

# Effectiveness of short-term audio mindfulness in the Chinese community: a pilot study

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<b>Registration date</b> 26/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/06/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Mindfulness is paying more attention to the present moment – to your own thoughts and feelings, and to the world around you. Becoming more aware of the present moment can help us enjoy the world around us more and understand ourselves better. When we become more aware of the present moment, we begin to experience afresh things that we have been taking for granted.

This is a study to test the effectiveness of a short-term audio mindfulness meditation (SAM) program for reducing signs of negative emotions in Chinese community-dwelling people during the period of COVID-19.

### Who can participate?

Community-dwelling adults in mainland China will be recruited online.

### What does the study involve?

Participants will be randomly allocated to the mindfulness meditation group or a waiting list control group. In the mindfulness group, participants will spend 10 to 20 minutes listening to the audio contents and practice daily mindfulness exercises throughout 3-week with a total of 21 sessions. At day 7, 14 and 21, participants will complete questionnaires to assess mental well being. After 21 days, the control group will also receive the meditation recordings.

### What are the possible benefits and risks of participating?

This study will provide evidence to support a cost-effective and efficacious SAM program for community-dwelling people in mainland China during the epidemic period when face-to-face intervention is not feasible. Potential risks vary from person to person. Studies showing mindfulness may produce side effects of false memory and burnout.

### Where is the study run from?

Department of Social Work at Hong Kong Baptist University (China)

### When is the study starting and how long is it expected to run for?

October 2020 to July 2021

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Joshua Nan, joshuanan@hkbu.edu.hk

## Contact information

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Effectiveness and moderated mediation of short-term audio mindfulness for Chinese community-dwelling people: a randomized controlled trial

### Acronym

MMCRCT

### Study objectives

The primary hypothesis is that negative emotions (anxiety, depression, stress, and negative affect) of community-dwelling people in mainland China will be reduced after mindfulness intervention and there are the potential mediation and moderation effect of anxiety through intervention effects on negative affectivity. Secondary hypotheses include positive emotions assessed, such as well-being, positive affect and mindfulness level, will be improved after the intervention.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 18/02/2021, Research Ethics Committee of Hong Kong Baptist University (Graduate School, Hong Kong Baptist University, Kowloon Tong, Hong Kong; no telephone number provided; hkbu\_rec@hkbu.edu.hk), ref: REC/20-21/0270

### Study design

Multicenter interventional non-blinded randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Quality of life

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Improvement of mental health in Chinese community-dwelling people during COVID-19 period

**Interventions**

Community-dwelling adults in mainland China will be recruited online and will be randomized using a computer-generated random number into an online audio-mindfulness meditation program and a waitlist control group. In the mindfulness group, participants will spend 10 to 20 minutes listening to the audio contents and practice daily mindfulness exercises throughout 3-week with a total of 21 sessions. They will fill in the scales about negative emotions (anxiety, depression, stress, and negative affect) four times (at baseline, 1-week, 2-week, and 3-week). Participants in the waitlist control group will need to fill in the same scales as the intervention group twice (at baseline and 3-week) and they will receive the same audio-mindfulness program for self-practice after all data collection procedures in the mindfulness group will be completed.

**Intervention Type**

Behavioural

**Primary outcome measure**

1. Stress will be measured using the Chinese version of the Perceived Stress Scale (CPSS) at baseline, 7-days, 14-days, and 21-days
2. Anxiety and depression will be measured using the Chinese Hospital Anxiety and Depression scale (HADS) at baseline, 7-days, 14-days, and 21-days
3. Negative affect will be measured using Positive and Negative Affect Schedule (PANAS) at baseline, 7-days, 14-days, and 21-days

**Secondary outcome measures**

1. Well-being will be measured using the World Health Organization 5-item Well Being Index (WHO-5) at baseline, 7-days, 14-days, and 21-days
2. Mindfulness will be measured using the Freiburg Mindfulness Inventory (FMI) at baseline, 7-days, 14-days, and 21-days
3. Positive affect will be measured using Positive and Negative Affect Schedule (PANAS) at baseline, 7-days, 14-days, and 21-days

**Overall study start date**

03/10/2020

**Completion date**

01/07/2021

**Eligibility**

**Key inclusion criteria**

1. Adults over 18 years old
2. Can understand and read Mandarin.
3. Have a smartphone with consistent internet access and can receive audio from the researcher every day
4. Have spare time to listen to audio for 10-15 minutes every day for 21 consecutive days

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

140 participants will be recruited and randomized into an online audio-mindfulness meditation program (n=70) and a waitlist control group (n=70).

**Total final enrolment**

100

**Key exclusion criteria**

1. Practiced mindfulness meditation before
2. Receive any medication or psychotherapy currently
3. Have been diagnosed with depression, anxiety, or other mental illness

**Date of first enrolment**

15/03/2021

**Date of final enrolment**

01/05/2021

**Locations****Countries of recruitment**

China

**Study participating centre**

Hong Kong Baptist University

Kowloon

Hong Kong

China

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# Sponsor information

## Organisation

Hong Kong Baptist University

## Sponsor details

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## Sponsor type

University/education

## Website

<http://buwww.hkbu.edu.hk/eng/main/index.jsp>

## ROR

<https://ror.org/0145fw131>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal which would share participant-level data as required by the WHO and ICMJE.

## Intention to publish date

28/07/2021

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			26/02/2021	No	No
<a href="#">Basic results</a>		10/01/2022	10/01/2022	No	No
<a href="#">Results article</a>		30/11/2022	06/12/2022	Yes	No
<a href="#">Results article</a>	Effects and mechanisms	23/12/2022	04/06/2024	Yes	No