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

Submission date
23/02/2021

Recruitment status
No longer recruiting

Registration date
26/02/2021

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Type(s)
Scientific

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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 mediation 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
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Sponsor information

Organisation
Hong Kong Baptist University

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Sponsor type
University/education

Website
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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?
Protocol file			26/02/2021	No	No
Basic results		10/01/2022	10/01/2022	No	No
Results article		30/11/2022	06/12/2022	Yes	No
Results article	Effects and mechanisms	23/12/2022	04/06/2024	Yes	No