ISRCTN34437131 https://doi.org/10.1186/ISRCTN34437131

Effectiveness of a digital mindfulness-based program on the mental health of college students: A randomized controlled trial in China

Submission date
08/09/2026

Recruitment status
No longer recruiting

Registration date
24/09/2026

Overall study status
Ongoing

Last Edited
04/11/2026

Condition category
Mental and Behavioural Disorders

[_] 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 a digitally delivered MBP for university students in China, a population with a high prevalence of mental health issues. Building off of a study of an in-person mindfulness-based program implemented in fall 2025, the primary goal of this study is to evaluate the impact of an app-based mindfulness-based program specifically tailored for university students. We will investigate the effects on the primary outcome of anxiety and depression symptoms.

Who can participate?
Undergraduate students at the participating university 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 (asynchronously delivered via an app).

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 three universities will participate in the study. The China-based PI (Prof. Lian Tong) will oversee the study implementation, facilitating participant recruitment and data collection. 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 September 2026. The intervention is planned to begin in October and last for eight 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), Dr. Lian Tong (ltong@fudan.edu.cn), or Cody Abbey (cjabbey@stanford.edu) for more information about this study.

Contact information

Type(s)
Scientific, Public

Contact name
Mr Cody Abbey

Contact details
616 Jane Stanford Way
Stanford
United States of America
94305
+1 650-724-9254
cjabbey@stanford.edu

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Huan Wang

Contact details
616 Jane Stanford Way
Stanford
United States of America
94305
+1 650-724-9254
huanw@stanford.edu

Type(s)
Principal investigator, Scientific, Public

Contact name
Prof Hui-Qi Tong

Contact details

616 Jane Stanford Way
Stanford
United States of America
94305
+1 650-724-9254
htong@stanford.edu

Type(s)
Scientific, Public

Contact name
Prof Xinshu She

Contact details
616 Jane Stanford Way
Stanford
United States of America
94305
+1 650-724-9254
xinshe@stanford.edu

Type(s)
Scientific, Public, Principal investigator

Contact name
Prof Lian Tong

Contact details
No. 220 Handan Road, Yangpu District
Shanghai
China
200433
+86-21-65642250
ltong@fudan.edu.cn

Type(s)
Principal investigator

Contact name
Prof Scott Rozelle

Contact details
616 Jane Stanford Way E501
Stanford
United States of America
CA 94305
-
rozelle@stanford.edu

Additional identifiers

Study information

Scientific Title
Effectiveness of a digital mindfulness-based intervention on the mental health of college students: A randomized controlled trial in China

Study objectives
Evaluate the effect of a digitally delivered mindfulness-based program on anxiety and depression symptoms in college students

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 8282803225; irbnonmed@stanford.edu), ref: IRB-75117

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Single

Purpose
Prevention

Study type(s)

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

Interventions
Current interventions as of 04/11/2026:
Intervention:
We will deliver an eight-week, mindfulness-based program via a phone-based digital platform. The platform will provide students access to mindfulness recordings and videos, discussion forum space to voluntarily reflect and share about their with other student participants, as well as check-in features to self-report practices and track their progress. 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. They will also learn formal mindfulness practices (e.g., sitting meditation, body scan, qigong) and informal mindfulness practices (e.g., mindful eating, mindful walking, and mindful daily routine activities) via the platform.

Treatment group students 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 period (pure control).

Study design:
The experimental design will be a randomized study with undergraduate students recruited online 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 control groups at baseline, we can confidently attribute any significant differences in outcomes between the control and intervention group to the program. We will use an online random number generator to assign students to either digital mindfulness treatment or control group.

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

Previous interventions:
Intervention:
We will deliver an 8-week, mindfulness-based program via a phone-based digital platform. The platform will provide students access to mindfulness recordings and videos as well as check-in features to self-report practices and track their progress. 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. They will also learn formal mindfulness practices (e.g., sitting meditation, body scan, qigong) and informal mindfulness practices (e.g., mindful eating, mindful walking, and mindful daily routine activities) via the platform.

Treatment group students 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 period (pure control).

Study design:
The experimental design will be a randomized study with undergraduate students recruited from three 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. We will use an online random number generator to assign students to either digital mindfulness treatment or control group.

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

Intervention Type
Behavioural

Primary outcome(s)

1. Anxiety symptoms measured using Generalized Anxiety Disorder-7 at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during intervention

2. Depression symptoms measured using Patient Health Questionnaire-9 at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during intervention

3. Perceived stress measured using Perceived stress scale-10 at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during intervention

Key secondary outcome(s)

1. Emotion regulation measured using Emotion Regulation Questionnaire at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during the intervention

2. Trait mindfulness measured using Five Facet Mindfulness Questionnaire - Short Form at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

3. Loneliness measured using UCLA Loneliness Scale at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

4. Sleep quality measured using Pittsburgh Sleep Quality Index at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during the intervention (two-item version)

5. Flourishing measured using Flourishing Scale at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

6. Life satisifaction measured using Satisfaction with Life Scale at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

7. Academic performance measured using previous semester GPA and/or gaokao score at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

8. Lifestyle behaviors measured using self-report items asking about the amount and frequency of behaviors such as screen use and exercise at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

9. Face-saving attitudes measured using Face Saving Scale (CPAI-2) at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

10. Somatic symptoms measured using Somatic Symptom Scale at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

11. Acceptability measured using self-report items about perceived benefits and adverse effects, as well as qualitative follow-up interviews at post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

12. Self-compassion measured using Self-compassion Scale short-form at Pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, biweekly during intervention

13. Experiential avoidance measured using Brief Experiential Avoidance Questionnaire at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

14. Gratitude measured using Gratitude Questionnaire at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during intervention

15. Stress mindset measured using Stress mindset scale at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

16. Online Social Support measured using Online social support scale (OSSS) at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

17. Smartphone addiction measured using Smartphone addiction scale at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

18. Mental health literacy measured using MHLq-SVa at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

19. State mindfulness measured using Multidimensional State Mindfulness Questionnaire at pre-intervention, post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up, biweekly during intervention

20. Mindfulness mindset measured using the Mindfulness Mindset Scale at baseline, week 4 (midpoint during intervention), post-intervention, 3-month follow-up, 6-month follow-up, post-graduation follow-up

Updated 04/11/2026 to add mindfulness mindset

Completion date
15/01/2027

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 engage in consistent use with the digital program and engage in mindfulness practice at home
4. 18 years or older

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
All

Total final enrolment
270

Key exclusion criteria
1. 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)
2. 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)
3. Is currently receiving psychotherapy and/or taking psychiatric medication
4. Presenting symptoms of psychoticism
5. Active substance (alcohol) abuse
6. Presenting symptoms of unresolved complex trauma

Date of first enrolment
20/09/2026

Date of final enrolment
21/10/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Stanford University

ROR
https://ror.org/00f54p054

Funder(s)

Funder type

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		26/09/2008	08/09/2026	No	No
Statistical Analysis Plan		03/11/2026	04/11/2026	No	No