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Promoting mental health for university students in China through mindfulness

Submission date
31/01/2025

Recruitment status
No longer recruiting

Registration date
10/02/2025

Overall study status
Completed

Last Edited
15/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] 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. The primary goal of this pilot 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, student inner resources such as mindfulness, emotion regulation skills, other indicators of wellbeing such as sleep quality and and academic performance. Later, in the full-scale RCT (to be implemented later this year), we intend to assess how the impact of the MBP varies when delivered in person or online.

Who can participate?
Undergraduate students with mild to severe symptoms of anxiety and/or depression.

What does the study involve?
Students in the intervention group will participate in an eight-week mindfulness program (in-person). Students in the waitlist control group will receive the intervention after the conclusion of the pilot study.

What are the possible benefits and risk of participating?
Potential benefits are improved physical and mental 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?
The two main participating universities in the pilot study in China will be Fudan University and Beijing Normal University. Researchers at Stanford University will work with these partners to implement the project in the pilot.

When is the study starting and how long is it expected to run for?
The study will begin recruitment for the pilot study in mid-February 2025. The intervention is planned to begin in late March 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.

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AEARCTR-0015090

Study information

Scientific Title
Promoting mental health for university students in China through mindfulness: a pilot randomized controlled trial

Study objectives
Current study hypothesis as of 09/04/2025:

Participation in the mindfulness-based program will reduce mental health symptoms and stress (perceived and physiological) more than an experimental waitlist control

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Previous study hypothesis:

Participation in the mindfulness-based program will reduce mental health symptoms and stress (perceived and physiological) more than an experimental control

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/12/2024, Stanford University Institutional Review Board (1705 El Camino Real, Palo Alto, 94306, United States of America; +1 (650) 723-2480; afbailey@stanford.edu), ref: 75117

Study design
Interventional randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Prevention, Treatment, Efficacy

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevention of severe mental disorders in students with mild to moderate mental health symptoms

Interventions
Current interventions as of 09/04/2025:

We will conduct a pilot study with 112 university students recruited online and offline from 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 waitlist control groups at baseline, we can confidently attribute any significant differences in outcomes between the control and intervention group to the program.

For this pilot study, 112 sample students will be randomly allocated into two experimental arms (in-person mindfulness-based program and a pure control). Using STATA 16 software (https://www.stata.com/), with 80% power, and a significance level of 0.05, we determined that a sample size of 51 students per arm was required to detect a difference of 0.5 standard deviations in outcome measures. Our recruitment of 56 students per arm (112 in total) allows for 10% 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.
Participants will learn foundational principles related to the role of mindfulness in specific domains such as emotion regulation, stress, social 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 an educational intervention unrelated to the mindfulness program.

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

Participants assigned to the control group will receive an educational intervention unrelated to the mindfulness program.

Intervention Type
Behavioural

Primary outcome measure
1. Anxiety symptoms will be measured using the General Anxiety Disorder Scale (GAD-7) at baseline, weekly during the intervention, and endline
2. Depression symptoms will be measured using the Patient Health Questionnaire Scale (PHQ-9) at baseline, weekly during the intervention, and endline
3. Stress (physiological) will be measured using cortisol levels. The cortisol levels will be measured starting one week prior to the intervention, for three days in a row, three times per day at consistent times. At the end of the intervention, the cortisol levels will be measured on

days 5-7 after participation in the program ends, three times per day (at the same times each day as before the intervention). Stress (physiological) will also be measured using heart rate variability, measured continuously during the intervention via a wearable device
4. Perceived stress is measured using the Perceived Stress Scale (PSS), measured at baseline, weekly during the intervention, and endline

Secondary outcome measures

1. Emotion regulation will be measured using the Emotion Regulation Questionnaire (ERQ) at baseline and endline
2. Coping strategies will be measured using the Coping Strategies Scale and the Simplified Coping Styles Questionnaire at baseline and endline
3. Adverse Childhood Experiences will be measured using the Adverse Childhood Experiences International Questionnaire (ACES-IQ) at baseline
4. Mindfulness will be measured using the short-form of the Five Facet Mindfulness Questionnaire (FFMQ-SF) at baseline and endline, and measured weekly during the intervention
5. Loneliness will be measured using the short-form of the 6-item UCLA Loneliness Scale at baseline and endline
6. Parent attachment will be measured using the Inventory of Parent and Peer Attachment (IPPA) at baseline and endline
7. Smartphone addiction will be measured using the Smartphone Addiction Scale (SAS) at baseline and endline
8. Positive and negative affect will be measured using the Positive and Negative Affect Schedule -short form (PANAS-SF) at baseline and endline, and measured weekly during the intervention
9. State mindfulness will be measured using the Multidimensional State Mindfulness Questionnaire (MSMQ) at baseline and endline, and measured weekly during the intervention
10. Recent stress will be measured using the Adolescent Self-Rating Life Events Check list (ASLEC) at baseline and endline
11. Diet will be measured using the Perceived Healthy Diet Scale at baseline and endline
12. Sleep quality will be measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and endline
13. Flourishing will be measured using the Flourishing Scale (FS) at baseline and endline
14. Academic performance will be measured using the semester GPA and national English test results at baseline and endline
15. Lifestyle behaviors will be measured using items asking about the amount and frequency of behaviors such as screen time, exercise, and sleep, at baseline and endline
16. Neuroticism will be measured using the Big Five Personality Inventory (brief version), at baseline and endline
17. Face Saving will be measured using the Face Saving Scale at baseline and endline
18. Somatic symptoms will be measured using the brief version of the Somatic Symptom Scale (SSS), at baseline and endline
19. Procrastination will be measured using the Short General Procrastination Scale, at baseline and endline
20. Perceived benefits and adverse effects and helpfulness of the program will be measured with Likert-type items measured weekly during the intervention
21. Compliance with mindfulness practice will be measured based on self-report length and frequency of practice, measured weekly during the intervention.
22. Acceptability of the intervention will be measured via qualitative interviews and focus groups with students and instructors
23. Self-compassion will be measured using the Self-Compassion Scale, measured at baseline and

endline, as well as weekly during the intervention
24. Sense of purpose will be measured using the Claremont Purpose Scale, measured at baseline and endline

Overall study start date
30/01/2024

Completion date
06/06/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/04/2025:

1. Undergraduate students enrolled in participating universities in China
2. 18+ years of age
3. Provide a written consent form
4. Can read, write, and speak Mandarin Chinese
5. Students reporting mild-severe levels of distress (PHQ-9 >= 5; GAD-7 >= 5)

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Previous inclusion criteria:

1. Undergraduate students enrolled in participating universities in China
2. 18+ years of age
3. Provide a written consent form
4. Chinese citizen
5. Can read, write, and speak Mandarin Chinese
6. Students reporting mild-moderate levels of distress (PHQ-9 = 5-10; GAD-7 =5-10)

Participant type(s)
Learner/student

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
112

Total final enrolment
111

Key exclusion criteria
Current exclusion criteria as of 09/04/2025:

The research team will screen for the following prior to enrollment in the study among potentially eligible participants:
1. Taking psychopharmaceutical medications
2. Receiving psychotherapy
3. Severe suicidality (severe suicidal ideation, intent and plan, recent suicidal attempts) and/or risk of causing harm to others
4. Presenting psychotic symptoms such as hallucinations and delusions*
5. Previously received structured mindfulness instruction
6. Has a structured meditation practice (practicing once per week or more)

*Students detected to potentially have the above conditions will be further screened by a licensed counselor and then referred out for a counseling/medical evaluation through the established university referral mechanism.

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Previous exclusion criteria:

The research team will screen for the following prior to enrollment in the study among potentially eligible participants:
1. Taking psychopharmaceutical medications
2. Presenting psychotic symptoms such as hallucinations and delusions
3. High suicidality (severe suicidal ideation, intent and plan, recent suicidal attempts)
4. Cognitive impairment
5. Major depressive disorder
6. Severe anxiety
7. Other conditions that might compromise group attendance such as severe social anxiety and inadequately treated PTSD*

*Students detected to potentially have the above conditions will be further screened by a licensed counselor and then referred out for a counseling/medical evaluation through the established university referral mechanism.

Date of first enrolment
17/02/2025

Date of final enrolment
15/03/2025

Locations

Countries of recruitment
China

Study participating centre

Beijing Normal University
19 Xinwai Ave, Beitaipingzhuang, Haidian District
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Study participating centre
Fudan University
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Sponsor type
University/education

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ROR
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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

Funder Name
Vincent Woo Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/09/2029

Individual participant data (IPD) sharing plan
Databases will be shared for replication studies upon request and reasonable conditions.
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IPD sharing plan summary
Available on request