

Project proposal: Effectiveness of short-term audio mindfulness in the community: a pilot study

Proposal summary

There is much evidence to show effectiveness of mindfulness-based interventions on mental health. This study explores the effectiveness of short-term audio mindfulness (SAM) on community people, and possible moderators and mediators of the efficacy. This study is a 2-arm, randomized controlled trial testing the effectiveness of SAM. Participants (n=140) in mainland China will be randomized into an intervention group (n=70) and a waitlist control group (n=70). Throughout 3-week and 21-session programs, participants spend 10 to 20 minutes on listening to the audio content and practicing exercises every day. The researcher will send the audio about mindfulness practice to participants via WeChat or QQ at 5 p.m. every day. After they finish the exercise, the researcher will confirm whether they finish the practice every day by asking the content of practices via chat tools to ensure fidelity. Participants need to fill in online assessments via the website. Participants in the mindfulness group will fill in the assessments four times (at baseline, 1-week, 2-week, and 3-week). Participants in waitlist control group only fill in the pre- and post-assessments (at baseline and 3-week). At baseline, participants need to provide their demographics and background information, such as WeChat account, phone number, age, gender, education level, and marital status. This study will use IBM Statistical Package for Social Sciences (SPSS) to analyze and compare the data in two groups. Moderated mediation analysis will be adopted to analyze the intervention outcomes on negative affectivity through anxiety. This study also will use unconditional quadratic latent growth model (LGM) to study the trajectories of anxiety and between-person variation on anxiety in the mindfulness group and allows non-linear growth on anxiety in Mplus 7.2.

Rationale of the study

The social scenario under the prolonged attack of the pandemic

The COVID-19 is a new viral disease caused by the newly emerged, highly contagious severe acute respiratory syndrome coronavirus in Hubei, China (Huang et al., 2020), which can achieve human-to-human transmission. People infected with the virus will experience symptoms of varying degrees, ranging from fevers and coughs to pneumonia or even symptoms that are lethal (Huang et al., 2020). As a result of the rapidly increasing numbers of confirmed cases and deaths, both medical staff and the public have been experiencing psychological problems, including anxiety, depression, and stress (Xiang et al., 2020; Kang et al., 2020). One online mental health surveys associated with the COVID-19 outbreak found the prevalence of depression to be 50%, of anxiety to be 45%, of insomnia to be 36%, and of stress-related symptoms to be 73% in China (Liu et al., 2020). However, the rapid spread of the virus from person to person obstructs traditional face-to-face psychological intervention (Liu et al., 2020), gives the opportunity for provision of online mental health services is safe. Online mental health education with communication tool, such as WeChat, Weibo, and TikTok, has been widely used during the outbreak for medical staff and the public (Liu et al., 2020).

Effectiveness of online mindfulness-based interventions in improving mental health was tested by the study (Spijkerman et al., 2016).

Mindfulness-based training: Origin, benefits of the practice

Mindfulness-based training is a program that concentrates on cultivating conscious awareness of current events at the present moment (Kabat-Zinn, 2005). As mindfulness has its theoretical root in Asian philosophies, so it is culturally adaptive interventions in the Chinese community (Hall et al., 2011). 4-day mindfulness practices can activate brain areas related to cognition controls and emotion regulations (prefrontal cortex, anterior cingulate cortex), sensory evaluations (anterior insula, primary somatosensory cortex and secondary somatosensory cortex), and sensory information (bilateral orbitofrontal cortex). More activations of the anterior cingulate cortex are associated with alleviation of pain and anxiety, and less activations of primary somatosensory cortex implicated in pain stimulation (Zeidan et al., 2013; Zeidan et al., 2011). Meta-analysis shows mindfulness-based program has a medium effect size in reducing anxiety, depression and stress in various samples, such as employees, students, adults with anxiety disorder, chronic pain, depression and so on (Khouri et al., 2013; Spijkerman et al., 2016).

Research gap: Short-term, online-based mindfulness training

Study provides evidence in support of the feasibility and effectiveness of short-term, self-guided online mindfulness intervention in a non-clinical population for perceived stress, anxiety and depression symptoms (Cavanagh et al., 2013; Cavanagh et al., 2018). However, few studies have evaluated short-term online audio-based mindfulness programs of community groups in mainland China. Most studies use the usual mindfulness program procedure which has long periods (e.g., 8-week to 12-week) and formal exercises (e.g., 45 minutes of meditation). For adults with busy schedules in fast-paced cities, their lack of time can be a hindrance to complete the program. To solve this problem, Mak et al. (2018) developed shorter intervention programs (e.g., 10 to 20 minutes per day, lasting for 28 days). The results show effectiveness these modified program in improving mental health and decreasing mental issues among adults in Hong Kong (Mak et al., 2018). Another study also shows that three 2-h mindfulness sessions can decrease psychological distress and improve life satisfaction and that a short-term mindfulness practice is good for community people who may not suffer severe symptoms of mental problems but aim to achieve better life satisfaction (Harnett et al., 2010). Therefore, this study will use a short-term audio-based mindfulness program (21 days). Participants spend 10-20min per day practicing relevant exercises adapted from the online mindfulness-based program that has been adopted in previous studies (Spijkerman et al., 2016). This study use audio-recorded guidance on the mobile phone to facilitate participants to practice mindfulness meditation at home or in any places.

Finally, although evidence shows the effectiveness of mindfulness in promoting mental health, there is little study pay attention to understand which individual difference

variables influence the effectiveness of mindfulness program and which can inform intervention options for various individuals. Previous research showed that a short-term mindfulness program is beneficial to those with moderate anxiety (Chen et al., 2013) and anxiety mediated the correlation between negative affectivity and mindfulness (Heuvel et al., 2015). To test who has benefited from the program in the study, the study hypothesized anxiety as the moderator and mediator. The slope and intercept of anxiety showed significance in the latent growth curve model from a brief online mindfulness intervention for first-year college students (Kim et al., 2020). This study also will explore the trajectories of levels of anxiety on community participants in mainland China.

Project pathways to impact statement

This project aims to improve participants mental health and relieve their symptoms during COVID-19 period in mainland China. It not only conducts community mental health surveys during the epidemic in mainland China, but also uses 21 consecutive days of mindfulness intervention to help community develop a healthy habit to relieve anxiety and stress, providing a professional and effective psychological intervention and techniques for negative symptoms of community caused by COVID-19 in mainland China.

Aims and objectives

1. To test the effectiveness of a 3-week audio-based mindfulness intervention for improving mental health among community in mainland China.
2. To test the mediation and moderation effects of anxiety on interventions.
3. To observe the growth trajectories of anxiety levels during the intervention.

Hypothesis

1. It assumes that participants in the program would significantly improve mental health at post intervention group.
2. It assumes that the level of anxiety was expected to mediate and moderate the effect of the intervention.
3. It assumes that participants have different initial status and growth trajectories on levels of anxiety.

Study design

Sample Size

Sample size estimate using G*Power for the repeated-measures analysis of variance (ANOVA) with 2 groups (mindfulness group and waitlist control group), and 4 phases (baseline, 1-week, 2-week, and 3-week) implied that 102 participants are required to test a small-to-medium effect size ($f=0.25$) data changes with alpha of 0.05, a power of 0.95, and a 0.5 correlation between repeated measures. The small-to-medium effect size is in line with previous studies (Harnett et al., 2010; Mak et al., 2018). Due to withdrawal, dropout, technical failure and data loss, the attrition rate is about 30% (Torous et al., 2020). The study needs to recruit more than 140 participants.

Intervention

This mindfulness program is a 21-session adapted from the online mindfulness-based program that has been developed in previous study (Mak et al., 2017). Mindfulness practice includes body scan, mindful breathing, mindful eating and walking, 3-min breathing space, as well as thought distancing practice (Chittaro & Vianello, 2014). It is audio-recorded form to facilitate participants to do the mindfulness exercises and the audio is recorded by a collaborator in mainland China who has three-year mindfulness practice experience and speaks Mandarin fluently. Participants would be provided with materials including basic concepts of mindfulness and common problems people may meet during the intervention period. Study suggests that mindfulness practice could be initially cognitively depleting because a brief mindful awareness induction has been shown to reduce pain tolerance to cold-pressor-challenge tasks, exhausting self-regulation (Evans et al., 2014). The cognitive requirement of using more reflective awareness of the experience of current moment may undermine, slow down or bias the response of others to cognitive tasks (Hafenbrack et al., 2014; Hopthrow et al., 2017), and improve false memory recall (Wilson et al., 2015). A PowerPoint about the introduction of mindfulness will send after they agreed to join the program. All participants in the intervention group will start the self-help mindfulness practice at the same date.

Participants

This research aims at recruiting participants in the community who meet the inclusion criteria:

- (1) over 18 years old;
- (2) can understand and read Mandarin;
- (3) have a smartphone;
- (4) the smartphone have consistent internet access and can receive audio from the researcher every day; and
- (5) have not practice mindfulness before.
- (6) not receiving any medication or psychotherapy currently.
- (7) have not been diagnosed with depression, anxiety, or other mental illness.

Research recruited participants by posting advertisements in social networking site (WeChat and QQ), which is a nation-wide range, and sending flyers in the community or online community groups, which is a regional range. Those who want to participate need to add the researcher's WeChat or QQ job account. The researcher would describe to participants about inclusion criteria, research objectives, length of this program, and method of randomization of groups. All participants will receive an electronic consent form on the chat tools (WeChat or QQ) after adding researcher's account. They need to sign the online consent form and then send back to the researcher on the chat tools.

Researchers will set two groups (intervention group and waitlist control group) randomly by using random number generator. Researchers will start the program after receiving all consent forms from all participants. At baseline, all participants need to provide their demographics and background information, such as phone number, age, gender, education level, and marital status. If the participant's anxiety and depression score is greater than 11 before the program, they will be advised to see the psychologists, but they still can decide whether continue this program after informed the nature of the program. Participants in the intervention group need to fill in scales three times (at 1-week, 2-week and 3-week) and to practice 21-day mindfulness every day. In the waitlist control group, participants need to fill in scales once (at 3-week) and they will receive all audios of mindfulness practice after 21 days.

Data collection

They need to seek for professional support in case of extreme emotional reactions aroused during the process of learning mindfulness practice. Regarding medical issues, they are strongly advised to consult their medical doctors. Researchers would provide information for consultation or referral for more intensive follow-up. Participants need to sign electronic consent forms after they agreed to participate in program and then they will be randomly assigned to mindfulness group and waitlist control group. After recruited 140 people, the researcher will start the intervention and send a 10-20 minutes mindfulness meditation practice audio to participants via WeChat or QQ at 5 o'clock every night. After they finish the exercise, the researcher will confirm whether they finish the practice every day by asking the content of practices via group sending function of chat tools at the next day before noon. If they missed the one training, they could make up for it in the next training. If participants do not reply the message, researchers will remind them again before send the audio. Participants will be deemed to automatically drop out if they do not respond to messages for more than three days or do not fill in the scales during the intervention. Researchers will keep a record of attendance or missed sessions for the participants every day.

Measures

Participants will fill in online assessments via the website. Participants in mindfulness group need to fill in the assessments four times (baseline, at 1-week, 2-week, and 3-week during the practice), and they will be asked whether finish 7-day/14-day/21-day practice in the scales. Participants in waitlist control group only fill in the pre- and post-assessments (baseline and 3-week).

Mental Well-Being

The World Health Organization 5-item Well Being Index (WHO-5) which is a 6-point Likert scale (0=never to 5=all of the time) can measure mental well-being (Bech, 1998). Respondents need to imply how they had been feeling over the past 2 weeks. The Chinese version of WBI has been validated (Kong et al., 2016).

Depression and Anxiety

Chinese Hospital Anxiety and Depression scale (HADS) measures depression (DEP) and anxiety (ANX) of respondents and has 7-item anxiety and 7-item depression subscales (Leung et al., 1993). This is a four-point Likert-type scale (zero to three) with 14-item and total score is forty-two, the score of each subscale is twenty-one. Higher scores suggest that respondents have higher levels of depression and anxiety. The validity and reliability and the internal consistency for anxiety subscale were .82 and for depression subscale were .71 (Spinhoven et al., 1997).

Positive and Negative Affect

Positive and Negative Affect Schedule (PANAS) involves positive affect (PA) scale (10 items) and negative affect (NA) scale (10 items) used as a measurement of mood (Watson et al., 1988). This is a 5-point Likert scale (1=not at all to 5=extremely) with total 20 items. The scale was validated in Chinese population including teenagers and young adults (Weidong et al., 2004).

Perceived Stress

The Perceived Stress Scale (PSS) (Cohen et al., 1983) is a 5-point Likert (1=not at all to 5=always) scale with total 14 items (7-item negatively stated and 7-item positively stated). Yang and Huang (Yang & Huang, 2003) develop the Chinese version of the Perceived Stress Scale (CPSS) to measure perceived stress with good reliability and validity. The alpha coefficient values for the positive and negative subscales were 0.86 and 0.77 (Leung et al., 2010).

Mindfulness

Freiburg Mindfulness Inventory (FMI) (Walach et al., 2006) has 14 items and is a 4-point Likert (1=never to 4=very often). Respondents need to rate how often they had been experiencing in the recent month (e.g., "I focus on what is behind my behaviors). The overall Alpha of FMI was .74. The Chinese version of FMI had acceptable internal consistency and test-retest reliability, which Cronbach's alphas are .76 (Chen & Zhou, 2014).

Data analysis

The study will use the IBM Statistical Package for Social Sciences (SPSS) version 25.0 (IBM Corp, Armonk, NY). Baseline characteristics of the two groups will be compared by using independent t-tests and chi-square tests. Paired sample t-test is used to test pre-post changes within two groups, and independent sample t-test is used to compare the between-group data at Time 0 and Time 3. A repeated-measure ANOVA is adopted to test data changes over time in the mindfulness group. If results do not meet the assumption of sphericity, the study would adopt the Greenhouse-Geisser adjustment (when epsilon is $<.75$) or the Huynh-Feldt adjustment (when epsilon $\geq .75$) to test results. It would use post-hoc analysis to explore how intervention group changed over times.

The PROCESS SPSS computational tool would be used to test the moderated mediation model (Hayes, 2012; Preacher & Hayes, 2008). Bootstrapping procedures will be set to

5000 samples to examine estimated indirect effects. If the 95% confidence interval (CI) of indirect effect do not involve zero, it implies that there are mediating effects. Moderation effect would be tested by simple slope test by pick-a-point approach and the Johnson-Neyman approach. The procedure of pick-a-point approach includes choosing values of moderators, calculating conditional effects of independent variables on dependent variables at that values, and producing a CI (Hayes & Matthes, 2009). Figure 1 shows the moderated mediation model. The binary treatment variable is short-term audio mindfulness (1=SAM, 0=control) and the outcome variable is Time 3 negative affect (T3NA). Anxiety at baseline (T0ANX) is the proposed moderator, and anxiety at Time 3 (T3ANX) is the proposed mediator. T0ANX as the pre-intervention variable is unrelated to the intervention due to randomization, and fulfill the moderator requirements of Kraemer et al. (Kraemer et al., 2008). The variable SAM*T0ANX, the product of SAM and mean-centered T0ANX, is adopted to test the potential intervention baseline interaction. The study involved age, gender, education and marital status as control variables in the model. In the case of significant interactions, explore conditional effects through plots and tests of simple effects to explore the interaction effects (Mean-1SD, Mean, Mean+1SD) across levels of T0ANX (Preacher et al., 2007). Effect sizes were expressed as a standardized difference between groups, with values of 0.2, 0.5 and 0.8 implying small, medium and large (Cohen, 1988).

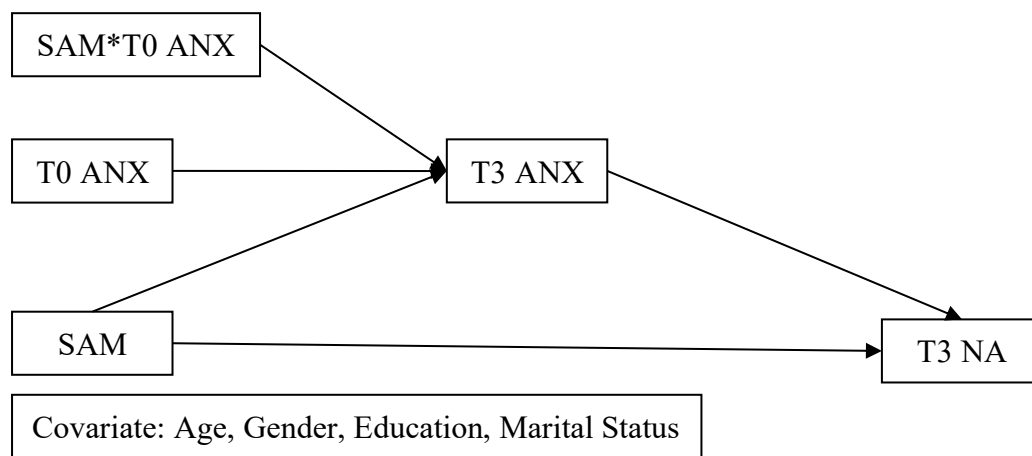


Figure 1 The moderated mediation model

The LGM will study the trajectories of anxiety and between-person variation on anxiety in mindfulness group and allows non-linear growth on anxiety (Curran et al., 2010; Duncan & Duncan, 2004) in Mplus 7.2 (Muthén & Muthén, 2007) under the robust maximum likelihood estimator. In LGM, latent intercept and slope represents the start levels of anxiety's trajectory and the change speeds of the trajectories of anxiety, respectively. Quadratic growth factors will be added into the model to test whether it had a better model fit the trajectory shape. Model fit is tested based on the Chi-Square (df), comparative fit index (CFI), root mean squared error of approximation (RMSEA) and standardized root mean square residual (SRMR) (Bollen & Curran, 2006; Fan et al., 1999; Hu & Bentler, 1999).

Ethical considerations

Potential risks

The situation varies from person to person. In case of feeling any discomfort or for whatever reasons, participants can withdraw from any phase of the project. They can also contact the research team for help including the PI Dr. Joshua Nan or the PhD student Ms. Connie Kang as the project coordinator. Participants will be reminded that the project is not equivalent to psychological counseling or treatment. If they feel psychologically unwell during the intervention process, they can contact the project coordinator who is familiar with the network of medical and psychological consultation. The participant will then be referred to an appropriate organization or party to provide further help. If they feel they have not been treated according to the descriptions in this proposal, or their rights as a participant in research have been violated during the course of this project, they may contact the Research Ethics Committee by email at hkbu_rec@hkbu.edu.hk or by mail to Graduate School, Hong Kong Baptist University, Kowloon Tong, Hong Kong.

Confidentiality

The Research Ethics Committee of the Hong Kong Baptist University will review the study to ensure the robustness of the study design, scales, and consent form. Prior consent for the participation of the study will be obtained. Each participant will be assigned a number code matched with their online assessment forms to ensure that personal identities cannot be ascertained from the questionnaires. Researchers will keep all participants' personal information confidential, and only authorized researchers can obtain this information. Participants' name or other information that can confirm their identity will not appear in any published materials, and researchers will not disclose it to a third party unless having participants' permission. All data will be securely stored by the PI only for research purposes. No personal identifiable information will appear in any reports published relevant to the study. All data will be destroyed three years upon completion of the study. The results of this research data may be published in academic journals/books and all participants will be well-informed.

Investigator (s) information

Dr. Joshua NAN, the PI, is an experienced art therapist and social worker with special interest in the use of various art therapy media in handling emotional regulatory issues. He is an advocate of the use of art for benefiting the community. Applying clay art therapy to adults with depressive signs in a randomized controlled trial (RCT), he demonstrated the significant effects of the intervention on depressive symptoms ($p < .05$, $d = 0.25$) (Nan & Ho, 2017). He has also treated youth survivors of the Sichuan earthquake in their traumatic experience and trained teaches with expressive art techniques in post-disaster training environments (Ho et al., 2012; Ho et al., 2016). He developed an intervention protocol for depression with the advanced art therapy model – Expressive Therapies Continuum (Nan, Hinz, & Lusebrink, 2020) and trained professionals to deal with death-related issues in elderly and terminally-ill patients,

which significantly raised professional sense of self-efficacy (Nan, 2019; Nan et al., 2019). His present project in adopting clay art therapy and art therapy with mixed media help secondary school students to cope with stress and increase resilience under the present pandemic. Pilot research results show significant improvements in the students' emotion regulation, resilience, and reduced negative affect (Nan & Wong, accepted for publication).

Man Ying KANG, is a PhD student of Department of Social Work in Hong Kong Baptist University. Her interested research fields include mindfulness-based and art-based interventions for mental health in different populations.

Kam Hei HUI, is a research assistant of Department of Social Work in Hong Kong Baptist University. He works with Dr. Joshua Nan, the PI, in developing art therapy for adolescence and is interested in trauma and art-based interventions.

Yee Ting WONG, is a research assistant of Department of Social Work in Hong Kong Baptist University. Working with the PI in art therapy for junior secondary students, she develops an interest in art psychotherapy and psychoeducation.

Cost & Justification

This is an online program and all materials (audio, scales, consent forms etc.) will be used and distributed via the Internet, so there is no cost for this program.

Details of project activities

| Time | Content |
|-------------|--|
| 2 months | <ol style="list-style-type: none"> 1. Promotion. 2. Screen participants according to the criteria. 3. Add participants as friends on chat tools, such as WeChat or QQ. 4. Collect online consent forms. 5. Divide participants into two groups (intervention group and waitlist control group) randomly on the chat tools. 6. In order to better management, it would divide intervention group into 4 small groups, each investigator will manage one small group with 17 or 18 participants. |
| 1 month | <ol style="list-style-type: none"> 1. Send out audio to participants for practicing 21-day mindfulness via WeChat or QQ at 5 p.m. every day in the intervention group. 2. Each investigator will confirm participants in their small group of the intervention group if they finish the practice and if there are any adverse |

| | |
|----------|--|
| | reactions every day before sending out the next audio during the intervention period. 3. Distribute and collect online scales every 7 days during practicing in intervention group and on the last day of intervention in the waitlist control group. |
| 1 month | 1. Sort out and handle data. 2. Analyze data by using SPSS and Mplus. |
| 2 months | Write draft paper and revise it, including abstract, results and discussion. |

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