individuals for extended periods, fostering a welcoming, family-like atmosphere.[20] Moreover, during the pandemic, administrative staff reported psychological distress levels similar to those of HCWs; (e) passed the validity check at the baseline assessment. The validity check consisted of a few simple questions at the end of each questionnaire, similar to those in the Italian Wechsler Memory scale (eg, 'Who is the current Queen of the United Kingdom?', 'What is the capital of Italy?'), with the aim of controlling for careless responding. If a respondent from either the DWM or the control group did not respond correctly to two out of three of these questions at baseline, they could still access an intervention individually, but would be excluded from the randomisation and data analysis. Participants were only excluded at baseline to prevent biases affecting the validity of the randomisation, with baseline accuracy as a proxy for careful responding in the 1-week follow-up assessment. At the study onset, the informed consent form provided all participants with details on the intervention study, such as psychological techniques for stress management and promotion of reflection on work roles and related emotions. At the study onset, participants were also informed about mental health services offering free support for workers.

Intervention

DWM intervention arm

Participants in the intervention arm received a scalable psychological intervention, the WHO's SH+ in its digital version DWM. DWM consists of a guided self-help stress management course based on the booklet 'Doing What Matters in Times of Stress', that, as mentioned previously, features techniques from ACT (eg, acting on values, being kind, 'unhooking' from negative experiences) and is supported by individual audio-visual tools.[21] The intervention was delivered online over 5 weeks throughout a webpage easily accessible to participants. DWM materials were used for supervised self-help activities, instructing participants to listen to each section of the audio course and review the corresponding book sections autonomously within a specified time frame. On each week of the intervention, participants received individual, password-protected access to written and recorded materials for one of the five core themes and related activities, adapted minimally from the official Italian translation of DWM. The weekly topics included respectively 'Grounding' (week 2 of the trial), 'Unhooking' (week 3), 'Acting on your values' (week 4), 'Being kind' (week 5) and 'Making room' (week 6). After their release, the materials were accessible anytime via a dedicated website on participants' mobile phones. After each session, participants were able to log their activities, by selecting precompiled descriptors, and to fill in an online diary. Participants were required to access and work through the materials at their convenience each week. They also received reminders via WhatsApp, text or email, from an assistant with a background in psychology, supervised by academics and healthcare professionals throughout the intervention.

Alternative control activity group

Participants in the control group were engaged in reading the Italian translation of the short novel 'Leaf by Niggle',[22] a lesser-known story by a non-Italian modern writer, likely unfamiliar to

Table 1 Sociodemographic and clinical variables at baseline (N=238)	
Variable	**n (%)**
At least moderate symptoms	108 (45%)
Gender female	210 (88%)
Age 18–30	32 (13%)
Age 31–40	50 (21%)
Age 41–50	86 (36%)
Age 51 or more	70 (29%)
At most middle school	47 (20%)
High school	111 (47%)
University	80 (34%)
Administrative staff	27 (11%)
Healthcare	180 (76%)
Technical staff	31 (13%)
COVID-19 contacts	69 (29%)
Three or more stories	128 (54%)
Stories useful	154 (65%)
Login once only*	39 (20%)
Variable	**Mean (SD)**
GAD score at baseline	6.86 (4.07)
IES-R score at baseline	23.96 (14.86)

*Among those who have at least one login (N=193).
GAD, General Anxiety Disorder Scale; IES-R, Impact of Event Scale-Revised.

the participants. Unlike the intervention group, this novel aimed to provide a compassionate reading experience through relatable characters without directly teaching stress management techniques. However, if it occurred, its impact on mood and stress coping was expected to be more transient and variable compared with the systematic approach of the DWM intervention.[15] Our goal was to select a control activity for a non-clinical population that would offer a neutral yet engaging experience without delivering therapeutic support or skill development, as structured psychotherapy does.[23–25] The reading of Leaf by Niggle was intended to provide participants with a compassionate, reflective experience without directly addressing stress or anxiety reduction, thereby aligning more closely with the nature of the intervention arm. It is also important to note that this control condition enabled the use of the very same infrastructure for intervention delivery, with analogous materials and time investment required from all participants. Any changes in the recorded outcomes cannot be due to systematic confounds, such as (among others) different means of delivery, different styles and sensory modalities used to deliver the materials, different styles of supervision, the sheer number of materials and activities required. Matched to the intervention group contents, participants received tailored written materials, audio files and exercises to reflect on the story's content and relate it to other fictional or historical characters or their own work. These materials were accessed by individual credentials via the same website as the DWM group. In parallel with the intervention group, each intervention week provided new materials, related to the progress of the story and titled 'Kind heart' (week 2 of the trial) 'Altruism' (week 3), 'Gratitude' (week 4) 'Collaboration' (week 5) and 'What matters' (week 6), respectively. During each corresponding week, participants were reminded to engage with materials through WhatsApp, text or email, like the reminders sent to the DWM group. The control group materials were specifically created by researchers to closely match the format and time requirements of the DWM materials. Participants in the control group also received reminders via WhatsApp, text or email, from the same assistant

of the intervention group, supervised by academics and healthcare professionals throughout the intervention.

Assessments and outcomes

Demographic data were collected including: age, gender, education level, job title, information about the geographical location of respondent's NH.

The following clinical variables were considered: anxiety symptoms measured at baseline, 1-week and 14-week follow-ups using the 7-item GAD (GAD-7).[17] This scale is brief and easy to administer, demonstrated solid psychometric properties, along with good test–retest reliability both in psychiatric and general populations across different languages. It specifically targets symptoms of GAD, a condition with high comorbidity, where its key characteristic—worry—appears in several psychological disorders. The scale assesses the frequency and severity of GAD symptoms over the past 2 weeks, using seven items on a 4-point Likert scale. Responses range from 0 (not at all), 1 (several days), 2 (more than half the days) to 3 (nearly every day), with total scores spanning from 0 to 21.[17] PTSD symptoms were assessed at baseline, 1-week and 14-week follow-ups using the IES-R. This scale is one of the most commonly used tools for evaluating various aspects of trauma and has demonstrated strong test–retest reliability and psychometric validity across different languages and populations exposed to potentially traumatic events. It measures post-traumatic symptoms over the past 7 days through 22 items rated on a 5-point Likert scale.[18]

Statistical analyses
Main analyses of the primary outcomes

In this study, we explored differences between participants receiving the DWM, and participants receiving the control activity in the reduction of moderate-to-severe anxiety (GAD-7 score ≥10) and/or moderate-to-severe PTSD symptomatology (IES-R score ≥26). In an intention to treat (ITT) analysis, the proportion of participants reporting at least moderate symptoms at the first (1 week) and at the second (14 week) follow-up was compared between the two groups using a χ^2 test. We then repeated the analysis for the two scales (GAD-7 and IES-R) separately, by using the same thresholds as for the composite outcome. In order to take multiplicity into account (ie, the joint consideration of two outcome measures simultaneously), at each timepoint, we used the Benjamini-Hochberg correction with a 0.1 threshold. Since two separate tests were implemented, this implied that the effect of DWM on one scale would be considered statistically significant, regardless of its effect on the other scale, if reaching the 0.05 p value threshold. At the same time, DWM would have been considered as significantly better than the alternative intervention for both scales, in the case of both tests reaching the 0.1 threshold. This corresponds to a false discovery rate of 0.1, meaning that, on average, no more than 10% of significant findings will be false (ie, due to chance rather than to an actual effect).[26]

Secondary analyses of the primary outcomes

We also performed PP analyses, restricted to participants performing at least five logins. More precisely, the analyses were performed both on the dichotomous outcomes of this manuscript (moderate-to-severe symptomatology) and on the dichotomous outcomes of Riello *et al*[14] (mild-to-severe symptomatology), together with analyses with the scores for GAD-7 and IES-R considered as continuous variables. Both at the 1-week and the 14-week follow-ups, we tested the effect of

DWM on GAD-7 and IES-R by performing seemingly unrelated regressions (SURs),[27] controlling for their baseline values. In case of joint statistical significance of the coefficients related to treatment status, the effect of treatment on each score was evaluated by performing the regression for each outcome separately, using the Benjamini-Hochberg correction with a 0.1 threshold. The inclusion of robust standard errors was performed in the case of the significance of White's test for heteroskedasticity.[28]

Furthermore, logistic regressions whose outcome was the presence of at least moderate symptoms in anxiety and/or post-traumatic symptomatology were performed, with treatment, having performed at least five logins, and their interaction as predictors, in order to explore a possible differential effectiveness of DWM based on whether the minimum number-of-logins was met or not. Such analysis was performed both at 1-week follow-up and at 14-week follow-up, using the Benjamini-Hochberg correction with a 0.1 threshold.

Additional analyses
The PP and interaction analyses were also performed for the outcome mild-to-severe anxiety (GAD-7 score ≥ 5) and/or post-traumatic symptomatology (IES-R score ≥ 9) (ie, the main outcome used by Riello et al[14]). Finally, based on the hypothesis of a differential effect depending on baseline severity, we repeated the analyses on the main outcome at 1-week and at 14-week follow-up, separately for participants with and without at least moderate symptoms at baseline, using the Benjamini-Hochberg correction with a 0.1 threshold.

RESULTS
The directors of 33 NHs (n=1781) were initially invited to participate in the study by our research team. A total of 22 NHs (including 1781 NH workers, to whom Directors communicated this opportunity via email) agreed to participate. We collected demographic information and baseline data from 443 NH workers. We excluded participants who provided incomplete data (N=81; of which 73 interrupted soon after having provided consent, eight after having completed the GAD-7 questionnaire) and who did not respond to a confirmation request or withdrew following completion of the baseline assessment (N=116), or who indicated a job type that did not belong to any of the categories of interest/was part of the research team (N=6). Finally, only one (the first to enrol) of any two or more responding workers from NH who shared their accommodation with one another was entered into the randomisation process. The others were still given access to the same intervention randomly assigned to the participant, to prevent contamination between interventions. This led to the exclusion of a further two (N=2) respondents from randomisation. On average, there were 11 (SD=5; range: 4–20) participants per recruitment centre. The mean number of employees in the participating NHs is 81 (SD 61; range: 20–129). The mean number of residents of NHs in North Italy is 70.[29] The randomisation script is available on the Open Science Framework.[14]

Main analysis of the primary outcomes
Baseline clinical and sociodemographic characteristics of our sample are reported in table 1.

At 14 weeks, the percentage of participants passing the threshold for moderate symptoms at the IES-R and/or the GAD-7 was 14.5% (10/69) for the DWM and 27.6% (21/76) for the alternative intervention (χ^2=3.712, p value 0.054). Looking at each separate outcome, statistical significance at the 0.1 level

was met for both GAD-7, prevalence of at least moderate symptoms being 5.8% (4/70) for the DWM versus 16.0% (12/76) for the alternative intervention (χ^2=3.791, p value 0.052), and IES-R, moderate-to-severe symptoms being found for 11.6% (8/69) for the DWM versus 23.7% (18/76) for the alternative intervention (χ^2=3.592, p value 0.058).

At 1 week, the percentage of participants passing the threshold for moderate symptoms at the IES-R and/or the GAD-7 was 30.6% (26/85) for the DWM and 28.2% (24/85) for the alternative intervention (χ^2=0.113, p=0.736).

No statistically significant difference was found by looking at each scale separately. In particular, for GAD-7 at 1 week, prevalence of at least moderate symptoms was 10.6% (9/85) for the DWM versus 9.4% (8/85) for the alternative intervention (χ^2=0.065, p=0.798) while, for IES-R, the prevalence of moderate-to-severe symptoms was 24.7% (21/85) for the DWM versus 27.1% (23/85) for the alternative intervention (χ^2=0.123, p=0.726).

Secondary analyses of the primary outcomes
At the 14-week follow-up, among individuals performing at least five logins (PP analyses), the proportion with at least moderate symptoms was 10.64% (5/47) for DWM versus 31.37% (16/51) for the alternative intervention, and such a difference is statistically significant (p=0.012). Evidence of a difference between interventions was also found for anxiety and PTSD separately: at least moderate anxiety was present in 6.25% (3/48) of the individuals receiving the DWM versus 19.61% (10/51) of the individuals receiving the alternative intervention (p value 0.049), and at least moderate post-traumatic symptomatology was found for 6.38% (3/47) of the DWM group versus 27.45% (14/51) of the alternative intervention group (p value 0.006). The global test on the treatment effects in the SUR equations also found statistical significance (p value 0.036). Performance of each regression separately found a significant association in the case of IES-R (coefficient=5.388, 95% CI 1.207 to 9.568), but not of GAD-7 (coefficient=1.170, 95% CI −0.134, 2.474).

The interaction between treatment and whether at least five logins were performed in the model to predict the presence of moderate symptoms shows an OR of 0.219 (95% CI 0.037 to 1.308; 90% CI 0.049 to 0.981), with a p-value of 0.096.

The percentage of people with at least moderate symptoms at 14-week follow-up separately for compliant only and for all participants is shown in figure 2. Results for the other follow-up times/cut-off combinations are in online supplemental figures S1 and S2, section 1 of the online supplemental material. Table 2 describes results from ITT and PP analyses for both 'moderate-to-severe' and 'mild-to-severe' symptoms (see also Riello et al, 2021[14]).

PP analyses did not show evidence of any difference between the DWM group and the control group at the 1-week follow-up. In particular, one-fourth (25.93%; 14/54) of individuals receiving the DWM versus one-third (33.33%; 18/54) of those receiving the alternative treatment showed at least moderate symptoms (p=0.399); as for GAD-7, the levels were 7.4% (4/54) for the DWM versus 11.1% (6/54) for the alternative intervention (p=0.507); for IES-R, the percentages were 20.37% (11/54) versus 31.48% (17/54) for the alternative treatment (p=0.188). Finally, performing SURs, the p value of the joint test on the parameters related to treatment effect was non-significant either (p value 0.667).

A logistic regression to predict the presence of moderate symptoms including the interaction between treatment and
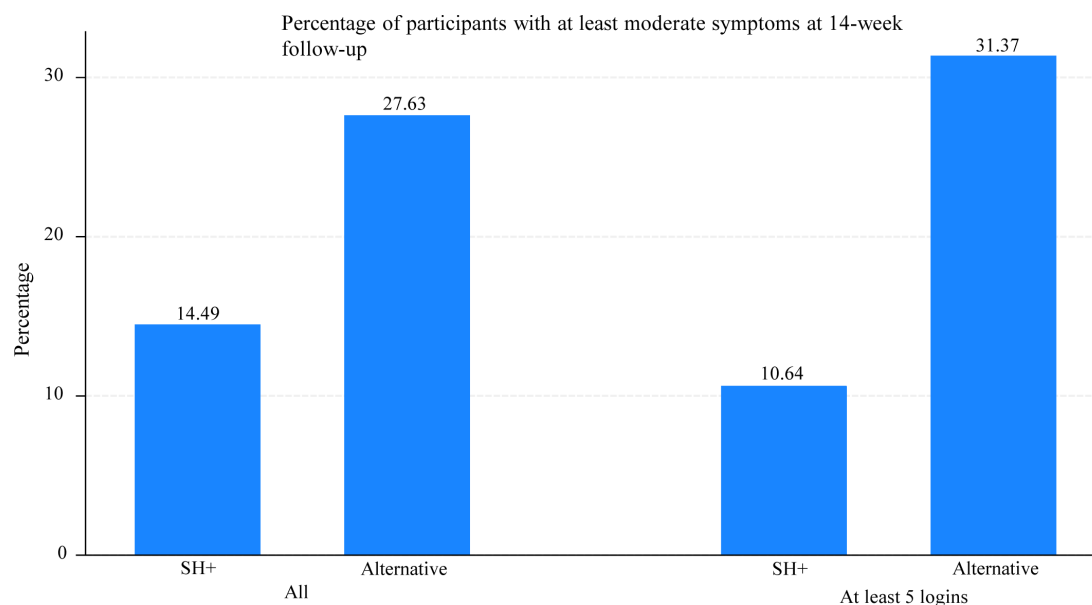
Percentage of participants with at least moderate symptoms at 14-week follow-up

Figure 2 Percentage of participants with at least moderate symptoms according to GAD-7 and IES-R at 14-week follow-up. GAD-7, 7-item General Anxiety Disorder Scale; IES-R, Impact of Event Scale Revised.

'compliance' shows an OR of 0.266 (95% CI 0.065 to 1.097; 90% CI 0.081 to 0.873), with a p value of 0.067. Thus, statistical significance at the 0.1 threshold was met for both time points. The percentage of people with at least moderate symptoms at 1-week follow-up for compliant only and for all participants is shown in (online supplemental figure S3.

Finally, results on the main outcome separately for participants with and without mild symptoms at baseline are shown in section 2 of the online supplemental material.

DISCUSSION

In the present study, we explored the effectiveness of the WHO psychological intervention SH+ in its digital version DWM in reducing anxiety and PTSD symptomatology in NH workers.

According to the ITT analysis at 1-week follow-up, we found no significant effect of the intervention on the primary outcomes. However, at the 14-week follow-up, we identified a beneficial effect in decreasing psychological symptoms. In the PP analysis, the intervention was effective at both the timepoints.

Our choice of focusing on moderate-to-severe anxiety and PTSD symptoms aimed to assess whether the intervention's effects differed by symptom severity at baseline. This focus is particularly important because individuals with more severe symptoms may respond differently to interventions compared with those with milder symptoms. The choice is also aligned with data from recent epidemiological studies, finding that at least mild symptoms are rather frequent.[30] In a cross-sectional

study conducted in France, the prevalence of anxiety, depression and peritraumatic dissociation symptoms was estimated at 50.4%, 30.4% and 32%, respectively, with the highest rates among nurses.[8] Additionally, a qualitative study in the Ireland found a prevalence of 45% for moderate-severe PTSD symptoms among NH staff during the pandemic.[6] In the same period, a study conducted in Saudi Arabia revealed a prevalence of mild (24.9%), moderate (14.5%), moderately severe (10%) and severe depression (5.8%); and moderate (11%) and severe (15.3%) anxiety symptoms among healthcare providers exhibiting mild-to-severe symptomatology.[9]

Regarding the effectiveness of SH+ in its digital version DWM, our results showed a positive effect at 14-week follow-up. These promising findings are consistent with those of an RCT conducted by Acarturk and colleagues on SH+ for asylum seekers and refugees in Turkey. The authors identified a strong beneficial effect of SH+ in reducing the frequency of mental disorders at 6 months, though not at postintervention.[31 32] This improvement at 14-week follow-up could be attributed to the opportunity for participants to practise the techniques and exercises learnt during the intervention, thereby becoming more independent in managing emotional distress. At the 1-week follow-up, participants may not have fully internalised the DWM techniques and needed additional time to integrate these practices into daily routines. The extended period likely provided ample time for reflection, practice and adaptation, helping participants build confidence and autonomy in

Table 2 Results from ITT and PP analyses for both moderate-to-severe and 'mild-to-severe' symptoms

		ITT			PP		
		DWM	Controls		DWM	Controls	
		n/N (%)	n/N (%)	P value	n/N (%)	n/N (%)	P value
1-week FU	Presence of at least mild symptoms	63/85 (74.12)	65/85 (76.47)	0.722	41/54 (75.93)	45/54 (83.33)	0.339
14-week FU		45/69 (65.22)	57/76 (75.00)	0.198	27/47 (57.45)	41/51 (80.39)	0.014
1-week FU	Presence of at least moderate symptoms	26/85 (30.59)	24/85 (28.24)	0.736	14/54 (25.93)	18/54 (33.33)	0.399
14-week FU		10/69 (14.49)	21/76 (27.63)	0.054	5/47 (10.64)	16/51 (31.37)	0.012

DWM, Doing What Matters in Times of Stress; FU, follow-up; ITT, intention to treat; PP, per protocol.

using the techniques to handle emotional challenges on their own. Although Acarturk and colleagues used a formal diagnostic tool to measure the frequency of mental disorders as a dichotomous outcome, while Riello et al[14] used rating scales for psychological symptoms, our results are a clinically significant proxy. Our results are also in line with data from another trial on HCWs, in which DWM was used as a first-line intervention strategy in a stepped care approach to reduce psychological distress.[15 33] Additionally, they align with research indicating a beneficial effect of face-to-face and non-face-to-face cognitive behavioural therapy interventions, mindfulness, eye movement desensitisation and reprocessing and ACT.[10 11 34] E-mental health interventions in general have also demonstrated effectiveness in alleviating stress and anxiety symptoms in HCWs, with small-to-moderate impacts in reducing depression symptoms.[35]

Our study has several limitations. First, this is a secondary analysis of an RCT powered for a different aim. Larger samples are needed to find reliable results at 14-week follow-up, as the power calculation was conducted for the 1-week follow-up, and attrition increases over time. Second, we lack data on longer term follow-ups. Even though our results showed a strong and positive effect at 14 weeks, research shows that the effectiveness of psychological interventions tends to decrease over time.[36] Therefore, introducing booster sessions to reinforce the intervention effects over time could be an important strategy. Booster sessions should be designed to enhance and optimise, and not only to merely maintain the effect of the intervention.[37 38] Additionally, the interpretation of our findings should take into account that our trial may have attracted participants who were highly motivated or particularly interested in improving their psychological well-being. This could limit the generalisability of the results to other groups, such as individuals experiencing greater distress or those who face challenges in balancing their workload with study participation. However, while generalisability is an important consideration, it primarily pertains to surveys, epidemiological studies, or, at the very least, the primary analysis of this study. One of the strengths of our study is its focus on a target population highly exposed to significant psychological distress—nurses and care home workers, including administrative staff who have close relationships with individuals in NHs. Our findings are relevant beyond the emergency caused by the pandemic. While COVID-19 has exacerbated these difficult working conditions, HCWs are chronically exposed to stressors and risk factors. Research indicates that HCWs may exhibit work-related syndromes, including depressive, anxiety and post-traumatic stress symptoms.[11] Moreover, few studies have targeted this population group, and the use of a closely matched alternative activity as the comparison in these analyses suggests that the effect may be highly specific, minimising the influence of nonspecific factors.[15]

Our results highlight the importance of encouraging intervention participation, compliance and study retention. Given the generalisability of these results to other work-related stress conditions of HCWs, it is crucial to keep individuals motivated and engaged, supporting compliance through repeated access to the intervention. Further studies are necessary to replicate and corroborate our findings. Additionally, the role of specific clinical and sociodemographic variables could be explored in depth to determine whether they have a potential impact on the interventions' outcomes. The pandemic highlighted the urgent need to adapt psychosocial interventions to diverse population groups and variable levels of distress. For instance, examining how age, pre-existing mental health conditions and cultural and socioeconomic status influence the effectiveness of interventions could provide crucial insights. These factors may have a direct moderating impact on outcomes, or an indirect one through participants' resilience, resources and overall engagement. These considerations highlight the importance of considering the adaptation of WHO psychological interventions according to the needs and characteristics of the target populations, resulting in tailored, more impactful support systems in future crisis contexts.

ORCID iDs
Marianna Purgato http://orcid.org/0000-0002-3783-8195
Roberto Mediavilla http://orcid.org/0000-0001-6411-9439
Jose Luis Ayuso-Mateos http://orcid.org/0000-0002-7544-826X

REFERENCES

1 Rink LC, Oyesanya TO, Adair KC, et al. Stressors Among Healthcare Workers: A Summative Content Analysis. *Glob Qual Nurs Res* 2023;10:23333936231161127.
2 Kunzler AM, Helmreich I, König J, et al. Psychological interventions to foster resilience in healthcare students. *Cochrane Database Syst Rev* 2020;7:CD013684.
3 Kaneda T, Greenbaum T, Patierno K. World Population Data Sheet. Washington, DC: Population Reference Bureau, 2019.
4 Il Sole 24 ore. Coronavirus in Italy: update map and case count. 2020.
5 Riello M, Purgato M, Bove C, et al. Prevalence of post-traumatic symptomatology and anxiety among residential nursing and care home workers following the first COVID-19 outbreak in Northern Italy. *R Soc Open Sci* 2020;7:200880.
6 Brady C, Fenton C, Loughran O, et al. Nursing home staff mental health during the Covid-19 pandemic in the Republic of Ireland. *Int J Geriatr Psychiatry* 2021;37.
7 Pappa S, Ntella V, Giannakas T, et al. Prevalence of depression, anxiety, and insomnia among healthcare workers during the COVID-19 pandemic: A systematic review and meta-analysis. *Brain Behav Immun* 2020;88:901–7.
8 Azoulay E, Cariou A, Bruneel F, et al. Symptoms of Anxiety, Depression, and Peritraumatic Dissociation in Critical Care Clinicians Managing Patients with COVID-19. A Cross-Sectional Study. *Am J Respir Crit Care Med* 2020;202:1388–98.
9 AlAteeq DA, Aljhani S, Althiyabi I, et al. Mental health among healthcare providers during coronavirus disease (COVID-19) outbreak in Saudi Arabia. *J Infect Public Health* 2020;13:1432–7.
10 Yoo IG. The effects of the type of delivery of cognitive-behavioral therapy for healthcare workers: A systematic review. *J Clin Psychol* 2022;78:149–66.
11 Sanz S, Valiente C, Espinosa R, et al. Psychological Group Interventions for Reducing Distress Symptoms in Healthcare Workers: A Systematic Review. *Clin Psychol Psychother* 2024;31:e2980.
12 WHO. BUILDING back better: sustainable mental health care after emergencies. 2013.110.

13 Epping-Jordan JE, Harris R, Brown FL, *et al*. Self-Help Plus (SH+): a new WHO stress management package. *World Psychiatry* 2016;15:295–6.

14 Riello M, Purgato M, Bove C, *et al*. Effectiveness of self-help plus (SH+) in reducing anxiety and post-traumatic symptomatology among care home workers during the COVID-19 pandemic: a randomized controlled trial. *R Soc Open Sci* 2021;8:210219.

15 Mediavilla R, Felez-Nobrega M, McGreevy KR, *et al*. Effectiveness of a mental health stepped-care programme for healthcare workers with psychological distress in crisis settings: a multicentre randomised controlled trial. *BMJ Ment Health* 2023;26:e300697.

16 Fournier JC, Forand NR, Wang Z, *et al*. Initial Severity and Depressive Relapse in Cognitive Behavioral Therapy and Antidepressant Medications: An Individual Patient Data Meta-analysis. *Cogn Ther Res* 2022;46:517–31.

17 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.

18 Weiss D, Marmar C. The impact of event scale — revised. In: Wilson JP, Keane TM, eds. *Assessing psychological trauma and PTSD*. New York, NY: Guildford Press, 1997: 399–411.

19 Purgato M, Tedeschi F, Riello M, *et al*. Effectiveness of self-help plus (SH+) in reducing anxiety and post-traumatic symptomatology among care home workers during the COVID-19 pandemic: protocol for a secondary analysis of randomized controlled trial data. 2024. Available: https://osf.io/t6sx5/

20 Brugiavini A, Carrino L, Pasini G. Long-term care in Italy. 2023.

21 WHO. Doing what matters in times of stress. 2020. Available: https://www.who.int/publications/i/item/9789240003927

22 Tolkien J. Leaf by niggle. In: Unwin GA, ed. *Tree and Leaf*. United Kingdom, 1964.

23 Hamdan W, Al Duaijy L, Al Sawy Y. Effectiveness of bibliotherapy in alleviating examination stress on college students: a quasi-experimental trial. *Health Info Libr J* 2021;38:172–81.

24 Andrews G, Basu A, Cuijpers P, *et al*. Computer therapy for the anxiety and depression disorders is effective, acceptable and practical health care: An updated meta-analysis. *J Anxiety Disord* 2018;55:70–8.

25 Mengin AC, Nourry N, Severac F, *et al*. Efficacy of the my health too online cognitive behavioral therapy program for healthcare workers during the COVID-19 pandemic: A randomized controlled trial. *Internet Interv* 2024;36:100736.

26 Benjamini Y, Hochberg Y. Controlling the False Discovery Rate: A Practical and Powerful Approach to Multiple Testing. *J R Stat Soc Ser B* 1995;57:289–300.

27 Zellner A. An Efficient Method of Estimating Seemingly Unrelated Regressions and Tests for Aggregation Bias. *J Am Stat Assoc* 1962;57:348–68.

28 White H. A Heteroskedasticity-Consistent Covariance Matrix Estimator and a Direct Test for Heteroskedasticity. *Econometrica* 1980;48:817.

29 Trabucchi M, De Leo D. Nursing homes or besieged castles: COVID-19 in northern Italy. *Lancet Psychiatry* 2020;7:387–8.

30 Shechter A, Diaz F, Moise N, *et al*. Psychological distress, coping behaviors, and preferences for support among New York healthcare workers during the COVID-19 pandemic. *Gen Hosp Psychiatry* 2020;66:1–8.

31 Acarturk C, Uygun E, Ilkkursun Z, *et al*. Effectiveness of a WHO self-help psychological intervention for preventing mental disorders among Syrian refugees in Turkey: a randomized controlled trial. *World Psychiatry* 2022;21:88–95.

32 Park A-L, Waldmann T, Kösters M, *et al*. Cost-effectiveness of the Self-Help Plus Intervention for Adult Syrian Refugees Hosted in Turkey. *JAMA Netw Open* 2022;5:e2211489.

33 Mediavilla R, McGreevy KR, Felez-Nobrega M, *et al*. Effectiveness of a stepped-care programme of internet-based psychological interventions for healthcare workers with psychological distress: Study protocol for the RESPOND healthcare workers randomised controlled trial. *Digit Health* 2022;8:20552076221129084.

34 Dunne PJ, Lynch J, Prihodova L, *et al*. Burnout in the emergency department: Randomized controlled trial of an attention-based training program. *J Integr Med* 2019;17:173–80.

35 Zhang Z, Hu Y, Liu S, *et al*. The effectiveness of e-mental health interventions on stress, anxiety, and depression among healthcare professionals: a systematic review and meta-analysis. *Syst Rev* 2024;13:144.

36 Bosmans JE, Bruijniks SJE, El Alili M, *et al*. Cost-effectiveness of twice-weekly versus once-weekly sessions of cognitive-behavioural therapy and interpersonal psychotherapy for depression at 12 months after start of treatment: randomised controlled trial. *BJPsych Open* 2023;9:e186.

37 Whisman MA. The efficacy of booster maintenance sessions in behavior therapy: Review and methodological critique. *Clin Psychol Rev* 1990;10:155–70.

38 Wesner AC, Gomes JB, Detzel T, *et al*. Booster Sessions after Cognitive-Behavioural Group Therapy for Panic Disorder: Impact on Resilience, Coping, and Quality of Life. *Behav Cogn Psychother* 2015;43:513–25.