

Mental health first aid training for China: a randomised controlled trial

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| Submission date 14/02/2023 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 18/02/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 19/12/2023 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Many people who meet the criteria for a mental disorder do not receive appropriate professional help. Improving professional help-seeking is likely to require improvements in mental health literacy as well as structural reform of services. Given the high likelihood of contact with a person with a common mental health problem, interventions that teach members of the public to provide early help towards a person developing a mental health problem or in a mental health crisis may play a role in improving access to services, social support, and mental health outcomes. Mental health first aid is the help offered to a person developing a mental health problem, or experiencing a worsening of an existing mental health problem or in a mental health crisis; the first aid is given until appropriate professional help is received or until the crisis resolves. This course, and related programs, have been developed by Mental Health First Aid (MHFA) International, a not-for-profit organisation that has disseminated the courses to organisations in over 25 other (mostly high-income) countries, which then facilitate the training and accreditation of instructors in those countries. However, MHFA trials have only been conducted in high-income countries. The appropriateness of the training for countries with less well-resourced mental health systems and cultural differences relevant to mental health is unknown. The current study will evaluate the effectiveness of culturally adapted MHFA Training for China. It will be a collaboration between three partner organisations: the University of Melbourne, MHFA International and the Shanghai Mental Health Center (SMHC).

Who can participate?

All participants (adults aged 18 years old and over) in each of the study settings in accordance with the criteria

What does the study involve?

The study will be conducted in 6 settings in Shanghai, two health services, two workplaces and two community settings, with each setting defined as a cluster. Intervention settings will be paired according to type and one of each pair will be randomly allocated to the intervention (the MHFA Training for China) or the wait-list control group, with a 1:1 allocation.

Participants will be asked to complete questionnaires at baseline (T1) and 1 month (T2) and 7 months after completing the training (T3). Participants in the control group will be asked to

complete questionnaires at corresponding times. The primary outcome will be intended support towards someone experiencing a mental health problem or in a mental health crisis. Secondary outcome measures will include recognition of depression in a vignette; beliefs about the helpfulness of interventions for mental health problems; helping actions taken; confidence in providing mental health first aid; stigmatising attitudes; and desire for social distance from a person with a mental health problem.

What are the possible benefits and risks of participating?

Possible benefits include improved mental health literacy and capacity to help a person developing mental health problems or in a mental health crisis. Risks may include distress related to discussing poor mental health.

Where is the study run from?

Shanghai Mental Health Center (China)

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

October 2022 to May 2025

Who is funding the study?

The National Health and Medical Research Council (Australia)

Who is the main contact?

Dr Yanling He, heyangling@smhc.org.cn (China)

Prof Nicola Reavley, nreavley@unimelb.edu.au (Australia)

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

GNT1142395

Study information

Scientific Title

Mental health first aid training for China: a randomised controlled trial

Acronym

MHFA-China

Study objectives

The study hypothesis is that Mental health first aid (MHFA) training in China will be more effective than no intervention (wait-list control) in improving participant intentions to help someone developing a mental health problem or in a mental health crisis; helping actions taken

to assist a person in this situation; confidence in providing mental health first aid; stigmatising attitudes; desire for social distance from a person with a mental health problem.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 02/02/2023, University of Melbourne Human Research Ethics Committee (The University of Melbourne, Office of Research Ethics and Integrity, Research, Innovation & Commercialisation, Level 5, Alan Gilbert Building, 161 Barry Street, Carlton, Victoria, 3010, Australia; +61 3 8344 7895; HumanEthics-Enquiries@unimelb.edu.au), ref: 2023-25658-36173-4

Study design

Randomized waitlist control study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Mental health literacy and stigma

Interventions

The intervention

Mental health first aid (MHFA) training for China is a major adaptation based on the Australian Standard MHFA 12-hour course. Course adaptation was undertaken members of the Shanghai Mental Health Center (SMHC) research team. As with the Australian MHFA materials, the MHFA China course includes an MHFA China manual, instructor teaching notes, PowerPoint slides, videos and activities that allow participants to practice their new skills. The content of the MHFA China manual was informed by guidelines developed in five Delphi expert consensus studies, undertaken in China with health professionals, people with lived experience and carers. The results of these studies outline culturally-appropriate actions to be taken to help a person developing depression, psychosis, problem drinking, at risk of suicide or at risk from a potentially traumatic event. Using these guidelines, the team came up with a simplified MHFA Action Plan, more suitable for countries that do not have good mental health literacy and good pathways to mental health care. The new Action Plan is: Recognise, Engage, Keep safe, and Support. The manual was organized into chapters covering each of these actions. Based on this manual, the teaching and curriculum notes were developed. The resulting English-language manual, teaching materials and PowerPoint slides were translated into Mandarin Chinese. Subtitles for three of the Australian MHFA videos were also translated. The course will be delivered over 2 days and will be conducted in health services, workplaces and community settings by instructors from SMHC. Training will be offered to approximately 20 participants per course group through face-to-face delivery, depending on COVID-19 restrictions in Shanghai.

Randomisation

Clusters will be paired according to setting (health services, workplaces and community settings) and randomly assigned to either the intervention or the control group with a 1:1 allocation. After the trial manager has recruited a pair of clusters, they will send the independent statistician blinded details about the clusters and the statistician will generate the allocation

using a random sequence generator within Stata. Due to the nature of the intervention, it will not be possible to blind participants to allocation. However, neither participants nor the cluster will be notified of the allocation prior to trial enrolment. Data analysis will be conducted blinded to allocation.

Intervention Type

Behavioural

Primary outcome(s)

Intentions to provide mental health first aid measured using the Mental health support scale – Intended at baseline (T1), 1 month (T2) and 7 months after completing the training (T3)

Key secondary outcome(s)

1. Recognition of depression measured by asking the participant to write a vignette at baseline, 1-month and 7 months
2. Beliefs about treatment and mental health professionals measured using a Chinese adaptation of a 16-item scale used in a Mental Health First Aid (MHFA) trial in Australia, at baseline, 1-month and 7 months
3. Confidence in providing MHFA for a person with depression measured by asking participants to rate how confident they would feel supporting this person, at baseline, 1-month and 7 months
4. Helping actions taken to assist a person with depression measured using the MHSS-Provided subscale Chinese version at baseline and 7 months
5. Desire for social distance from a person with a mental health problem measured using the Link Social Distance Scale at baseline, 1-month and 7 months
6. Personally stigmatising attitudes about a person with depression, measured using the Depression Stigma Scale at baseline, 1-month and 7 months
7. Course quality and satisfaction measured using a 5-item questionnaire at 1 month

Completion date

01/05/2025

Eligibility

Key inclusion criteria

Adults aged 18 years old and over

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Previously completed an MHFA course
2. Low level of literacy (below middle school)
3. A high level of mental health knowledge based on their professional role (e.g., psychologists and psychiatrists)

Date of first enrolment

15/02/2024

Date of final enrolment

01/06/2024

Locations

Countries of recruitment

China

Study participating centre

Shanghai Mental Health Center
600 Wanping Rd (S), Xuhui District
Shanghai
China
200032

Sponsor information

Organisation

University of Melbourne

ROR

<https://ror.org/01ej9dk98>

Funder(s)

Funder type

Government

Funder Name

National Health and Medical Research Council

Alternative Name(s)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available on request from Prof Nicola Reavley (nreavley@unimelb.edu.au). The type of data that will be shared is de-identified data stored in a repository. These data will be available subsequent to any publications and for up to 15 years. Consent from participants was required and obtained on the Plain Language Statement. A unique identifier for each participant will be generated, allowing data linkage across time points. The research team will keep a separate, secure record matching participants' personal information with their unique identifiers. No ethical or legal restrictions have been identified.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|--------------------------|--------------|------------|----------------|-----------------|
| Participant information sheet | Plain Language Statement | | 15/02/2023 | No | Yes |