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Promoting mental health for university students in China through mindfulness: A randomized controlled trial across six universities

Submission date
05/09/2025

Recruitment status
No longer recruiting

Registration date
09/09/2025

Overall study status
Ongoing

Last Edited
27/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Mindfulness-based programs (MBPs), rooted in contemplative practices, have emerged as promising interventions for promoting mental well-being and resilience. Unfortunately, no large-scale study has assessed the efficacy of MBPs for university students in China, a population with a high prevalence of mental health issues. Building off of a pilot study implemented in spring 2025, the primary goal of this larger-scale study is to evaluate the impact of a mindfulness-based program specifically tailored for university students. We will investigate the effects on mental illness symptoms, stress (perceived and physiological), state and trait mindfulness, emotion regulation skills, and other indicators of well-being, such as sleep quality and somatic symptoms. We will also conduct ecological momentary assessments for one week (both pre- and post-intervention), four times per day, to explore the effects on direct, immediate experience.

Who can participate?
Undergraduate students at participating universities with mild to severe symptoms of anxiety and/or depression (see inclusion and exclusion criteria above).

What does the study involve?
Students in the intervention group will participate in an eight-week mindfulness program (in-person).

What are the possible benefits and risk of participating?
Potential benefits are improved mental and physical health. Students will also receive small financial rewards for participating in the study.

Potential risks are unlikely, but may include increased awareness of mental or physical discomfort, as well as time stress due to extra time dedicated to participation.

Where is the study run from?
Overall, students from six universities will participate in the study. The two main China-based universities (Fudan University and Beijing Normal University) will oversee the study implementation, facilitating participant recruitment and data collection at five other universities in China. Researchers at Stanford University will work with these partners to implement the project.

When is the study starting and how long is it expected to run for?
The study will begin recruitment for the mid-September 2025. The intervention is planned to begin in mid-October and last for nine weeks.

Who is funding the study?
Study funders include the Cyrus Tang Foundation, the Enlight Foundation, and Vincent Woo Foundation.

Who is the main contact?
Researchers may contact Dr. Huan Wang (huanw@stanford.edu), Dr. Hui-Qi Tong (htong@stanford.edu), or Cody Abbey (cjabbey@stanford.edu) for more information about this study.

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
AEARCTR-0016685

Study information

Scientific Title
Promoting mental health for university students in China through mindfulness: A randomized controlled trial across six universities

Study objectives
Current study objectives as of 27/01/2026:

Participation in the mindfulness-based program will reduce anxiety and depression symptoms more than a control group.

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Previous study objectives:

Participation in the mindfulness-based program will reduce anxiety and depression symptoms more than an experimental waitlist control.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/12/2024, Stanford University Institutional Review Board (1705 El Camino Real Palo Alto, Stanford, 94305, United States of America; +1 (650) 724-7141; kateri.noble@stanford.edu), ref: 75117

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Treatment

Health condition(s) or problem(s) studied
Prevention of chronic mental disorders in students with depression and/or anxiety symptoms

Interventions
Current interventions as of 27/01/2026:

We will conduct a randomized study with 360 undergraduate students recruited from six universities in China. Using the RCT method of impact evaluation, we will be able to ensure that the intervention and control groups have similar characteristics at baseline, which is vital for drawing a causal connection between the intervention and any changes in student outcomes. By assuring the similarity of characteristics (such as sex, baseline mental health, etc.) between the treatment and control groups at baseline, we can confidently attribute any significant differences in outcomes between the control and intervention group to the program.

For this study, the 360 sample students will be randomly allocated into two experimental arms (in-person mindfulness-based program and a control). Using STATA 16 software (https://www.stata.com/), with 80% power, a significance level of 0.05, we determined that a sample size of 139 students per arm was required to detect a difference of 0.30 standard deviations in outcome measures. Our recruitment of 180 students per arm (360 in total) allows for 20% attrition.

In-person mindfulness instruction:
- The in-person mindfulness instruction will consist of weekly 90-minute group sessions, held in a university classroom over eight consecutive weeks, not including a introductory session prior to the formal start of classes.
- Participants will learn foundational principles related to the role of mindfulness in specific domains such as responding to stress, mindful communication in relationships, and gratitude.
- Participants will also be taught formal mindfulness practices (e.g., sitting meditation, body scan, qigong, loving-kindness meditation) during the weekly sessions and informal mindfulness practices (e.g., mindful eating, mindful walking, and mindful daily routine activities) during the weekly sessions.

They will be asked to commit to completing assigned mindfulness practice independently throughout the intervention period.

Participants assigned to the control group will receive no other intervention during the program (pure control).

All study participants will receive adequate financial compensation for participating in the study.

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Participants assigned to the control group will receive no other intervention during the program (pure control).

All study participants will receive adequate financial compensation for participating in the study.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety symptoms will be measured using the General Anxiety Disorder Scale (GAD-7) at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention (post-graduation from undergraduate studies)
2. Depression symptoms will be measured using the Patient Health Questionnaire Scale (PHQ-9)

at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention (post-graduation from undergraduate studies)

Key secondary outcome(s))

Current secondary outcome measures as of 24/09/2025:
1. Physiological stress will be measured using cortisol levels. The cortisol levels will be measured via saliva samples starting one week before the intervention, three times on the same day at consistent times. At the end of the intervention, the cortisol levels will be measured one week after the course ends, three times on the same day (at the same times as before the intervention).
2. Perceived stress is measured using the Perceived Stress Scale (PSS), measured at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention
3. Emotion regulation will be measured using the Emotion Regulation Questionnaire (ERQ) at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention
4. Coping strategies will be measured using the Coping Strategies Scale at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
5. Trait mindfulness will be measured using the short-form of the Five Facet Mindfulness Questionnaire (FFMQ-SF) at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
6. State mindfulness will be measured using the Multidimensional State Mindfulness Questionnaire (MSMQ) baseline, endline, measured weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
7. Loneliness will be measured using the short-form of the 6-item UCLA Loneliness Scale at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
8. Recent stressful events will be measured using the Adolescent Self-Rating Life Events Checklist (ASLEC) at baseline and endline, and in several follow-ups at three months, six months, and four years after the intervention
9. Sleep quality will be measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline, at endline, and in several follow-ups at three months, six months, and four years after the intervention
10. Flourishing will be measured using the Flourishing Scale (FS) at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention
11. Life satisfaction will be measured using the Satisfaction with Life Scale (SWLS) at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
12. Academic performance will be measured using the semester GPA and national English test results at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
13. Lifestyle behaviors will be measured using items asking about the amount and frequency of behaviors such as screen use and exercise at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
14. Face will be measured using the CPAI-2 at baseline and endline, and in several follow-ups at three months, six months, and four years after the intervention
15. Somatic symptoms will be measured using the brief version of the Somatic Symptom Scale (SSS), at baseline and endline, and in several follow-ups at three months, six months, and four years after the intervention

16. Perceived benefits and adverse effects and helpfulness of the program will be measured with Likert-type items measured weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
17. Compliance with mindfulness practice will be measured based on self-report length and frequency of practice, measured weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
18. Acceptability of the intervention will be measured via qualitative interviews and focus groups with students and instructors
19. Self-compassion will be measured using the Self-Compassion Scale, measured at baseline and endline, as well as weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
20. Sense of purpose will be measured using the Meaning of Life Questionnaire, measured at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
21. Experiential avoidance will be measured using the Brief Experiential Avoidance Questionnaire at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
22. Emotion Reactivity and Instability will be measured using the RIPOST-Y at baseline, endline, weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
23. Career outcomes will be measured using items asking about post-graduation trajectories four years following the intervention
24. Interpersonal tolerance will be measured using the CPAI-2 at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
25. Perceived ostracism will be measured using the Ostracism Experience Scale (OES-A), measured at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
26. Fear of negative evaluation will be measured using the Brief Fear of Negative Evaluation Scale (BFNE-II), measured at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
27. Neuroticism will be measured using the Big Five Personality Inventory (brief version), at baseline and endline
28. Openness will be measured using the Big Five Personality Inventory (brief version), at baseline and endline
29. Emotion reactivity will be measured using the Perth Emotion Reactivity Scale, measured at baseline and endline
30. Gratitude will be measured using the five-item Gratitude Questionnaire, measured at baseline, endline, weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
31. Stress mindset will be measured using the Stress Mindset Scale, measured at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention
32. Positive and negative emotions will be measured using the PANAS, measured at baseline, endline, weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
33. Interpersonal tolerance will be measured using the tolerance scale of the CPAI-2, measured at baseline, endline, and in several follow-ups at three months, six months, and four years after the intervention

Ecological momentary assessment scales are conducted for one week (both pre- and post-intervention), four times per day, to explore the effects on direct, immediate experience:
1. State mindfulness (MSMQ-9)

2. Depression (PHQ-2)
3. Anxiety (GAD-2)
4. Life satisfaction (SWLS-2)
5. Positive and negative emotions (14 emotion words, drawn from the I-PANAS-SF, PANAS-X, and parts of the LAPA)
6. Sleep duration and quality (one item each from the PSQI)
7. Perceived stress (one self-developed item)
8. Emotion regulation efficacy (two self-developed items)
9. Negative and positive events (seven self-developed items each)
10. Overall daily emotional stability (adapted from the TIPI)

Previous secondary outcome measures:
1. Stress (physiological) will be measured using cortisol levels. The cortisol levels will be measured via saliva samples starting one week before the intervention, three times on the same day at consistent times. At the end of the intervention, the cortisol levels will be measured one week after the course ends, three times on the same day (at the same times as before the intervention).
2. Perceived stress is measured using the Perceived Stress Scale (PSS), measured at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention
3. Emotion regulation will be measured using the Emotion Regulation Questionnaire (ERQ) at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention
4. Coping strategies will be measured using the Coping Strategies Scale at baseline and endline
5. Adverse Childhood Experiences will be measured using the Adverse Childhood Experiences International Questionnaire (ACES-IQ) and Childhood Trauma Questionnaire short form (CTQ-SF) at baseline
6. Trait mindfulness will be measured using the short-form of the Five Facet Mindfulness Questionnaire (FFMQ-SF) at baseline and endline
7. State mindfulness will be measured using the Multidimensional State Mindfulness Questionnaire (MSMQ) at baseline and endline, and measured weekly during the intervention
8. Loneliness will be measured using the short-form of the 6-item UCLA Loneliness Scale at baseline and endline
9. Attachment style will be measured using the Revised Adult Attachment Scale at baseline and endline
10. Recent stress will be measured using the Adolescent Self-Rating Life Events Checklist (ASLEC) at baseline and endline, and in several follow-ups at three months, six months, and four years after the intervention
11. Sleep quality will be measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline, at endline, and in several follow-ups at three months, six months, and four years after the intervention
12. Flourishing will be measured using the Flourishing Scale (FS) at baseline, weekly during the intervention, at endline, and in several follow-ups at three months, six months, and four years after the intervention
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14. Academic performance will be measured using the semester GPA and national English test results at baseline and endline, at endline, and in several follow-ups at three months, six months, and four years after the intervention
15. Lifestyle behaviors will be measured using items asking about the amount and frequency of behaviors such as screen use and exercise at baseline and endline
16. Neuroticism will be measured using the Big Five Personality Inventory (brief version), at baseline and endline

17. Openness will be measured using the Big Five Personality Inventory (brief version), at baseline and endline
18. Face will be measured using the CPAI-2 at baseline and endline, and in several follow-ups at three months, six months, and four years after the intervention
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24. Sense of purpose will be measured using the Meaning of Life Questionnaire, measured at baseline and endline
25. Experiential avoidance will be measured using the Brief Experiential Avoidance Questionnaire at baseline and endline
26. Emotion Reactivity and Instability will be measured using the RIPOST-Y at baseline, endline, weekly during the intervention, and in several follow-ups at three months, six months, and four years after the intervention
27. Career outcomes will be measured using items asking about post-graduation trajectories four years following the intervention
28. Interpersonal tolerance will be measured using the CPAI-2 at baseline and endline
29. Harmony will be measured using the CPAI-2 at baseline and endline
30. Self vs. social orientation will be measured using the CPAI-2 at baseline and endline

Completion date
30/01/2030

Eligibility

Key inclusion criteria
1. Undergraduate student enrolled at participating universities in China
2. Reporting mild, moderate, or severe symptoms of depression and/or anxiety (PHQ-9>=5; GAD-7 >=5)
3. Willing to attend weekly classes and engage in mindfulness practice at home
4. 18 years or older

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Total final enrolment
342

Key exclusion criteria
1. In graduating year of undergraduate program
2. Has moderate/severe risk of self-harm or harm to others (thoughts of self-harm and/or harm to others occurring several or more days per week)
3. Has received formal, teacher-led mindfulness meditation training before and/or has a regular meditation practice (once or more per week over the past two months)
4. Is currently receiving psychotherapy and/or taking psychiatric medication

Date of first enrolment
15/09/2025

Date of final enrolment
07/10/2025

Locations

Countries of recruitment
China

Study participating centre
Beijing Normal University
19 Xinwai Ave, Beitaipingzhuang, Haidian District
Beijing
China
100875

Study participating centre
Fudan University
220 Handan Rd, Yang Pu Qu
Shanghai
China
200437

Sponsor information

Organisation
Stanford University

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Charity

Funder Name
Cyrus Tang Foundation

Alternative Name(s)
CTF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Enlight Foundation

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Databases will be shared for replication studies upon request and reasonable conditions.
huanw@stanford.edu

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		25/01/2024	27/01/2026	No	No