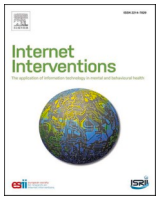
Internet Interventions 28 (2022) 100541

Contents lists available at ScienceDirect

Internet Interventions

journal homepage: www.elsevier.com/locate/invent



Psychological stress self-help interventions for healthcare workers in the context of COVID-19 in China: A randomized controlled trial protocol

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ARTICLE INFO

Keywords:
Self-help
Psychological stress
Randomized controlled trial
Healthcare workers
COVID-19

ABSTRACT

Background: Public health emergencies may lead to severe psychological stress, especially for healthcare workers, including frontline healthcare workers and public health workers. However, few stress management interventions have been implemented for healthcare workers even though they require more comprehensive interventions than the general public. Self-Help Plus (SH+) is a novel psychological self-help intervention developed by the World Health Organization. It is accessible, scalable, and cost-effective and has the potential to be quickly applied to help people cope with stress and adversity. The major objective of this study is to evaluate the effectiveness of SH+ interventions on the alleviation of stress levels and mental health problems among healthcare workers.

Methods: A randomized controlled trial of SH+ will be conducted to investigate the stress level and mental health status of Chinese healthcare workers and control subjects in Guangzhou. Assessments will be performed before (baseline), at the end of (1 month), and 2 months after (3 months) the intervention. After completing the baseline screening questionnaire, eligible participants will be randomly assigned to one of the two groups in a 1:1 ratio by block randomization. During the 1-month intervention period, the intervention group will receive the SH+ intervention and the control group will receive information about mental health promotion. The intervention will be delivered by the research assistant via social media platforms. The primary outcome is the level of stress, which will be measured by a 10-item Perceived Stress Scale. Secondary outcomes including mental health symptoms will also be collected.

Discussion: Given the potential for multiple COVID-19 waves and other infectious disease pandemics in the future, we expect that SH+ will be an effective stress management intervention for healthcare workers. The findings from this study will facilitate the application of SH+, and the trial is expected to be extended to a larger population in the future.

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https://doi.org/10.1016/j.invent.2022.100541
Received 8 January 2022; Received in revised form 11 April 2022; Accepted 15 April 2022
Available online 20 April 2022

1. Key questions

What is already known?

- Healthcare workers have a high risk of mental health problems during the COVID-19 pandemic and require comprehensive interventions.
- Self-Help Plus is a novel psychological self-help intervention developed by the World Health Organization that can be delivered by non-professionals.

What are the new findings?

- This study will evaluate the effectiveness of the Self-Help Plus intervention on alleviating stress levels and mental health problems among healthcare workers.
- Findings will better interpretate the mental health status of healthcare workers in the context of public health emergencies.

What do the new findings imply?

- The innovative self-help stress management intervention may be a promising tool to improve the psychological stress of healthcare workers in the context of public health emergencies.
- The self-help stress management tool in this study may be tailored for other populations as needed.

2. Introduction

In recent years, public health emergencies, such as the severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome outbreaks and the coronavirus disease 2019 (COVID-19) pandemic, have become major challenges facing humanity. For example, the COVID-19 pandemic has had a major impact on human health, and the pandemic continues to remain a threat globally (Zoa-Assoumou et al., 2021; Faria et al., 2021; Davies et al., 2021a; SeyedAlinaghi et al., 2021; Davies et al., 2021b).

Public health emergencies may lead to severe psychological stress, and they often pose significant challenges to the mental health service system (Jiang et al., 2020). It is especially true for healthcare workers, including frontline healthcare workers and public health workers (PHWs). During outbreaks, frontline healthcare workers and PHWs often experience burnout, and they have a high risk of mental health problems due to stress related to medical resource shortages, a high risk of infection, a heavy workload, and fatigue (Jiang et al., 2020; Zhang et al., 2021a; Luo et al., 2020; Wu et al., 2009; She et al., 2021). Healthcare workers suffer from a possible risk of various psychological illnesses from the time an outbreak begins until at least 3 years after the outbreak (Galli et al., 2020). Previous studies have reported a high prevalence of depression, anxiety, post-traumatic stress disorder, and sleep problems among healthcare workers during the SARS outbreak (74%, 77%, 10%, and 52%, respectively) (Wu et al., 2009; Chong et al., 2004). During the COVID-19 pandemic, a review of 65 studies including 97,333 healthcare workers between December 2019 and August 2020 showed a combined prevalence of 21.7% (95% confidence interval [CI], 18.3–25.2%) for depression, 22.1% (95% CI, 18.2–26.3%) for anxiety, and 21.5% (95% CI, 10.5–34.9%) for post-traumatic stress disorder (Li et al., 2021a). In addition, healthcare workers have been reported to experience poor self-rated health (9.8%) and work-related fatigue (6.85%) during the pandemic (Li et al., 2021b; Zhang et al., 2021b).

Zaçe et al. suggested that mental health interventions, including psychoeducation and training, mental health support teams, peer support and counseling therapy, digital platforms, and remote support, are warranted for healthcare workers during infectious disease outbreaks (Zaçe et al., 2021). In the aftermath of COVID-19 outbreaks, several countries implemented a series of psychological crisis interventions for the general population (Jiang et al., 2020; Luo et al., 2020; Bao et al., 2020; Zhang et al., 2020a). However, few interventions have been implemented for healthcare workers. Because of the unique nature of their work, healthcare workers are under tremendous pressure from multiple sources, and therefore, they have a high risk of pandemic-related psychological problems and are more likely to experience extensive psychological difficulties. Thus, healthcare workers require more comprehensive interventions than the general public. The need for psychological assistance for healthcare workers is more acute during a pandemic, especially in developing countries and resource-poor areas. In addition, the general stigma attached to psychological problems and the lack of access to resources when seeking psychological help often tend to discourage people from seeking help (Clement et al., 2015; Hooper et al., 2021). Thus, there is an urgent need to assess the effectiveness and feasibility of simple, authoritative, and effective mental health self-help interventions for large-scale application in response to global public health emergencies.

Self-Help Plus (SH+) is a novel psychological self-help intervention that can be delivered by non-professionals (Purgato et al., 2019). It was developed by the World Health Organization (WHO) based on recommendations for stress management interventions (Tol et al., 2013). SH+ consists of a five-part illustrated self-help booklet supplemented with eight short audio sessions corresponding to the content of the booklet. It was designed to provide help for a wide range of psychological difficulties that may be distressing, but do not necessarily meet the appropriate clinical diagnostic criteria, and it can be quickly applied to a large number of people to help them cope with psychological stress and adversity (Epping-Jordan et al., 2016). The SH+ material is based on the principles of acceptance and commitment therapy (ACT), a distinctive form of cognitive behavioral therapy (Hayes et al., 2013) that is useful for addressing a range of mental health issues and has been used successfully in a guided self-help format (Fledderus et al., 2012; At et al., 2015) across populations. ACT incorporates mindfulness and other acceptance-based practices to help people accommodate difficult thoughts and feelings (Karyotaki et al., 2021; Galante et al., 2021), cope with stress, respond compassionately to themselves and others, and live according to their values. Self-Help Plus incorporates these ACT factors are expected to alleviate people's stress level through improved levels of positive affect and compassion. Currently, SH+ is being pilot tested in Syrian refugees in Syria and Turkey and South Sudanese refugees in northern Uganda (Purgato et al., 2019; Brown et al., 2018). SH+ has received positive feedback in initial studies, as it significantly reduced psychological distress in South Sudanese women refugees within 3 months (Tol et al., 2020), and it may become part of the WHO Low-Intensity Psychological Intervention (Epping-Jordan et al., 2016). We identified only one study that tested SH+ in a sample of healthcare workers. Riello et al. performed the first randomized controlled trial of SH+ among Italian nursing and care home workers during the COVID-19 pandemic, which found that SH+ has a marginally significant effect (p-value is 0.097) in reducing anxiety and post-traumatic symptomatology (Riello et al., 2021). However, this study's sample size was medium, and the dropout rate was relatively high, leading to inadequate statistical power to detect the between group differences. It is still necessary to further validate the effect of SH+ among other general samples of healthcare workers in different cultural settings. As a novel stress intervention, SH+ is simple to apply, accessible, scalable, and cost-effective and may be replicable in other populations.

As the first country to face an outbreak of COVID-19, China has various types of healthcare workers who have taken on several COVID-19 prevention and control tasks (Li et al., 2021b; National Health Commission of the People's Republic of China, 2020). The pressure associated with performing these tasks is enormous. Despite the differences in healthcare systems across countries, healthcare workers in other countries may face similar challenges due to similarities in COVID-19 control requirements (Li et al., 2021b). The contribution of healthcare workers in all fields during the control and prevention of the

outbreak has been indispensable, but also stressful. Although some studies have focused on mental health of healthcare workers in the context of public health emergencies, these studies have mainly been cross-sectional studies exploring the prevalence of multiple mental health problems (Li et al., 2021a), whereas few longitudinal studies have been conducted to evaluate relevant psychological interventions; as a result, the efficacy of these interventions has not yet been determined (Fiol-DeRoque et al., 2021; Brog et al., 2021). Due to the busy workload of healthcare workers and the lack of accessible psychological services, there is a critical need for effective, low cost, sustainable and flexible mental health interventions (Yang et al., 2021a). SH+ intervention is thus a promising approach for improving mental health for this population. In addition, previous studies have been conducted primarily on frontline healthcare workers in clinical settings. Further research is needed to assess the efficacy of these interventions for all types of healthcare workers. Previous studies have suggested that social networking systems can be used as platform of mental health interventions, while reducing the cost of implementation and increasing the effectiveness of the intervention (Li et al., 2021c; Yang et al., 2020a). A specific aim of this study will be to test the feasibility and the efficacy to implement SH+ interventions via social networking platforms among healthcare workers, e.g., QQ and Wechat.

A randomized controlled trial of SH+ among Chinese healthcare workers (including clinical workers and public health workers) will be conducted. It will investigate the stress and mental health status of SH+ intervention and control groups before (baseline), at the end of (1 month), and 2 months after (3 months) the intervention. Healthcare workers in this study was defined as people who worked in hospitals or CDC, including general hospitals, specialty hospitals, maternal and child health centers, Chinese medicine hospitals, the CDC, and community healthcare centers. We will aim to (1) explore the effectiveness of the SH+ intervention on alleviating stress levels and mental health

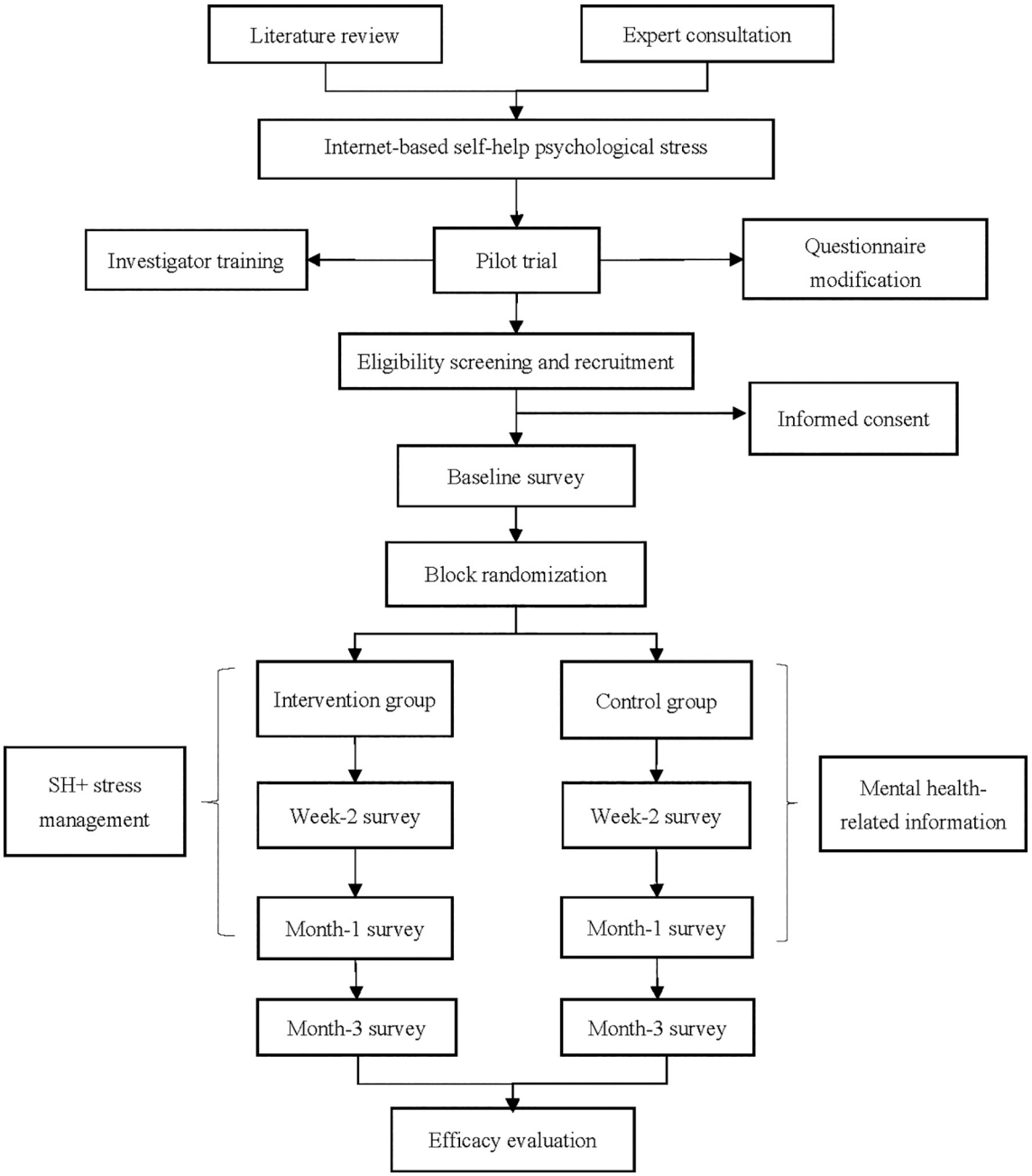

Fig. 1. Flow chart of the study.

problems; (2) explore the mental health status of healthcare workers in the context of public health emergencies; and (3) investigate the mechanisms by which SH+ alleviates stress levels and improves mental health problems. It is hypothesized that positive affect and self-kindness will be improved by the SH+ intervention and act as mediators of the intervention effect on reducing stress level.

3. Methods

3.1. Study design

The study will be a prospective, single-center, non-blinded, parallel-designed randomized controlled trial comparing the effectiveness of an Internet-based self-help stress management program and conventional access to mental health-related information at improving psychological stress. After completing a baseline screening questionnaire, eligible participants will be randomly assigned to one of the two groups in a 1:1 ratio by block randomization. The study flow chart is shown in Fig. 1. Participants will be followed for a period of 3 months. Those in the access to mental health-related information group (control group) will receive the same self-help stress management intervention as the intervention group after they complete the Month-3 survey.

3.2. Study setting

The study center will be located at the School of Public Health, Sun Yat-sen University. All data will be collected through an online questionnaire using the Questionnaire Star online survey tool (www.wjx.cn), from all levels of general hospitals, all levels of specialty hospitals, all levels of Centers for Disease Control and Prevention (CDC), and community healthcare centers in all municipal districts (i.e., Yuexiu, Tianhe, Liwan, and Haizhu) in Guangzhou, Guangdong province, China.

3.3. Participant involvement

3.3.1. Eligibility criteria

All interested persons will be required to complete and sign an electronic informed consent form and will be asked to complete a baseline screening questionnaire to assess their eligibility prior to block randomization.

Potential participants will be eligible for inclusion if they (1) are at least 18 years old; (2) are currently a healthcare worker (including clinical, nursing, and public health fields); (3) exceed the threshold of 15 points on the 10-item Perceived Stress Questionnaire (PSS-10) (Cohen et al., 1983; Weiner et al., 2020); (4) can independently complete online questionnaires; and (5) have a mobile communication device, such as a mobile phone or tablet with Internet access at all times. Potential participants will be excluded if they (1) have a serious mental disorder or suicidal ideation; (2) could not be reached through the contact information left after three days of attempts at different times; or (3) have frequent business trips out of Guangzhou planned in the next month.

3.3.2. Recruitment

Recruitment information will be distributed through contacts within various institutions, including general hospitals, specialty hospitals, maternal and child health centers, Chinese medicine hospitals, the CDC, and community healthcare centers. Those interested in participating in the study will be able to use the QR code on the recruitment information to allow them to provide their corresponding contact information, including their mobile phone number and QQ, WeChat, and other social media platform account information. The research assistant will then contact the participants through the social media platform account provided.

3.3.3. Informed consent

Those interested in participating will be able to ask the project research assistants research-related questions through social media platforms or photo messages and emails. The research assistant will provide details of the purpose, significance, and content of the study; the risks and benefits of participation; and the principles of confidentiality and will send an electronic version of the informed consent form through the social media platform for the participants to sign. This study has been approved by the Public Health Ethics Committee of Sun Yat-sen University [2021-120] and is registered with the China Clinical Trials Center under the registration number ChiCTR2100052402.

3.4. Intervention

3.4.1. Intervention group

The intervention will be a 4-week, Web-based self-administered stress management program known as Self-Help Plus (SH+), with appropriate instructions. SH+ was developed by the WHO and collaborators working in the humanitarian field. The Chinese version was translated by a team from the Department of Nursing, Medical College of Xi'an Jiaotong University in 2020 (Yang et al., 2021a). The translated version was also approved and released by the WHO. Details of the intervention schedule are shown in Table 1.

SH+ has two components: a pre-recorded course and an illustrated self-help atlas (Epping-Jordan et al., 2016). The pre-recorded audio material, which consists of eight segments, will teach key information about stress management and will guide participants through individual exercises. To increase participants' understanding of the audio material, an illustrated self-help book will be used to review the essential content and concepts. The book has five chapters, the first of which includes information on engaging in and focusing on the present moment. In the second chapter, participants will receive information on how to "ground" themselves when they experience an emotional storm. Chapter 3 focuses on how to act based on your values. Chapter 4 focuses on learning how to be kind to ourselves and others. Chapter 5 teaches how to make room for troubling thoughts and feelings. The audio materials and books will be divided into seven exercises that the research assistant will distribute to participants in the intervention group over a 4-week period through the Questionnaire Star online survey system. The contents of the seven SH+ exercises are described in Table 2. The illustrated guide requested participants do the exercise every few days (Organization WH, 2020). In addition, according to a previous systematic review of internet-delivered ACT intervention studies, the intervention period for ACT typically ranges from 2 to 12 weeks (Kelson et al., 2019). In this study, the intervention will also be tailored in similar frequency and duration. The SH+ exercises will be distributed via social network platforms to the participants over a 1-month intervention period, with approximately two exercises per week. Each exercise will take approximately 10 min to complete.

3.4.2. Control group

During the 1-month intervention period for the control group, the research assistant will send information about mental health promotion to the participants weekly via their personal social media accounts. These materials were developed by a health psychologist in consultation with the directors of non-governmental organizations and are detailed in Table 3. In addition, the SH+ intervention materials will be made available to the control group after they complete the Month-3 survey.

3.4.3. Pilot trial

A 2-week pilot trial will be conducted with 10 participants to assess the feasibility and acceptability of the intervention and to identify potential problems with the wording or length of the questionnaire. The results of the pilot trial will inform the design of the optimized intervention. Therefore, following the pilot study, the wording of some of the measures may be modified, and the corresponding experimental procedures may be adjusted based on participant feedback. During the pilot trial phase, the project research assistant will be observed and

Table 1
Enrollment and intervention schedule.

	Study period					
	Enrollment	Allocation	Post-allocation			Close-out
Time point	T0 Baseline	T0 Baseline	T1 2 weeks	T2 1 month	T3 3 months	T3 3 months
Enrollment						
Eligibility screening	×					
Informed consent	×					
Allocation		×				
Intervention						
Intervention group		←	—	→		
Control group		←	—	→		

Table 2
The content of the Internet-based self-help stress management intervention.

Topic	Content
1. Building awareness	Learn ways to engage in your life or focus on something you are doing in the moment.
2. Grounding exercise 1	Learn how to "ground" yourself when experiencing an emotional storm.
3. Grounding exercise 2	Learn more about how to "ground" yourself when experiencing an emotional storm.
4. Notice and name	Learn how to eliminate negative emotions and thoughts that cause stress.
5. Acting on your values	Learn how to bring your actions closer to your values when under stress.
6. Being kind	Learn ways to be kind to others and yourself, despite adversity.
7. Making room	Learn ways to make room for thoughts and feelings that bother you, without being hurt by them.

Table 3
The content of the mental health promotion information for psychological stress.

Section	Content
Part 1	An introduction to mental health, the main factors affecting mental health, and a description of positive mental health
Part 2	An introduction to the link between physical and mental health
Part 3	An introduction to mental illness and why it occurs
Part 4	Details on how to promote mental health and prevent mental illness

supervised and will be alerted to any unmotivated performance or behavior, such as failure to complete intervention material exercises or questionnaire administration in a timely manner. After the pilot study, additional training sessions will be provided to the project research assistant as necessary to enhance participant compliance.

3.5. Measurements

All assessments will be completed online via a self-reported questionnaire. Baseline measurements will be taken at T0. The first, second, and third follow-up assessments will occur 2 weeks (T1), 1 month (T2), and 3 months (T3) after the baseline measurement, respectively. An overview of all outcome measures and the corresponding measurement time points are detailed in Table 4.

3.6. Primary outcome

3.6.1. Stress

A 10-item Perceived Stress Scale (PSS-10) will be used to measure the participants' reported stressful events that occurred in the past month (Cohen et al., 1983). The scale consists of 10 items rated on a 5-point Likert scale: 0, never; 1, almost never; 2, occasionally; 3, often; and 4, frequently. Six items in the PSS-10 are considered negative (items 1, 2, 3, 6, 9, and 10) and will be used to measure the level of stress. The other four items are positive (items 4, 5, 7, and 8). Positive items will be reverse coded when calculating the total PSS-10 score, which ranges from 0 to 40, with higher scores indicating higher levels of stress. The Chinese version of the scale has been shown to have good reliability and validity (Leung et al., 2010).

Table 4
Assessment schedule.

	Study PERIOD			
	Enrollment	Follow-up		
Time point	T0 Baseline	T1 2 weeks	T2 1 month	T3 3 months
Primary outcome variable				
Stress	×	×	×	×
Secondary outcome variables				
Burnout	×			×
Depressive symptoms	×			×
Anxiety symptoms	×			×
Insomnia	×			×
Positive affects	×		×	×
Self-kindness	×		×	×
Baseline variables				
Sociodemographic characteristics	×			
Work-related information	×			
Physical exercise	×			
Alcohol use	×			
Process evaluation				
Intervention utilization		×	×	×
Intervention adherence		×	×	×
Contamination		×	×	×

3.7. Secondary outcomes

3.7.1. Depressive symptoms

Depressive symptoms in the past 2 weeks will be measured using the Chinese version of the Patient Health Questionnaire Depression Scale (PHQ-9) (Spitzer et al., 1999). The scale has a total of nine items that are rated on a 4-point Likert scale: 0, not at all; 1, rarely; 2, many times; 3, almost every day. The total score of the PHQ-9 ranges from 0 to 27, with a score of 10 usually considered as the cut-off point for having significant depressive symptoms (Kroenke et al., 2010). The Chinese version of the PHQ-9 scale has been shown to have good reliability and validity (Wang et al., 2014).

3.7.2. Anxiety symptoms

Anxiety symptoms in the past 2 weeks will be assessed using the

Chinese version of the Generalized Anxiety Disorder Scale (GAD-7) (Spitzer et al., 2006). This scale has seven items that are rated on a 4-point Likert scale: 0, not at all; 1, rarely; 2, many times; and 3, almost every day, with a total score ranging from 0 to 21. A score of 10 on this scale is usually considered the cut-off point for having significant anxiety symptoms (Spitzer et al., 2006). The Chinese version of the GAD-7 scale has been shown to have good reliability and validity (Tong et al., 2016).

3.7.3. Insomnia

Insomnia will be assessed by the Insomnia Severity Index (ISI). The ISI is a 7-item scale, with each item rated from 0 to 4 (Morin et al., 2011). The scale has a total score of 28, with 0–7 indicating no insomnia, 8–14 indicating subclinical insomnia, 15–21 indicating moderate insomnia, and 22–28 indicating severe insomnia (Wong et al., 2017a). The scale will be used to assess the severity of insomnia in the last 2 weeks. This scale has been shown to have good reliability and validity in Chinese population (Wong et al., 2017b).

3.7.4. Burnout

The general version of the Maslach Burnout Inventory (MBI-GS) will be used, as it is applicable to people aged 16 years and older in all industries (Maslach, 1981). The Chinese version of the scale contains 15 items in three dimensions: emotional exhaustion, depersonalization, and lack of personal accomplishment (Li CPS, 2003). The MBI-GS is a 7-point, 0–6 Likert-type scale in which 0 indicates "never" and 6 indicates "every day," with higher scores indicating more severe burnout. No positive score for any of the three dimensions will indicate zero burnout; a positive score for any one dimension will indicate mild burnout; a positive score for any two dimensions will indicate moderate burnout; and a positive score for all three dimensions will indicate severe burnout (Maslach, 1981). This scale has been shown to have good reliability and validity (Xu et al., 2020).

3.7.5. Positive affectivity

Positive affectivity will be evaluated using the positive affect subscale of the Positive and Negative Affect Scale (PANAS) (Watson et al., 1988). The PANAS consists of two subscales: positive affect (PA) and negative affect. The PA subscale contains five emotional descriptors, each with the following five options: "almost none," "relatively little," "moderate," "more," and "very strong," which correspond to scores of 1, 2, 3, 4, and 5, respectively. The total PA score ranges from 5 to 25, with a higher score indicating a more positive emotional experience (Watson et al., 1988). The PANAS has good reliability and validity in the Chinese population (Li et al., 2020).

3.7.6. Self-kindness

Self-kindness will be measured using the 5-item self-kindness subscale of the 26-item Self-Compassion Scale (SCS) (KD, 2003). This scale is rated on a 5-point Likert-type scale, with responses ranging from "1, very unconforming" to "5, very conforming." Scores will be calculated for each item, and higher scores will be used to indicate that individuals are able to treat themselves kinder when dealing with adversity (KD, 2003). Previous studies, including studies on Chinese youth, have shown that the SCS has good reliability and validity (Li et al., 2021d; Sun et al., 2020).

3.8. Baseline variables

3.8.1. Sociodemographic characteristics

A self-administered sociodemographic characteristics questionnaire will be used to collect the basic information of the participants. The characteristics collected will include sex, age, educational level, marital status, monthly income, and family situation.

3.8.2. Work-related information

A self-administered work-related questionnaire will be used to collect the work-related information of the participants. Work-related information will include the type of workplace, length of service, job title, work environment, and work hours (per week).

3.8.3. Physical exercise

Physical exercise will be measured using the Physical Activity Rating Scale (PARS-3), which was revised by Liang (1994). The scale has three items and is scored using a 5-point Likert scale. It examines physical activity in terms of intensity, time, and frequency. The score, which ranges from 0 to 100, is calculated as follows: exercise volume = intensity × (time − 1) × frequency. The following assessment criteria will be used for exercise volume: low exercise volume ≤ 19 points, medium exercise volume 20–42 points, and high exercise volume ≥ 43 points. This scale has been shown to have high reliability and validity (Yang et al., 2021b).

3.8.4. Alcohol use

The three-item Alcohol Use Disorders Identification Test-Concise (AUDIT-C) will be used to measure the amount and frequency of regular and irregular alcohol use (Saunders et al., 1993). Each item is scored from 0 points to 4 points. This scale has been shown to have good reliability and validity (Zhang et al., 2017).

3.9. Process assessment

In addition, process evaluation indicators will be measured. The main components of the subjective process assessment will be contamination (e.g., "Did you subscribe to any other information resources that provided information about the mindfulness intervention or mindfulness in general?" for the intervention group and "Have you viewed the SH+ exercise materials for the intervention group?" for the control group) and the adherence of the self-help stress intervention (e.g., "Did you complete the atlas for each exercise?" and "Did you finish listening to the audio materials for each exercise?"). For each exercise, a question from the material will be used to test whether the participant was serious about using the intervention materials. Objective process evaluation indicators, including whether each intervention was submitted, how long it took to complete each exercise, and how many times the exercise was repeated, will be collected from the backend of the Questionnaire Star program.

3.10. Sample size estimation

A 90% efficacy and an alpha level of 0.05 in a two-tailed test was used to calculate the sample size for the study. A previous study of the effect of ACT-based intervention at reducing stress showed an effect size of 0.63 (Wersebe et al., 2018). We used Power Analysis and Sample Size software (NCSS, Kaysville, UT, USA) to calculate the required sample size of 108 (54 per arm). In addition, based on previous data, a 50% compliance rate at month 6 of follow-up was assumed (Geary and Rosenthal, 2011), resulting in a minimum sample size of 216 (108 per arm).

3.11. Group allocation

Twelve research assistants with experience in research project management will be responsible for recruiting participants and delivering the materials for intervention or control groups. Research assistants will also be requested to refer the participants to psychiatric professional institutes if any major risks were identified. Prior to beginning the study, all research assistants will receive four 1-h training sessions on recruitment, data collection, intervention specifications, and counseling on psychologically relevant information. Research assistants will be trained by principal investigators and co-investigators who are experts in public health, psychology and epidemiology. After the research assistants have confirmed the eligibility of potential

participants and obtained their informed consent, the participants will be invited to complete a baseline assessment and will then be randomly assigned to the intervention or control groups in a 1:1 allocation ratio. Block randomization, with a block length of 4, will be used to generate random numbers using SPSS.

3.12. Blinding method

The results of the allocation will be known to the researcher. In addition, because participants will either receive direct access to the self-help stress management exercises or will have a waiting period, they will know their group allocation. For participants in the control group, they will be told to receive self-help stress management materials three months after the start of the program.

3.13. Data collection methods

The baseline assessment will be initially performed by sending the survey link to the participants via social media platforms, such as QQ and WeChat, or phone messages and email. Demographic data (e.g., age and gender), work-related data (e.g., type of workplace and, work hours,), behavior-related data (i.e., physical exercise and alcohol use), and data related to tress and mental health status (e.g., psychological stress, depressive symptoms, and anxiety symptoms) will be collected.

Follow-up assessments will be scheduled at 2 weeks, 1 month, and 3 months after the baseline assessment. The content of the follow-up assessment at each time point will be described to the participants, and outcome variables and intervention compliance variables will be collected. A link to the online questionnaire will be sent by the research assistant to all participants via social media platforms, and the participants will be able to complete the questionnaire on any electronic device, such as a smartphone or tablet. Questionnaires will be checked weekly after each delivery, and reminders will be sent via social media platforms to participants who have not completed the questionnaire within the specified time. Participants who complete the baseline assessment and the follow-up questionnaire at 2 weeks, 1 month, and 3 months will receive an online cash transfer of $4.00, $0.80, $0.80, and $3.00 ($8.60 total), respectively. For those who did not finish the online questionnaires or interventions in time, the research assistant will try 3–4 times to send them the link to kindly remind them to finish it. In addition, for the participants in the intervention group who follow the study protocol and complete all the SH+ intervention materials, we will provide them with several gifts worth about $15.70 to choose from, such as quarterly membership of common video APP, Starbucks gift cards, and online supermarket gift card.

3.14. Data storage and management

All Web files, including informed consent forms, intervention materials, and participants' data will be stored in the Sun Yat-sen University Enterprise version of the Questionnaire Star system. At the end of the study, the data will be downloaded, stored on a password-protected computer, and permanently deleted from the Questionnaire Star server. To maintain confidentiality, all personal information in the data files will be removed and replaced with the research project ID, which will also be protected with a password. Only members of the study team will be able to access and use this data. No personal information will be recorded on the research assistant's social media platform account, and each participant joining the survey will be given the last four digits of their mobile phone number as their research project ID.

3.10. 3.15Statistical analysis

A chi-square test will be used for categorical variables (e.g., the presence of significant depressive and anxiety symptoms), and a Student's *t*-test will be used for continuous variables (e.g., perceived stress scores and self-kindness scale scores) to test between-group differences at baseline and at follow-up time points. Within-subject analyses will also be performed to compare baseline responses with follow-up responses. Intervention effects will be assessed according to the principle of intention-to-treat using data collected from all randomized participants. If there are non-random missing, robust multiple imputation approach (Erler et al., 2016) will be used to deal with these missing data. The result will be presented in the sensitivity analysis section. To examine the overall effect of the intervention and control groups while controlling for potential covariates, generalized estimating equations will be used for repeated measures analysis. Mediation analysis will be conducted by using four-step method of Baron and Kenny (1986) to test the separate mediation effect of each potential mediator, and using structural equation model to test the overall mediation effects of all mediators. All data analysis was done by R4.0.3. and AMOS 24.0.

4. Discussion

The aim of this study is to deliver a psychological intervention to Chinese healthcare workers in the context of the COVID-19 pandemic using self-help stress management material developed by the WHO as part of their "Doing What Matters in Times of Stress" guidelines. We aim to evaluate the feasibility and effectiveness of the intervention through a randomized controlled trial. This innovative self-help stress management intervention may be a promising tool to improve the psychological stress of healthcare workers in the context of public health emergencies. Moreover, this self-help stress management tool may be tailored for other populations as needed. The study is currently underway, and the effectiveness of the intervention will be reported after data collection.

Previous studies have shown that guided self-help intervention programs may be more effective than pure self-help intervention programs and give similar results to face-to-face psychotherapy (WHO Guidelines Approved by the Guidelines Review Committee, 2016). The SH+ intervention format is innovative and ensures that key intervention materials are distributed as intended without the need for a large number of trainers to be involved. It focuses on prevention rather than treatment; has one or more primary outcome indicators of psychological distress, rather than clinically diagnosed psychological disorders; and is easily adaptable to different cultures and languages. Therefore, SH+ reaches a broad audience and is safe and meaningful for people with and without psychiatric disorders. Compared with traditional psychological interventions, SH+ interventions are less time-consuming, are inexpensive to implement, and are simple to apply. SH+ is accessible, can be used on a large scale, and can be applied to any type of adversity to quickly alleviate mental health problems in populations (Epping-Jordan et al., 2016). Although its application currently focuses on refugee populations, which have great needs but limited resources (Brown et al., 2018; Tol et al., 2020), SH+ is also expected to be an ideal self-help stress intervention for other populations in adversity, especially healthcare workers working during the COVID-19 pandemic for long periods of intense and stressful work.

To the best of our knowledge, this study will be the first to implement a psychological intervention using SH+ for healthcare workers in China. During the COVID-19 pandemic, especially in the context of severe epidemic control in China, a large number of healthcare workers have been under chronic stress and need effective methods to improve their mental health (Zhang et al., 2020b). In addition, given the potential for multiple COVID-19 waves and other infectious disease pandemics in the future, and the relative lack of available mental health resources in China (Li et al., 2013), we expect that SH+ will be an ideal mental health intervention for healthcare workers. The COVID-19 pandemic represents a situation that is well suited to the application of SH+, and the intervention is expected to be extended to a larger population in the future.

4.1. Limitations

We would like to acknowledge that there are some limitations with the current trial design. First, this study will use convenience sampling and participants will be recruited mainly by distributing recruitment

posters on social media platforms. This may create some bias in the representativeness of the sample.

Second, this study will be conducted only on Chinese healthcare workers, although other populations in China, such as elderly individuals, are also under great stress and have poor access to mental health services during the pandemic (Yang et al., 2020b). The limitations of the selection of the study population may affect the generalization of the results to the general population, and further randomized controlled trials of this method in other populations may be needed in the future.

Third, as this study is a Web-based online intervention, the number of participants lost to follow-up may be relatively high. Based on Web-based online interventions conducted in previous studies, the number of participants lost to follow-up may be approximately 50% (Geary and Rosenthal, 2011). We will aim to reduce the rate of attrition by setting up a reward mechanism and a reminder service. In addition, due to the nature of the content of the intervention, the study will have an open study design, such that participants will not be blinded to the intervention. Thus, participants in the control group will be aware that they will not receive SH+ until 3 months later, which may increase the number of missed follow-up visits in the control group.

Fourth, even several efforts are taken to improve the participation motivation of the healthcare workers and the compliance with the intervention, the incompliance of participants may still be a significant limitation.

Finally, we will not be able to control for other factors that may contaminate the study results, although we will record some potential contaminants to help interpret the results (e.g., whether the control group received positive thinking-related information from other sources or whether any SH+ materials from the intervention group were viewed during the control intervention).

Despite these potential challenges, determining the effectiveness of preventive psychological interventions is a public health priority because they have the potential to help large populations in a short time. Preventive psychological interventions are feasible, sustainable, and cost-effective. SH+, which is based on a self-help approach, may be particularly advantageous for populations with limited access to social and health services, but with high needs.

Funding

The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Data sharing

The data of this study will be available from the corresponding author on reasonable request.

Patient consent and ethical approval

This study has been approved by the Public Health Ethics Committee of Sun Yat-sen University [2021-120] and is registered with the China Clinical Trials Center under the registration number ChiCTR2100052402.

CRediT authorship contribution statement

All of the authors participated in the formulation of the study methodology. JG and JL conceived the research questions, assembled the team of collaborators, and conducted quality control. RL designed the first draft of the questionnaire. RL and PG drafted the manuscript and coordinated the field work. MS, YC, JH, and YH assisted in the editing and writing of the protocol. PKM, AMW, RDX, and JTL revised the manuscript and gave scientific comments. JG and JL finalized the questionnaire and the manuscript. All of the authors assisted with the questionnaire design and commented on the intellectual content of the manuscript. The author(s) read and approved the final manuscript.

Declaration of competing interest

None declared.

Acknowledgements

We would like to thank Zhikang Li, Xu Wang, Mingyu Chen, Luxin Zheng, Senyao Cai, Yuxuan Chai, Jintao Han, and Jingxian Wu for their great assistance with this study. We greatly appreciate all participants in this study and all research assistants for their support.

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