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The feasibility, acceptability and efficacy of an app-based intervention (the coping camp) in reducing stress among chinese school adolescents: protocol of a cluster randomised controlled tria

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ABSTRACT

Background: Regardless of increasing evidence suggesting the effectiveness of mental health apps for adolescents, there has not been a mental health app developed for stress management among Chinese adolescents. This study aims to evaluate the feasibility, acceptability and efficacy of a mental health app (the Coping Camp) that was developed for stress management among Chinese adolescents.

Methods: This study will employ a two-arm cluster randomized controlled trial design. Adolescents will be recruited from two high schools in Mianyang City in China. Participants will be randomly allocated to the intervention group, who will have access to the Coping Camp for 11 weeks, and the control group, who will not have access to it. Study outcomes relating to perceived stress, depression, anxiety, coping behaviours and mental health well-being will be assessed at baseline (T0), 11 weeks after the baseline (T1) and 19 weeks after the baseline (T2). Intent-to-treat analysis will be employed and repeated measure design with linear mixed model (LMM) will be performed.

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We use this protocol and it's working

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Background

1 Stress refers to “the condition or feeling that arises when individuals perceive that the demands of a situation exceed their personal, psychological, or social resources” (1). Adolescence is a period known to be particularly sensitive to stress (2). In China, stress affects a significant portion of adolescents, with approximately 90 per cent reporting experiencing stress (3). Moreover, stressful life events have been found to be significantly associated with a higher prevalence of depression, anxiety, and suicidal ideation in this population (4).
Managing stress and related mental health issues remains a challenging endeavour due to various barriers in mental health service provision and utilization. These barriers encompass insufficient mental health resources (5), disparities in the distribution of these resources (6), low perceived need for mental health services (6), and concerns about the cost and stigma associated with seeking such services (6).
Mobile health (mHealth) refers to health services delivered through mobile devices (8). mHealth offers several advantages, such as reaching individuals in remote areas, reducing travel costs, and saving time in scheduling (9, 10, 11). It has been widely utilized in mental health service delivery, including the treatment of depression (12), anxiety (13), post-traumatic stress disorder (PTSD) (14), and substance abuse (15). Mental health apps, in particular, have been designed to monitor symptoms and provide psychoeducation, mood-regulation techniques, and evidence-based therapies (16). Despite the emerging evidence supporting the effectiveness of mental health apps for adolescents (17), there is a notable lack of mental health apps designed specifically for stress management among Chinese adolescents. Therefore, this study aims to address this research gap by evaluating the efficacy of a mental health app, which was developed for Chinese adolescents, in managing stress and related mental health outcomes.

Research objectives

2 -To evaluate if the app-based intervention, the Coping Camp, is effective in reducing stress, depression, and anxiety among Chinese adolescents
-To evaluate if the Coping Camp is effective in changing stress-coping behaviours among Chinese adolescents
-To evaluate if the Coping Camp is effective in improving mental health well-being among Chinese adolescents

-To evaluate if the use of the Coping Camp is feasible among Chinese adolescents
-To evaluate if the use of the Coping Camp is acceptable among Chinese adolescents

Methods

3 study design

3.1 This study will be a two-arm cluster randomized controlled trial. Participants will be randomized by classes (i.e., clusters) on a 1:1 ratio to either the intervention group or the control control group.

4 Setting

4.1 Participants will be recruited from two high schools in Mianyang city of Sichuan province in China.

5 Participant eligibility criteria

5.1 Our inclusion criteria will incldue: (1) own a smartphone and be permitted by parents and teachers to use the smartphone. The exclusion criteria included: (1) students should not have suicidal ideation; (2) and should not be diagnosed with a mental disorder at the time of recruitment; (3) and not be taking psychiatric medications and (4) they should not be receiving regular mental health counseling services. The eligibility criteria will be assessed via self-reported questionnaires.

6 Random allocation

6.1 The randomization will be conducted by an independent researcher without the research group. The online randomizer (www.randomizer.org) will be used to allocate participants.

7 Blinding

7.1 Given the nature of the intervention, it will not be possible to blind either the participants or the intervention implementer. However, the outcome assessors and the researcher who will conduct the randomization will be blinded to the students' condition.

8 Procedures

8.1 Students who express their interest to participate in the study will be screened against eligibility criteria by using a questionnaire. Only who are eligible will be included in the study. The intervention will be delivered one session (25-45 minutes) per week, lasting for 11 weeks. There will be no home assignments, however, students in the intervention group will have the opportunity to review the contents of the app outside of intervention sessions.

9 Intervention condition

9.1 Participants who are assigned to the intervention group (IG) will download the Coping Camp app. The app will be available on mobile devices with Android and IOS systems. After downloading the app, participants will be required to create a personal account to log into the app.

The intervention will be based on Stress inoculation Training (SIT). The stardard SIT consists of three phases: the educational phase, the skills acquisition phase, and the application phase. The SIT were modified to suit the Chinese adolescent population based on our previous study with Chinese high school students and teachers. Then, Chinese academics and professionals were invited to review the content of our SIT intervention, minor changes were made according to their suggestions. As a result, the modified SIT had 11 sessions (see Table 1 for the content of the modified SIT intervention). The app will be in Chinese language.

Bugs will be fixed through a pilot trial.

Table 1. Content of the modified SIT intervention

	A	B	C
	Session 1	**Conceptualisation**	· The definition of stress· How stress happens and exacerbates · Analyse participants' stress response · Provide participants with their stress transactional model. · Provide participants with the outline of the Coping Camp sessions and explain how the sessions fit with their stress model.· Quiz and feedback
	Session 2	Progressive relaxation	· The definition of progressive relaxation· The benefit of progressive relaxation to reduce stress and improve sleep quality.· Distinguish between tense muscle groups and relaxed muscle groups.· Practice progressive relaxation (with downloadable audio)· Quiz and feedback
	Session 3	Mindfulness	· The definition of mindfulness · The benefit of practising mindfulness to reduce stress· Techniques of mindful sitting, mindful eating, mindful walking, mindful seeing· Guide participants to practice mindful sitting, mindful eating and mindful seeing. · Quiz and feedback
	Session 4	Psychoeducation about cognitive restructuring	· Introduction of ABC theory· Introduction of the cognitive triangle · The benefit of practising cognitive restructuring to reduce stress.· Introduction to cognitive distortion and how it relates to mood problems.· Practice distinguishing between rational cognition and distorted cognition.· Introducing common cognitive distortions· Quiz and feedback
	Session 5	Cognitive restructuring training	· Techniques to challenge distorted cognition and practice these techniques. · Quiz and feedback
	Session 6	Goal setting	· Definition and benefit of goal setting to reduce stress.· Techniques of goal setting and practice (clarify values, SMART rules of setting goals, setting long-term and short-term goals, techniques of making a plan for achieving a goal)· Quiz and feedback
	Session 7	Time management	· Definition and benefit of time management to reduce stress.· Techniques of time management (four quadrants) and practice · Balance between leisure time and study time · Quiz and feedback
	Session 8	Problem-solving	· Definition and benefit of problem-solving in reducing stress.· Techniques of problem-solving (5 steps: 1: identify a problem to work on and set a goal, 2: brainstorm options, 3: evaluate and choose the best option, 4: make a plan, 5: evaluate the result)· Quiz and feedback
	Session 9	Assertiveness	· Definition of assertiveness and the benefit of assertiveness to reduce interpersonal stress.· Distinguish between passive, assertive and progressive communication.· Techniques of assertiveness and practice· Quiz and feedback

	A	B	C
	Session 10	Imaginal rehearsal	· Participants generate a stressful scenario from their own experience. · use positive self-statements.· Participants practice coping with the stressful scenario by using choosing a skill learnt in previous sessions. · Evaluate the skill's effect on a 1-10 scale before and after they use each skill; once they are happy with the effect, they stop. Otherwise, they could choose another skill and repeat the process until they are satisfied with the effect.· Quiz and feedback
	Session 11	Dealing with setbacks and troubleshooting	· What is a setback in stress management?· Normalization of setbacks in stress management· Techniques to deal with setbacks.· Online and in-person mental health resources, and how to access these services when needed.· Quiz and feedback

The Coping Camp app will consist of 11 sessions of SIT content, notification functions, three assessment,s and a discussion board (see Fig. 2). The 11 sessions will be locked and participants will only be able to access the next session after completing the previous one. The three assessments will also be locked and accessible at the time of assessment. The discussion board will be open during the intervention. The discussion board will allow students to talk about their stress experience and their coping strategies, thus serving as a platform for peer support and role modeling. There will be a moderator to monitor the posts on the discussion board.

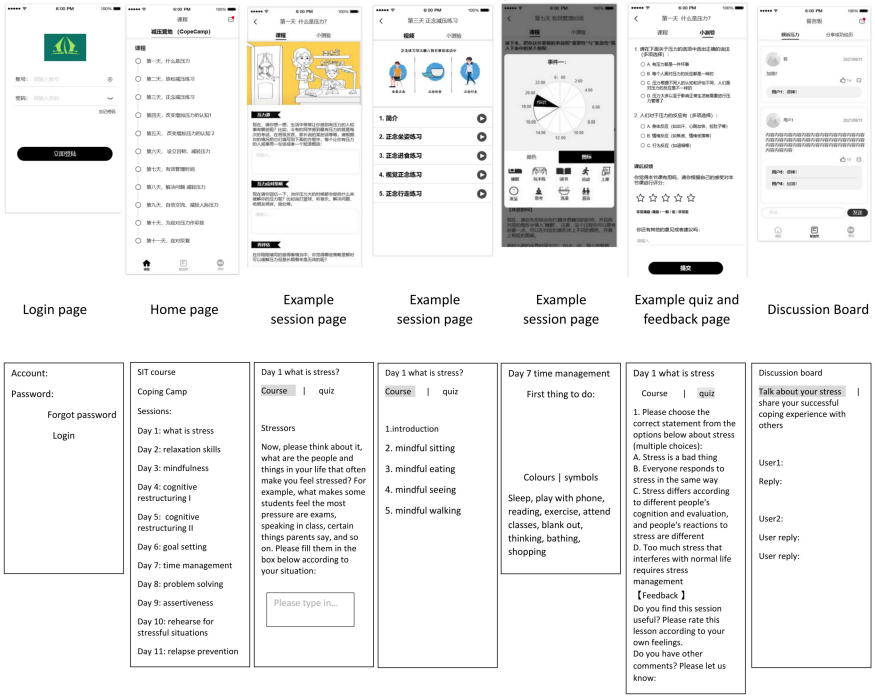

Fig.2 Example pages of the app prototype

10 Control group

10.1 Participants who are allocated to a control group (CG) will attend their regular psychology classes as arranged by the schools.

11 Measures

11.1 Participants will be assessed at baseline, 11 weeks after the baseline, and 19 weeks after the baseline.

11.2 Demographic variables including gender, year of birth, class, grade, name of the school, residence (urban or rural), and guardians (parents, relatives, others) will be collected.

11.3 Perceived stress will be assessed by using the Perceived Stress Scale 10 Items (PSS-10). Depression and anxiety will be assessed by using the Depression, Anxiety, and Stress Scale (DASS-21). Mental health well-being will be assessed by using Outcome Rating Scale (ORS-4). Coping Behaviours will be assessed by using the short form of the Coping Inventory for Stressful Situations (CISS-SFC).

11.4 Negative events will be assessed using a short questionnaire asking participants if they have confronted any unfavorable changes.

11.5 Acceptability of the intervention will be assessed by using a short questionnaire at the end of

each session in the app. The questionnaire will have two questions: the first question will ask participants to rate their perceived usefulness of the app on a 5-point scale, with 1 indicating that the app is not useful at all, and 5 indicating that the app is most useful. The second question will allow participants to provide their comments about each session.

12 Sample size calculation

12.1 According to a meta-analysis on internet interventions on stress reduction, the overall mean effect size for stress at post-test was Cohen's d = 0.43 (95% CI 0.31-0.54). Small but significant effects were also found for depression (Cohen's d = 0.34, 95% CI 0.21-0.48) and anxiety (Cohen's d = 0.32, 95% CI 0.17-0.47). Therefore, effect sizes of d = 0.43 for perceived stress, d = 0.34 for depression, and d = 0.32 for anxiety were chosen. For a cluster randomized trial assuming the same values as for the original design, allowing for variation in cluster size up to a coefficient of variation of 5, an intra-cluster correlation up to 0.25, an individual autocorrelation as low as 0.5, and up to 10% drop out in each cluster, 5 clusters per group with an average size of 22 will be needed to detect this effect (d = 0.43) with a power (1− β) of 0.80 at an alpha of 0.05, resulting in a total of 220 participants for all clusters across both groups.

13 Statistical analysis

13.1 Statistical analyses will be conducted using software R (the R Foundation for Statistical Computing, Vienna, Austria). This study's accepted significance level will be set at 95%. To determine baseline differences between the intervention group and control group, independent t-tests will performed on continuous baseline variables and Chi-squared tests will be performed on categorical or nominal variables. To evaluate the efficacy of the intervention, intention-to-treat (ITT) analyses will be conducted separately for each outcome. The ITT analysis included data from the entire randomized sample. A repeated measures design with a linear mixed model (LMM) will be used to investigate the effects of time and groups on outcome variables. The LMM will be performed with time, group, time*group, gender, school, grade, guardian, and residence treated as fixed effects, while students and classes will be treated as random effects. Covariates that are not significant will be removed from the model, therefore the primary analyses will only include significant covariates. Cluster effects will be examined by using aregression model, where cluster (i.e., class) will be used as a fixed effect, for each outcome at T1 and T2 separately. Additionally, given the large endpoints, p values will be adjusted using the Benjamini-Hochberg method to control for false discovery rate.

Missing data handling

14

14.1 When participants drop out of the trial, their data on previous time points will still be used in the data analysis as per the requirement of ITT analysis. When participants miss one or more questions on a single assessment (e.g., PSS-10), their data will be removed from the LMM analysis on that particular outcome. A sensitivity analysis will be conducted to assess the robustness of the analysis. Additionally, participants who drop out will be compared with those who do not as regards their demographic characteristics and study outcomes.

15 Ethical review

15.1 Ethics approvals will be obtained from two institutions: the Human Ethics Office at The University of Queensland in Australia and the Research Ethics Office at Tianjin Normal University in China. Informed written consent forms will be obtained offline from both the participants and their guardians as most of the participants will be under the age of 18 at the time of the interview. All participants will be anonymized prior to data analysis.

16 Trial registration

16.1 This randomised controlled trial was registered via Australian New Zealand Clinical Trials Registry (ANZCTR). Registration number: 380316. Link to the trial registration: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=380316&isReview=true.

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