

Effects of an Online Mindful Living With Challenge (MLWC) Intervention on Mental Health and Quality of Life Among COVID-19 Patients in China: A Protocol of a Randomized Controlled Trial

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Study Protocol

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Abstract

Background COVID-19 can lead to increased psychological symptoms such as post-traumatic stress disorder (PTSD), depression, and anxiety, especially for patients with COVID-19. Studies suggest that mindfulness-based intervention is an effective, easily delivered and non-aggressive online therapy for patients with mental disorders. This study aims to explore the efficacy and possible mechanism of a Mindful Living With Challenge (MLWC) intervention designed for Chinese COVID-19 survivors in alleviating their psychological problems caused by both the disease and the pandemic.

Methods This study is a protocol for a randomized controlled trial. More than 1600 eligible participants will be assigned 1:1 to an online MLWC intervention group or a waitlist control group. All participants will be asked to complete online questionnaires at baseline, post-program, and 3-month follow-up. The primary outcome is mental health status which includes PTSD and other psychological symptoms (i.e. depression, anxiety). The secondary outcomes are related physical symptoms including fatigue and sleeplessness assessed by verified scales such as the Fatigue Scale-14, Pittsburgh Sleep Quality Index. In addition, Five Facets Mindfulness Questionnaire, the Nonattachment Scale, the Stillness Scale, the Resilience Style Questionnaire and the Social Support Scale will be used to assess the mindfulness, stillness, nonattachment level, resilience and perceived social support before and after the intervention, which may be the possible mediators and moderators of the link between the MLWC intervention and target outcomes. Data will be analyzed based on an intention-to-treat approach, and SPSS software will be used to perform statistical analysis.

Discussion This study will provide scientific evidence on the efficacy and possible mechanism of the MLWC intervention in improving the quality of life and psychological status among COVID-19 survivors in China. Findings from this study will contribute to a growing research field that assesses the effectiveness of mobile-based and theoretically guided interventions for improving the psychological status of the COVID-19 survivors. Moreover, findings from this study will also contribute to the prevention and management of the psychological complications patients face during such public health emergencies.

Trial registration Chinese Clinical Trial Registry (ChiCTR), ChiCTR2000037524; Registered on August 29, 2020, <http://www.chictr.org.cn/showproj.aspx?proj=60034>.

Article Summary

Strengths and limitations of this study

- With more than 1600 COVID-19 survivors included, this is the largest trial ever performed to test the effect of the mindfulness-based intervention on psychological well-being and quality of life
- The current study will use RCT, double-blind, evidence-based meditation design, and a longer period of intervention and follow-up, which may ensure more solid conclusions

- With verified standard scales, the measurement quality of the target outcome variables can be ensured
- The hierarchical multiple regression analyses will be used to determine how mindfulness training affects the outcome variables and to evaluate mindfulness, stillness, nonattachment, resilience and perceived social support as the possible mediators and moderators of the link between the tailored Mindful Living With Challenge (MLWC) intervention and target outcomes
- It is difficult to avoid contamination between the intervention group and the control group if participants who know each other will be assigned to different groups

1 Background

Coronavirus disease (COVID-19), the infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first reported on December 31, 2019. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 as a pandemic due to its rapid global spreading. Globally, there have been 53,766,728 COVID-19 cases and 1,308,975 deaths (2.43% of total cases), particularly among vulnerable populations such as patients with chronic diseases and the elderly.[1, 2] As of 24:00 pm on Nov 15, China alone has resulted in 92,452 cases and 4,749 deaths due to COVID-19.[3] It can be seen that the mortality rate of COVID-19 has been declining recently, which means that more and more patients have been released from the hospital after being cured. Therefore, the focus has now been shifted to taking measures to rehabilitate COVID-19 survivors, including the restoration of their physical functions and psychological development.

Evidence suggests that this disease has psychological consequences on healthcare workers, students and other population, especially for COVID-19 patients.[4–11] Immediately after the outbreak, a considerable proportion of patients with COVID-19 reported post-traumatic stress disorder (PTSD) (more than 33.0%), depression (60.2%), and anxiety (55.3%) symptoms in Shanghai, China.[8] In addition, a survey conducted in March showed that 45.9% of patients had symptoms of depression, 38.8% had anxiety and 54.1% had insomnia in Wuhan, China.[9] COVID-19 survivors in other countries have similar psychological status.[10, 11] In Ecuador, one of the most affected countries by the COVID-19 pandemic in Latin America, of the 759 confirmed or suspected COVID-19 patients, 20.3% showed moderate to severe depressive symptoms, while 22.5% showed moderate to severe anxiety.[10] In addition, after one month of hospitalization for 402 COVID-19 survivors in Milan, the reported PTSD was 28%, depression was 31%, anxiety was 42%, and insomnia was 40%.[11] Over time, while the mental symptoms and quality of life of COVID-19 survivors will improve, they are still significantly worse when compared to the rest of the population who didn't suffer from COVID-19. Therefore, the psychological impacts of COVID-19 should not be overlooked and should be examined from the long-term public health perspectives.

In view of the current epidemic prevention and control requirements, Internet-based interventions can provide an alternative to face-to-face therapy in enhancing mental health and quality of life for patients with COVID-19. Increasing evidence has shown the efficacy of Internet-based interventions in the treatment of mental health, especially mindfulness-based interventions.[12–14] Mindfulness-based

intervention (MBI) is an approach that focuses on the cultivation of conscious awareness, and orientation towards the present moment with curiosity and openness.[15] It emphasizes the transience of all sensations, thoughts and feelings. During systematic training, mindfulness is cultivated through exercises such as mindfulness breathing, sitting meditation, body scan, and stretching exercises.[16] In addition to practicing within the intervention period, participants will be encouraged to practice mindfulness activities daily.

In mainland China, WeChat App and its small programs have dominated the browsing time of mobile phone users.[17] Given the emerging need for psychological rehabilitation among COVID-19 survivors recently, this randomized controlled trial will be conducted in this population to examine the effectiveness and feasibility of a 6-week Mindful Living With Challenge (MLWC) intervention focusing on mental health and quality of life via WeChat. We hypothesized that the training could enhance the physical and mental health at post-program and 3-month follow-up.

2 Methods/design

2.1 Study design

This is a prospective, randomized, parallel-group, double-blind, blank controlled trial involving an online 6-week MLWC intervention with a 3-month follow-up. More than 1600 COVID-19 survivors over 18 years old will be randomized to: (1) intervention group: this group will receive a baseline questionnaire followed by a 6-week web-based MLWC intervention, and two questionnaire surveys at post-program and 3 months after the intervention, or (2) waitlist control group: participants in this group will receive three questionnaire surveys conducted simultaneously with the intervention group, and start the same intervention after a 3-month waitlist period (Fig. 1). This study protocol is reported in accordance with SPIRIT reporting guidelines and results will be reported in line with the Consolidated Standards of Reporting Trials (CONSORT) statement and the CONSORT statement for non-pharmacological interventions.[18–20]

2.2 Study objectives

- ▶ The primary study objective is to assess the efficacy of the MLWC intervention on PTSD, depression, and anxiety among COVID-19 survivors.
- ▶ The secondary study objective is to investigate the effects of the MLWC intervention on fatigue and sleep quality among COVID-19 survivors.
- ▶ The exploratory objective is to determine how mindfulness training affects mental state and quality of life among COVID-19 survivors and to evaluate mindfulness, stillness, nonattachment, resilience and perceived social support as the possible mediators and moderators of the link between the MLWC intervention and target outcomes.

2.3 Settings

The study will be carried out at the Wuhan Jinyintan Hospital, Hubei province, China. All researchers and support staff in this project will be trained based on the same protocol and are required to have an educational background in medicine or public health. Digital informed consent will be obtained from all subjects to ensure their voluntary participation. This study is planned to be performed in December 2020 and will last for about 4 months.

2.4 Sample size

A priori power analysis has been conducted on G*power software. The trial between the MLWC intervention group and the control group will be testing superiority in promoting mental health status at a superiority margin of 10%. Thus, with a 1:1 allocation to each group and allowing for a 40% attrition rate, at least 1600 participants will be recruited (power = 0.9, α = 0.05, two-tail).

2.5 Recruitment

Participants will be recruited through advertisements posted in hospitals and publicity by doctors in outpatient clinics or patient contact groups. Interested participants will be informed about the benefits and possible risks of participation in the study, including failure to achieve the expected intervention effects. Completion of electronic informed consent will be required before screening the eligibility of participating in the study.

Once the informed consent is obtained, a psychiatrist will complete the eligibility checklists and record the candidates who fail to meet the inclusion criteria. Furthermore, a senior nurse will record the mobile phone number of participants to facilitate follow-up services. All of the above personal information will be kept confidential on an encrypted laptop and used for research purposes only. Table 1 shows schedule of enrolment, interventions and assessments.

Table 1
Schedule of enrolment, interventions, and assessments

STUDY PERIOD						
	Enrolment	Allocation	Post-allocation			Close-out
TIME POINT	0	t ₀	t ₁	t ₂	t ₃	t ₄
			baseline	Intervention period	Post-assessment	Follow-up assessment
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
The Mindful Living With Challenge intervention group				X		
Waitlist control group				X		
ASSESSMENTS:						
Primary outcome measures						
Impact of Events Scale-Revised			X		X	X
Patient Health Questionnaire			X		X	X
Generalized Anxiety Disorder Questionnaire			X		X	X
Peace of Mind Scale			X		X	X
Secondary outcome measures						
Fatigue Scale-14			X		X	X
Pittsburgh Sleep Quality Index			X		X	X
The possible mediators and moderators						

STUDY PERIOD			
Five Facets Mindfulness Questionnaire	X	X	X
The Nonattachment Scale	X	X	X
The Stillness Scale	X	X	X
The Resilience Style Questionnaire	X	X	X
The Social Support Scale	X	X	X

2.6 Eligibility criteria

2.6.1 Inclusion criteria

Participants must first agree to electronic informed consent in order to participate in the study as required by the ethics committee. The participants have to meet the following criteria:

- 1) Over 18 and under 65 years old
- 2) Have a history of COVID-19 infection
- 3) Proficiency in Chinese
- 4) Be able to independently cooperate with doctors to complete various scale assessments and corresponding tests
- 5) Have a mobile communication equipment such as a mobile phone, and a WeChat account.
- 6) Mobile equipment can access the Internet at any time
- 7) Have not received medications for PTSD, depression, anxiety, fatigue, or sleep disorders within 1 month prior to enrollment in the study.

2.6.2 Exclusion criteria

Those who meet any of the below criteria will be excluded:

- 1) With serious mental illness or suicidal tendencies
- 2) Suffering from serious heart, brain, lung, kidney, liver, and other medical diseases or tumors
- 3) Having difficulty cooperating with the questionnaire survey and intervention

2.7 Randomization and blinding

Participants who meet the eligibility criteria will be randomly assigned (in a 1:1 ratio) to the online MLWC intervention group or waitlist control group. They are supposed to provide informed consent by clicking the 'I agree to join in the research' button on the electronic details page of the study. After that, a QR code will pop up on the page. By scanning this code, participants will be randomly assigned to the intervention or control group (in a 1:1 ratio) by computer-generated numbers. The trial will blind all people who might influence the outcome assessments, including the participants, data analysts, and outcome assessors. Before the trial, the principal investigator of the project will organize training on the randomization procedure and ensure that each employee is clearly aware of their responsibilities.

2.8 Intervention

2.8.1 The Mindful Living With Challenge (MLWC) intervention

Participants in the intervention group are required to follow the developed WeChat small program by scanning the code, and then receive the online MLWC intervention. The MLWC intervention will be developed by two psychiatrists, and one of them has been certified in the Training of Mindfulness Facilitation program at the UCLA Mindful Awareness Research Center. The MLWC intervention adopts some elements from mindfulness-based stress reduction and Mindful Awareness Practices. The MLWC intervention includes mindfulness meditation and mindful stretching as core components. A similar intervention has been successfully used on attention monitoring and acceptance in pregnant women in China.[14] Through a series of mindfulness training courses, participants are hypothesized to increase their ability to regulate their emotions and learn to observe the physical pain and psychological frustration caused by COVID-19 infection with equanimity. The purpose of the study is to help participants improve their skills in coping with psychological symptoms, improve their quality of life during recovery, and prepare to return to a normal life.

The MLWC intervention will involve Internet-based mindfulness training conducted in 6 weekly sessions of 2 sessions a week and 0.5 hour per session, which focus on the four important parts of MBI: attention control, self-awareness, acceptance and discernment, and relating to difficult thoughts/emotions. Two new sessions of online lessons will be updated weekly in six weeks. The study participants are expected to spend an average of 1 hour per week viewing each lesson, which consisted of a theoretical instrument, some meditation practices, and homework in the form of audio and video. Participants will be required to perform formal/informal mindfulness practice at home for 5 minutes daily initially, advancing to 20 minutes daily at the end of the intervention period, and to record or report their difficulties and progress during the practice. See Table 2 for the context of the MLWC intervention.

Table 2
The Content of Mindful Living With Challenge (MLWC) intervention

Session	Theoretical instrument	Meditation practice	Homework
1	Explanation of the 5 facets of mindfulness (i.e. describing, acting with awareness, non-judging, and non-reacting), and of the importance of the mindfulness practices which is a means to attention control, how can we incorporate mindfulness into daily life, previous application and scientific findings of mindfulness based interventions.	Mindful eating practice, mindful breathing meditation	Participants will be asked to conduct daily life mindfulness practices and mindful breathing meditation for 5–10 minutes daily for 7 days a week. Participants will also be asked to record and provide feedback on any difficulties and their experience during the training.
2	Explanation of the brain's mode of action and being, thoughts/emotions/body feeling. Instructing participants to talk to their bodies, relieve the pain and pressure in the healing process. Recognize the pain and try to persuade themselves to accept it, and realize self-awareness in the process.	Mindful body scan practice, three-minute breathing space practice	Participants will be asked to conduct mindful body scan practice, three-minute breathing space practice, and filling in pleasant/unpleasant experiences calendar for 10–15 minutes daily for 7 days a week respectively. Participants will also be asked to record and provide feedback on any difficulties and their experience during the training.
3	Introduce the scientific understanding of sleep, sleep hygiene education, and seven attitudes of practicing mindfulness.	Sitting meditation (mountain meditation and mindful sleep meditation)	Participants will be asked to conduct sitting meditation and mindfulness clock for 15 minutes daily for 7 days a week respectively. Participants will also be asked to record and provide feedback on any difficulties and their experience during the training.

Session	Theoretical instrument	Meditation practice	Homework
4	Introduce mindful living with thoughts, using the 'STOP' and 'RAIN' principle to dealing with a storm of thoughts and emotions	Mindful walking meditation, sitting meditation (lake meditation)	<p>Participants will be asked to conduct mindfulness listening practice, mindfulness movement, and STOP/RAIN practice for 15–20 minutes daily for 7 days a week respectively.</p> <p>Participants will also be asked to record and provide feedback on any difficulties and their experience during the training.</p>
5	Introduce mindful movement for relaxing body and mind. Explanation of identification of avoidance response, allowing and letting it go	Mindful yoga practice	<p>Participants will be asked to conduct sitting meditation for 15 minutes daily for 7 days a week and practice mindful yoga three times a day as appropriate.</p> <p>Participants will also be asked to record and provide their feedback on any difficulties and their experience during the training.</p>
6	Introduce tired funnel and how to balance our daily life, mindful living with a challenge, and how to live a mindful life, live in the present.	Sounding meditation; loving and kindness meditation	<p>Participants will be asked to list nourishing/consuming activities and weave their own mindfulness parachute.</p> <p>Participants will be encouraged to engage in various mindfulness practices on a daily basis in the future.</p> <p>Participants will be asked to complete the post-program questionnaire and give feedback on the content, form, and organization of the intervention.</p>

To enhance adherence, push notifications from the WeChat small program will be sent to participants daily to remind them about their weekly attendance and regular practice. In addition, participants can share experiences, discuss barriers, and progresses during each practice with the program manager (i.e. staff with nursing background) at any time on the WeChat platform. Furthermore, an experienced nurse will determine whether some participants exhibit severe psychological symptoms through reviewing the station letter and online consultation records, which will ensure the safety of participants and the quality of this study.

2.8.2 Control group

Participants in the waitlist control group will receive the full 12-session online MLWC intervention upon completion of all treatment procedures by the intervention group after the 3-month follow-up survey.

2.9 Patient and public involvement

There was no patient or public involvement in the study design and conduct of the study.

3 Measures

3.1 Adherence

Participants will be informed of the importance of attending each session and required to complete the homework, as the effectiveness of the MLWC intervention on mental health and quality of life is dependent on compliance. Adherence to the intervention was examined through documentation of completed sessions. Firstly, the Internet-based intervention platform can automatically record which participant has logged into each session and how much time they spend on mindfulness training per week. In addition, participants will be asked to report their homework to the researchers when completing each session. Moreover, the post-program questionnaire will be sent to the participants at the end of the intervention to ask about their compliance issues.

3.2 Outcome measurements

3.2.1 Primary outcome: PTSD, depression, anxiety and peace of mind

Impact of Events Scale-Revised

The psychological impact of COVID-19 will be assessed by the Impact of Event Scale-Revised (IES-R). IES-R is a self-administered questionnaire that has been well-validated in the Chinese population for determining the extent of psychological impact after exposure to a public health crisis within one week of exposure.[21, 22] This 22-item questionnaire is composed of three subscales and aims to measure the mean avoidance, intrusion, and hyperarousal. Total score can be divided into 0–23 (Normal), 24–32 (Mild

psychological impact), 33–36 (Moderate), and > 37 (Severe). Cronbach's α for the Chinese version of IES-R is more than 0.80.[23]

Patient Health Questionnaire

The 9-item Patient Health Questionnaire (PHQ-9) assesses depression in primary care and other medical settings on a 4-point Likert scale (0 = Never; 3 = Always).[24] Total possible scores range from 0 to 27, cutoffs are 5, 10, 15, and 20 for mild, moderate, moderately severe, and severe depression, respectively. The standard cut-off score of 10 or greater maximized combined sensitivity and specificity.[25] The Chinese version of the PHQ-9 has been well-validated (Cronbach's α = 0.86).[26]

Generalized Anxiety Disorder Questionnaire

The 7-item Generalized Anxiety Disorder Questionnaire assesses the level of general anxiety on a 4-point Likert scale (0 = Never; 3 = Always).[27] Total possible scores range from 0 to 21, with higher scores indicating higher levels of anxiety, and a cutoff score > 6 is recommended to identify anxiety symptoms.[28] Cronbach's α for the Chinese version of GAD-7 is 0.89.[28]

Peace of Mind Scale

The 7-item Peace of Mind Scale was developed by Lee et al. to measure the peace of mind, one part of the well-being in the Chinese culture.[29] Each item can be scored on a 1–5 scale and a higher score indicates a higher level of peace. A Chinese version of FS-14 has been validated (Cronbach's α = 0.90).[30]

3.2.2 Secondary outcomes: fatigue and sleep quality

Fatigue Scale-14

Fatigue scale-14 (FS-14) assesses the patient's level of physical fatigue (8 items) and mental fatigue (6 items).[31] Each item can be scored on 1 (Yes) or 0 (No), and a higher score indicates greater severity of fatigue. A Chinese version of FS-14 has been validated (Cronbach's α = 0.81).[32]

Pittsburgh Sleep Quality Index

The 19-item Pittsburgh Sleep Quality Index (PSQI) assesses respondent's sleep disturbances during the past month on a 4-point Likert scale of 0–3.[33] PSQI can be divided into 7 component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of medication, and daytime dysfunction.[33] Total possible scores range from 0 to 21, with lower scores indicating better sleep quality. The Chinese version of the PSQI has shown good reliability and validity (Cronbach's α = 0.84).[34]

3.2.3 The possible mediators and moderators

Five Facets Mindfulness Questionnaire

To evaluate the mindfulness level, 39 items from the Five Facets of Mindfulness Questionnaire (FFMQ) will be used. FFMQ is a self-reported questionnaire with 5 mindfulness domains: observing, describing, acting with awareness, non-judgment, and non-reactivity.[35] The items are rated on a 5-point Likert scale ranging from 1 (Never true) to 5 (Always true), and higher total scores indicate greater mindfulness.

Cronbach's α for the Chinese version of FFMQ is 0.86.[36]

The Nonattachment Scale

To measure nonattachment, the 7-Item Nonattachment Scale (NAS-7) will be used. NAS-7 is a short form of the original 30-item NAS.[37, 38] Each item can be scored on a scale from 1 (Disagree strongly) to 6 (Agree strongly). Sample items include, 'I can let go of regrets and feelings of dissatisfaction about the past', 'I do not get 'hung up' on wanting an 'ideal' or 'perfect' life,' etc. Cronbach's α of the Chinese version is 0.82.[39]

The Stillness Scale

To measure the extent to which participants experience stillness, the 11-item Stillness Scale will be used. It is developed and validated by one of the authors with three subscales: tranquility, concentration, and equanimity. Each item can be rated on a scale from 1 (Completely not like me/never) to 6 (Very much like me/always). Sample items includes: 'I can stabilize my emotion to create a feeling of calmness.' Cronbach's α of the Chinese version ranges from 0.72–0.75 (The reference of this scale is under review).

The Resilience Style Questionnaire

To measure participants' resilience, the 17-item Resilience Style Questionnaire (RSQ) will be used. Participants will be rated on a 5-point Likert scale from 1 (Never) to 5 (Always), with higher scores indicating higher levels of resilience. The Chinese version has been proved a valid and reliable tool in assessing resilience among Chinese general population and clinical patients. The Cronbach's alpha is 0.88.[40]

The Social Support Scale

The level of emotional and material social support that participants receive will be measured with two items: 'How much support can you obtain from family/friends/colleagues when you need to talk or to obtain emotional support?' and 'How much support can you obtain from family/friends/colleagues when you need material support (e.g financial help)?'. Each item can be recorded on scales that rang from 0 (None) to 10 (Tremendous). The Cronbach's α of the scale is 0.68.[41]

3.3 Data collection, management, and monitoring

Data will be collected at baseline (1 week before the intervention), post-intervention (1 week after the last session), and at 3-month of follow-up. The questionnaire comprises structured and open-ended questions about mental health status, quality of life, and satisfaction with the program. Demographics will be

collected at baseline, including age, employment status, education level, marital status, and other information.

Electronic questionnaires powered by the REDCap software will be used to collect data, so there will be no formal data monitoring committee. Survey questions filled up by the participants will be automatically uploaded to the read-only web-based database to ensure the authenticity of the data. Moreover, our researchers will promptly check the collected data after each questionnaire survey.

3.4 Statistical analysis

IMB SPSS Statistics 22.0 will be used to process data and conduct a t-test, chi-square test, and correlation analysis. Analyses will be conducted based on an intention-to-treat approach, and two-sided with $p < 0.05$ will be considered statistically significant. Quantitative data accords with normal distribution will be described as mean \pm standard deviation (SD), and qualitative data will be expressed as the number (percentage). Student's t-test and the chi-square test will be employed to examine between-group differences in the baseline. The repeated measures ANOVA will be used to compare the scores for the six instruments, and the paired-samples t-test will be used to test for within-group differences. We will also conduct a correlation analysis to test the associations between variables in pre-program and post-program in each group. Structural Equation Model will be conducted to explore the interaction of the variables.

Furthermore, in order to elaborate on the meaning of the relationship between the mindfulness training and the outcome variables of mental state and quality of life among COVID-19 survivors, an analysis of mediator or moderator effects will be conducted and some more in-depth information about the research may be explained. We will use the hierarchical multiple regression analyses to test how or why some facets of mindfulness may take a role in our outcomes.

4 Discussion

There is no doubt that the COVID-19 pandemic has created an unprecedented global health challenge. At the same time, we cannot ignore the secondary crisis of mental health that the outbreak may cause. Currently, there are 86,761 COVID-19 survivors cured and discharged from hospital in the Chinese mainland, about one-third of them (i.e. 27,000 patients) may be suffering from mental illness as reported by the survey results in Wuhan, China.[3, 9] Prolonged exposure to stressful hospitalization, complex medical examination procedures, and worries about the difficulty of returning to normal life can lead to long-term psychological harm.[42] This will undoubtedly affect the normal operation of many families and bring huge health and economic pressure to the country. Thus, innovative measures with social distancing merit mental health support to be implemented during the COVID-19 pandemic and its aftermath.

Previous studies showed that mindfulness practices are effective to alleviate anxiety, recurrent depression, reduce PTSD symptoms, and improve sleep.[12–14, 43] The intervention research based on

the internet platform can increase the timeliness, convenience, and interaction of intervention training, which is more in line with the particularity of psychological intervention. Nevertheless, the WeChat App and its small programs to be used in the current study have become an integral part of everyday life for an enormous number of users in China.[17] In addition, in order to ensure the effectiveness and feasibility of the intervention, our content and process of intervention will be reviewed and supervised by a psychiatrist with mindfulness training qualification, and the project will be jointly managed by the medical staff of the hospital's rehabilitation department.

The evaluation of the online MLWC intervention proposed in this study for the treatment of psychological symptoms among COVID-19 survivors is scarce in the international literature. The current study will use RCT, double-blind, evidence-based meditation design, and a longer period of intervention and follow-up, which may ensure more solid conclusions compared to similar studies.[13, 44] Moreover, some studies have found that the mindfulness intervention did not affect all of the mindfulness facets.[45, 46] Therefore, we can also explore the 12 sessions of the MLWC intervention as intermediaries on the outcome measures, to determine which sessions have the greatest impact on the outcome, and provide a new intervention direction for future psychological interventions. Furthermore, given the inexpensive and portable features of the online MLWC intervention, it can be more easily implemented in harder-to-reach but Internet-accessible populations.

This article describes the design and content of a parallel-group RCT. The study aims to test differences in mental health and quality of life between COVID-19 survivors receiving the online MLWC intervention and the control group and uncover the underlying mechanism. The expected benefits of this research project might be numerous, as it will provide a series of evidence-based and interactive mindfulness interventions, with social-distancing merits, to treat psychological symptoms and promote quality of life among COVID-19 survivors in China and all over the world. The intervention materials also have the potential to be utilized in other populations in various similar situations.

Abbreviations

COVID-19: Coronavirus Disease 2019

MLWC: Mindful Living With Challenge

MBI: Mindfulness-based intervention

PTSD: Post-traumatic stress disorder

RCT: Randomized Controlled Trial

CONSORT: Consolidated Standards of Reporting Trials

IES-R: Impact of Events Scale-Revised

PHQ-9: Patient Health Questionnaire

GAD-7: Generalized Anxiety Disorder Questionnaire

PoM: Peace of Mind Scale

FS-14: Fatigue Scale-14

PSQI: Pittsburgh Sleep Quality Index

FFMQ: Five Facets Mindfulness Questionnaire

NAS-7: The Nonattachment Scale

RSQ: The Resilience Style Questionnaire

SD: Standard Deviation

P: Probability

Declarations

Ethics approval and consent to participate

This study has been approved by the Ethical Review Committee of Institute of Pathogen Biology, Chinese Academy of Medical Sciences, Beijing, China (IPB-2020-22). Electronic informed consents will be obtained from all participants prior to the baseline survey. Trial results and findings will be published in peer-reviewed journals and scientific conferences.

Consent for publication

Not applicable.

Availability of data and materials

The original data generated from this study and the analyzed results will be available from the corresponding author upon reasonable request.

Competing interests

None.

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Authors' contributions

Xiaoyou Su, Mingyu Si and Weijun Xiao prepared the first draft. Qiuping Tang and Chen Pan provided overall guidance for the mindfulness-based interventions. Hao Wang, Yiman Huang and Jun Lian were responsible for the questionnaire design. Winnie WS Mak provided instrumental support for the part of outcome measures. Chen Wang and Zhiwei Leng will be responsible for the overall project in Wuhan, China. Luzhao Feng, Weizhong Yang and Yu Jiang finalized the manuscript based on the comments from other authors.

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Not applicable.

Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study will be approved by the Ethical Review Committee of Institute of Pathogen Biology prior to implementation. Other minor amendments will just be agreed upon by the cooperation team and documented in a memorandum.

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Figures

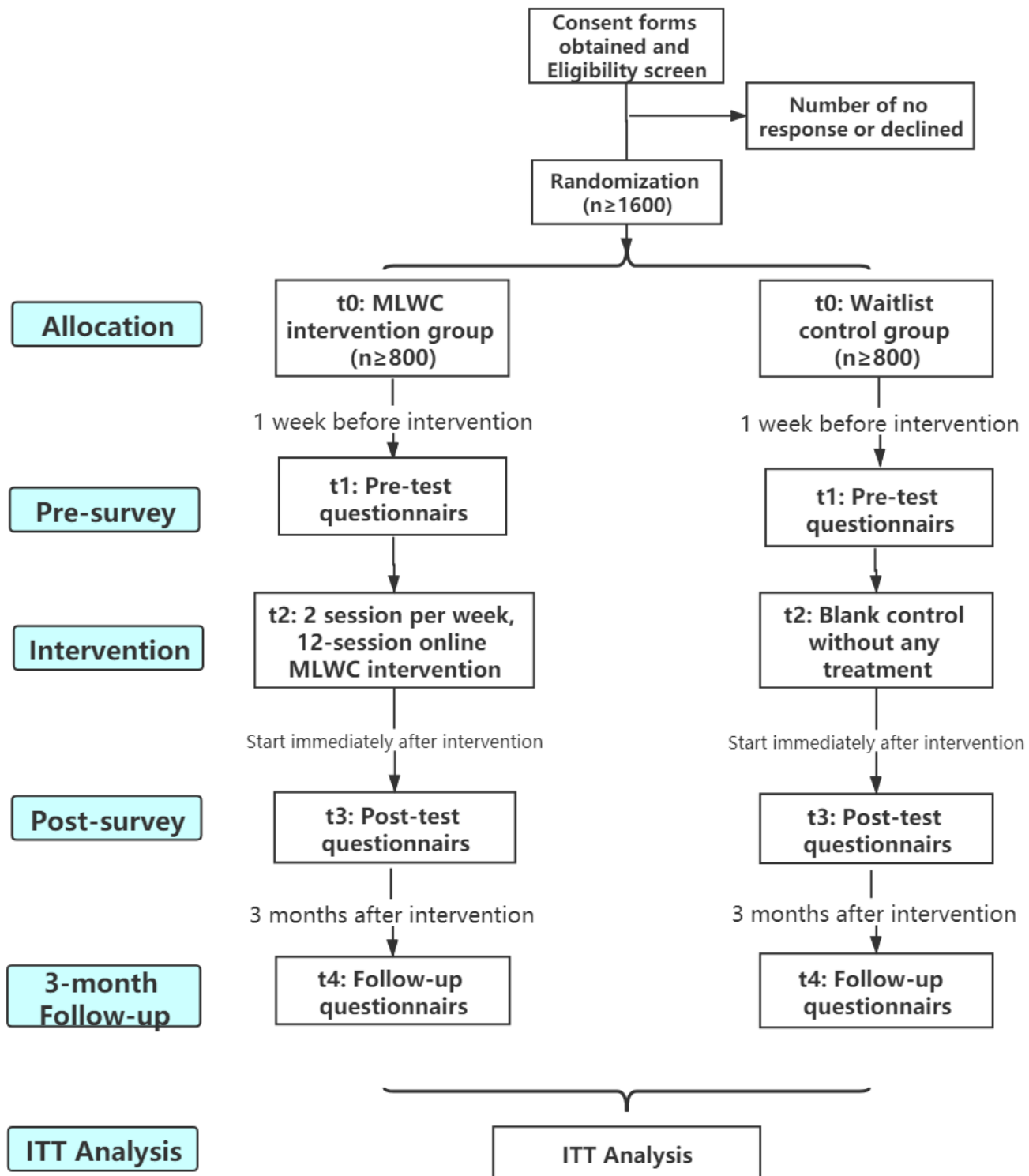


Figure 1

Flow Chart

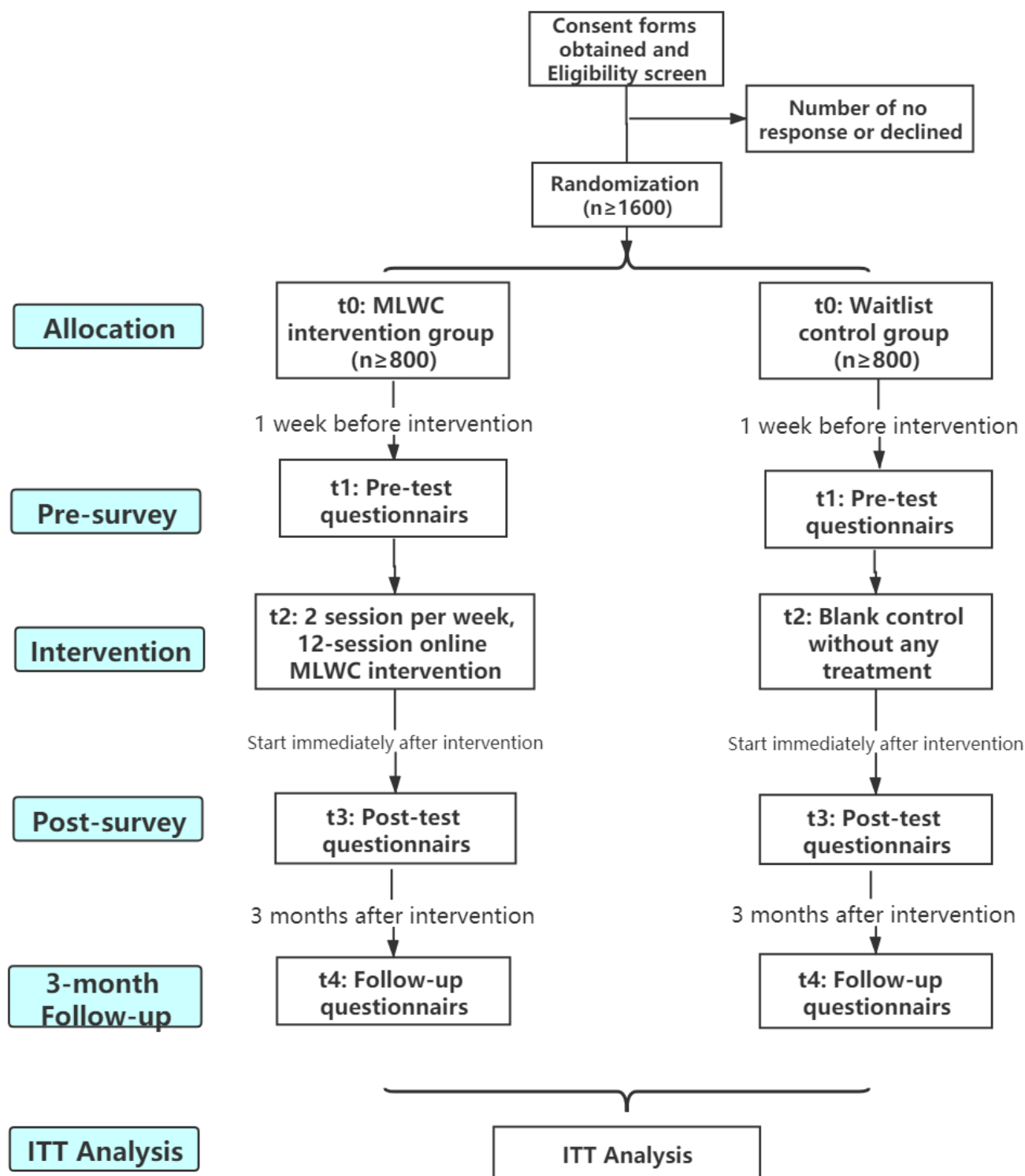


Figure 1

Flow Chart

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