

STUDY PROTOCOL

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The effectiveness of information-motivation-behavioral skills (IMB)-based stress self-management health education on reducing stress among nursing students: a study protocol for a cluster-randomized controlled trial

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Abstract

Background Nursing students frequently experience high levels of stress, which can impact their psychological, physiological, and social well-being. Stress among nursing students is closely associated with cognitive, motivational, and behavioral determinants. The information-motivation-behavioral skills (IMB) model provides a coherent framework for conceptualizing these determinants and promoting adaptive stress regulation. Based on this model, the present study will implement an IMB-based stress self-management health education program to mitigate stress among nursing students.

Methods This cluster-randomized controlled trial aims to evaluate the effectiveness of an IMB-based stress self-management health education program on reducing stress among nursing students. The 8-week program includes eight modules, with the first seven covering distinct topics and the final module for discussion. One hundred and six nursing students from 22 clusters, based on sample size estimation, will be randomly allocated to either the intervention or waitlist control group. The primary outcome is stress, with secondary outcomes including stress knowledge, stress mindset, perceived social support, self-compassion, and resilience. Baseline characteristics and outcome variables will be summarized using descriptive statistics. The program's effectiveness will be evaluated using an intention-to-treat approach, with longitudinal changes and between-group differences analyzed using a generalized linear mixed model that accounts for clusters as random effects.

Discussion The IMB-based stress self-management health education program is expected to enhance stress management among nursing students and highlight the innovative application of the IMB theory.

Trial registration ChiCTR2400088589. Registered on August 21, 2024.

Keywords Stress, Nursing student, IMB, Health education

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Introduction

Background and rationale {6a}

Stress is a complex, multidimensional response, encompassing physiological, psychological, behavioral, and neurobiological components, which collectively shape individuals' reactions to challenging or demanding situations [1–5]. Stress poses a substantial burden on public health [6], and it is particularly pronounced in emerging adulthood (ages 18–29), a developmental stage marked by heightened vulnerability to psychological distress [7, 8]. Nursing students represent one of the most vulnerable groups within this population, reporting greater stress than peers in other disciplines [9].

Existing evidence highlights both the severity and persistence of this problem among nursing students. An umbrella review synthesizing data from 30,024 nursing students estimated a pooled prevalence of 27%, with 21% experiencing mild stress, 33% moderate stress, and 14% severe stress [10]. Regional analyses further indicate that nearly 40% of Asian nursing students experience moderate to high stress, compared with 35% in Europe; notably, the burden of severe stress appears to be increasing, rising from 2% before 2010 to 15% in subsequent years [11].

Consistent with these global trends, evidence from China indicates that nursing students also experience moderate to high stress across academic stages and regions, with moderate stress being most prevalent and a notable proportion reporting high or severe stress. For instance, 81.2% of senior-year students nearing clinical graduation reported moderate stress [12], while over 10% of students in Hong Kong and Henan were classified as experiencing high stress [13, 14]. These findings indicate that excessive stress among Chinese nursing students represents a persistent and substantial burden and highlight the need for the present study.

Stress has widespread and multidimensional effects on the psychological, physiological, and social well-being of nursing students. Psychologically, stress exacerbates emotional vulnerabilities, including neuroticism [15] and test anxiety [16], and contributes to emotional distress [17], depression [18, 19], anxiety [19], and suicidality [18, 20]. Physiologically, it is linked to sleep disturbances [21, 22] and somatic complaints, such as gastrointestinal symptoms [23], and can reduce quality of life [24], reflecting its substantial impact on physical health. Socially, stress undermines academic performance and clinical competence [25, 26], heightens academic maladjustment, including self-regulatory fatigue [12], dropout intention [27], and burnout [12, 28]; and promotes maladaptive coping behaviors such as procrastination [29], excessive use of electronic devices [30], and unhealthy eating [31]. Collectively, these findings underscore the multifaceted impact

of stress on nursing students' well-being and functioning, highlighting the urgent need for effective interventions.

Cognitive, motivational, and behavioral factors collectively shape nursing students' stress experiences. Cognitive determinants, including appraisal processes and preparedness, critically influence stress perception, with cognitive lapses exacerbating stress and access to structured knowledge mitigating stress responses [32]. Motivational factors further modulate coping trajectories: students who adopt stress-enhancing mindsets and perceive strong social support tend to regulate stress more adaptively [33–36]. Behavioral skills, particularly self-compassion and resilience, consistently act as buffers against stress by supporting adaptive coping strategies [37, 38]. These factors can be conceptually mapped onto the information-motivation-behavioral skills (IMB) framework, which posits that effective responses to challenges depend on individuals' knowledge, motivation, and behavioral capacities [39, 40]. Specifically, cognitive appraisal aligns with the “information” component, mindset and social support with “motivation,” and resilience and self-compassion with “behavioral skills,” highlighting pathways that are potentially modifiable through targeted interventions. Beyond these core determinants, sociodemographic and attitudinal characteristics, such as age [41], sex [42], financial strain [43], parental education [44], reasons for choosing nursing, and professional affinity [45], further shape stress experiences by influencing available resources, expectations, and engagement. Viewed through this integrated lens, stress in nursing students emerges as a dynamic and modifiable phenomenon, shaped by their knowledge, motivation, skills, and contextual factors, offering a structured foundation for designing evidence-based stress management interventions.

Given the profound impact of excessive stress on nursing students, timely and evidence-based interventions are essential. In Chinese universities, however, mental health education remains largely lecture based and didactic, offering limited experiential learning or skill practice. As a result, interventions are often formalistic, unsystematically designed, and misaligned with students' psychological needs, while shortages of trained personnel and students' concerns about confidentiality further reduce engagement [46, 47].

Although various stress interventions exist, a recent systematic review indicates that most programs lack rigorous design and rarely integrate multiple theoretical constructs; meta-analytic evidence further shows that interventions grounded in multiple constructs or with extensive use of theory yield significantly larger effect sizes [48]. Notably, to our best knowledge, no IMB-based

stress self-management program has been implemented or evaluated among Chinese nursing students, highlighting a critical gap in theory-driven, comprehensive interventions targeting cognitive, motivational, and behavioral factors.

To address this gap, the present study implements an IMB-grounded health education program tailored to undergraduate nursing students in China. The program aims to enhance cognitive appraisal of stress (information), foster adaptive motivation such as positive stress mindset and social support (motivation), and strengthen self-regulatory capacities, including self-compassion and resilience (behavioral skills). Its effectiveness will be assessed through both short- and long-term outcomes, providing empirical evidence for theory-informed, locally relevant strategies in stress self-management.

Objectives {7}

The overall purpose of the study is to evaluate the effectiveness of the IMB-based stress self-management health education program in enhancing stress knowledge, stress mindset, perceived social support, self-compassion, and resilience and subsequently reducing stress among nursing students in Changzhi Medical College, China.

The study's null hypotheses are as follows:

- 1 At baseline, there are no significant differences between the intervention and waitlist group in demographic characteristics, including age, sex, per-

ceived family economic status, father's educational level, mother's educational level, reasons for choosing nursing, and liking for the nursing profession.

- 2 At baseline, there are no significant differences between the intervention and waitlist control groups in stress knowledge, stress mindset, perceived social support, self-compassion, resilience, and stress scores.
- 3 The IMB-based stress self-management health education program is expected to effectively enhance stress knowledge, stress mindset, perceived social support, self-compassion, and resilience, while reducing stress, compared with the waitlist control group over time.

Trial design {8}

Figure 1 presents the CONSORT flow diagram. This study is designed as a parallel-arm, superiority trial employing a cluster-randomized controlled design with a 1:1 allocation ratio. Clusters are defined at the level of student dormitory units, which constitute stable residential groups in which students cohabit and share daily routines throughout the academic term. The adoption of a cluster-randomized design is intended to minimize the risk of contamination of intervention content between study arms while aligning with the natural social structure of student life. Individual randomization is considered unsuitable in this context, as co-location of intervention and control participants within the same dormitory could facilitate frequent interpersonal

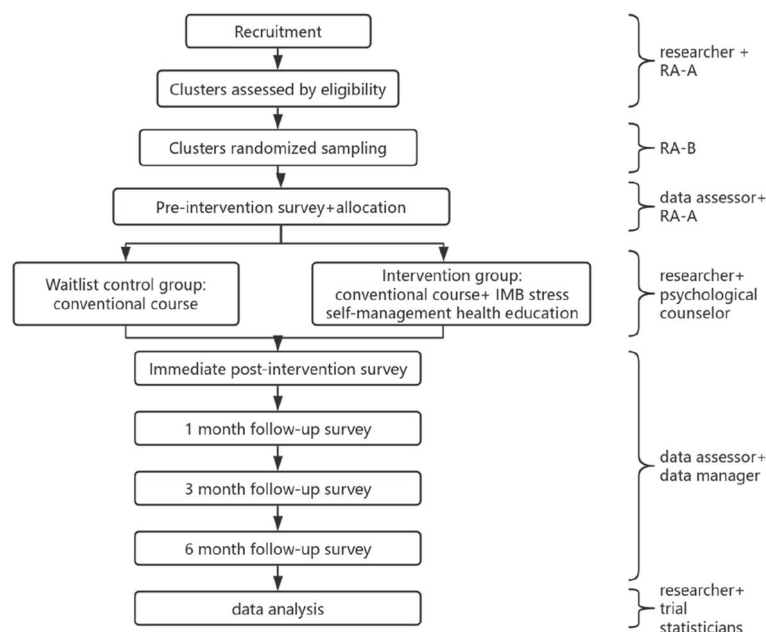


Fig. 1 CONSORT flow diagram. Note: RA, research assistant

interactions, potentially resulting in inadvertent exposure of control participants to intervention materials and thereby compromising internal validity.

To preserve cluster integrity while supporting individualized learning, each participant will be provided with a unique online platform account for independent study. In contrast, cluster-level activities, such as group discussions, will be strictly confined to their respective dormitories. Platform access will be restricted to assigned participants, and students will be explicitly instructed not to share materials across dormitories. Although absolute isolation cannot be guaranteed, these measures are expected to substantially reduce the likelihood of cross-cluster contamination, thereby safeguarding both the fidelity of the intervention and the internal validity of the study findings.

The study development adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist to ensure methodological rigor (see supplementary material 1), and implementation and reporting follow CONSORT cluster-randomized controlled trial (cluster-RCT) principles [49].

Method: participants, interventions, and outcomes **Study setting {9}**

This study will be conducted at Changzhi Medical College, China.

Eligibility criteria {10}

This cluster-randomized study applies eligibility criteria at both cluster and individual levels. Clusters are eligible if they are dormitories within Changzhi Medical College, where all members are undergraduate nursing students, and at least four individuals are willing to participate; otherwise, they will be excluded.

Individuals should be first-year undergraduate nursing students, aged 18 years or above, with access to a mobile device and the Internet. Students are excluded if they self-report mental disorders or severe physical conditions or if they have participated in structured stress management or psychological interventions within the past 6 months.

Withdrawal is permitted on an individual basis. Participation remains entirely voluntary, and students may discontinue at any time by revoking informed consent without penalty. Participants who engage in other structured psychological studies during the intervention period are also required to withdraw to prevent potential contamination of outcomes.

Who will take informed consent {26a}

During the recruitment phase, the researcher provides participants with an overview of the study and invites

them to complete a registration form voluntarily. Participants then review and sign the informed consent agreement before participating in the research.

Additional consent provisions for collections and use of participant data and biological specimens {26b}

This study does not involve the collection or use of biological specimens, as it focuses solely on questionnaire-based data collection.

Interventions

Explanation for the choice of comparators {6b}

The study includes a waitlist control group and an intervention group to assess the efficacy of the IMB-based stress self-management health education program. Nursing undergraduates in the waitlist control group receive the standard psychological health services provided by the school, such as counseling and mental health resources, ensuring they have basic support through the study period. Participants in the intervention group receive an online IMB-based stress self-management health education program, in addition to standard psychological health services, allowing for a comprehensive comparison of outcomes between the two groups.

Intervention description {11a}

Guided by the IMB model, the eight-module stress self-management health education program is systematically structured to strengthen nursing students' capacity for adaptive stress regulation. Each module operationalizes specific IMB constructs, progressing logically from informational enhancement to motivational activation and behavioral consolidation.

The first three modules focus on developing informational understanding and motivational awareness.

- Module 1, "Realizing Stress," introduces the definition, sources, and both physiological and psychological responses associated with stress, as well as its impact on well-being. Through learning and guided reflection, this module aims to deepen students' conceptual grasp of stress mechanisms and enhance their awareness of how stress manifests in everyday contexts. Reflective activities, such as drawing one's vicious circle of stress, are intended to translate theoretical knowledge into personalized insight and stimulate initial motivation for self-management.
- Module 2, "Thinking and Mentality Under Stress," builds on this foundation by addressing cognitive processes. Through learning about automatic and biased thinking and stress warning signs, participants learn to recognize their habitual reactions and identify early indicators of maladaptive stress responses.

Complementary exercises, such as recording three good things daily, aim to cultivate positive inner dialogue and reframe stress as a manageable and growth-enhancing experience, thereby reinforcing personal motivation for adaptive coping.

- Module 3, “Social Support,” emphasizes social motivation and interpersonal resources. Participants learn the concept, foundations, and strategies for building effective social support systems. By mapping personal support networks and developing action plans to strengthen them, this module enhances informational awareness and fosters social motivation, reinforcing the perceived importance of connection and mutual support in sustaining long-term stress management behaviors.

Modules 4–6 integrate all three IMB constructs, translating knowledge and motivation into practical self-regulation skills.

- Module 4, “Relieve Your Pain,” introduces mindfulness, self-kindness, and shared humanity as core components of self-compassion. Through experiential exercises, including *finding your own words of kindness* and *breathing relaxation practice*, participants learn to respond to distress with acceptance rather than self-criticism, thereby strengthening emotional flexibility and intrinsic motivation for self-care.
- Module 5, “Take Care of Your Difficult Emotions,” focuses on cultivating emotional regulation and cognitive resilience. Video-based learning and audio-guided exercises on dealing with difficult emotions provide structured opportunities to practice adaptive emotion management. Out-of-class activities such as thought replacement, thought stopping, emotion transformation, and relaxation exercises are designed to consolidate behavioral competence in emotion regulation and enhance confidence in applying these strategies to real-life situations.
- Module 6, “Acceptance,” emphasizes psychological flexibility and prosocial motivation. Through conceptual exploration of acceptance and its benefits and group practices such as exchange of advantages and gratitude reflection, participants learn to embrace imperfection, accept themselves and others, and adapt to uncontrollable circumstances. These experiences are expected to strengthen resilience, deepen empathy, and foster enduring engagement in stress-management behaviors.

The final two modules focus on sustaining motivation and consolidating behavioral change.

- Module 7, “Embrace a Better Life,” broadens participants’ perspective toward appreciation and meaning in life. By exploring *appreciating beauty*, *tasting and gratitude*, *living deeply*, and *awakening passion*, this module aims to enhance intrinsic motivation and emotional resilience. Activities such as *identifying personal strengths*, *ideal self*, and *gratitude journal* are designed to promote self-reflection, gratitude, and a sustained sense of purpose and self-compassion.
- Module 8, “Ending,” serves as a reflective consolidation of learning and behavioral commitment. Conducted through an online group discussion, participants share their insights, emotional experiences, and intended coping strategies, reinforcing motivation for continued stress self-management. This collective reflection is expected to foster a sense of community and support that sustains adaptive behaviors beyond the intervention period.

To ensure intervention fidelity, a comprehensive management and monitoring system will be implemented. The lead author, who also developed the program, will oversee overall coordination and quality control, including the development, release, and tracking of all learning materials. All instructional components—pre-recorded video lectures, structured handouts, and assignments—will be standardized and distributed through the Chaoxing Learning Platform according to a fixed weekly schedule to ensure consistent and timely delivery. Each instructional video will follow a unified teaching plan specifying weekly themes, objectives, and key concepts aligned with the IMB framework. This standardized design will minimize instructor variability and maintain procedural fidelity.

Participant engagement will be continuously monitored through the platform’s analytics, capturing metrics such as access frequency, time spent, and task completion rates. Satisfactory adherence will be defined as completion of at least 80% of learning tasks. Deviations from the protocol will be documented and reviewed during regular team meetings to ensure timely corrective actions.

A certified psychological counselor will monitor students’ psychological well-being and remain available to provide support if emotional distress arises, safeguarding both the educational and ethical integrity of the intervention.

Before program initiation, all research staff will receive standardized fidelity training. Participants will be informed that their participation is voluntary and will not affect their academic evaluation. To prevent role conflict, the lead author—although a faculty member—does not teach or assess students from the participating

cohort. Data collection will be conducted by independent research assistants.

Together, these procedures are designed to ensure the fidelity and ethical soundness of the intervention, thereby enhancing its internal validity, replicability, and theoretical coherence.

An overview of the weekly course modules and their content is presented in Table 1.

Criteria for discontinuing or modifying allocated interventions {11b}

Suppose an outcome assessor or facilitator identifies an adverse event or serious adverse event during the trial. In that case, it will be promptly reported to the research team, the psychological consultant, the class counselor, and the ethics committee. Participants identified as at risk will be referred to appropriate professional support.

Specifically, participants reporting suicidal ideation or assessed to be at immediate risk of suicide will be referred to specialized services and may be withdrawn from the trial.

Strategies to improve adherence to interventions {11c}

To improve participant adherence, several strategies are implemented. First, the intervention design is optimized by offering flexible online learning options, enhancing convenience. Second, participant motivation is increased by outlining the benefits of the program and providing material incentives (e.g., small gifts, such as keychains and notebooks) to encourage both intrinsic and extrinsic motivation. Additionally, interaction and feedback are enhanced through group activities, discussions, and timely responses, fostering communication and sustained engagement. Finally, regular monitoring and evaluation

Table 1 Content of IMB-based stress self-management health education program

Week	Module	Content	In-class activities	After-class exercises	IBM's construct
1	Realize "stress"	1. The definition of stress 2. Response to stress 3. The source of stress 4. The impact of stress	Draw your own vicious circle of stress	Continue classroom activities	Information, motivation
2	The thinking and mentality under stress	1. Automatic thinking and biased thinking 2. Stress warning signs 3. Positive inner dialogue improves stress response	What are your stress warning signs?	Record three good things every day	Information, motivation
3	Social support	1. The introduction of social support 2. The basis of social support 3. Techniques for building good social support	Draw your own social support system	Write down strategies to enhance your social support	Information, motivation
4	Relieve your pain	1. Mindfulness 2. Self-kindness 3. Human community 4. Reconstruct your inner dialogue	Finding your own words of kindness	Practice: breath relaxation	Information, motivation, behavioral skills
5	Take care of your difficult emotions	1. Take care of your difficult emotions 2. Keep humor 3. Restructure your infrastructure	Audio exercise: dealing with difficult emotions	Thought replacement, thought stopping, emotion transformation, relaxation exercises	Information, motivation, behavioral skills
6	Acceptance	1. The introduction of acceptance 2. The benefits of acceptance 3. Accept yourself and others 4. Accept your situation	No	Continue classroom activities	Information, motivation, behavioral skills
7	Embrace a better life	1. Appreciate the beauty 2. Tasting and gratitude 3. Living deeply 4. Awaken passion	How do I view my strengths?	Exercise: ideal self, gratitude journal	Motivation, behavioral skills
8	Ending	Share experience, feelings, and opinions about this course	No	No	Behavioral skills

of learning progress are conducted, with open communication channels established to address issues promptly and effectively.

Provisions for posttrial care [30]

The IMB-based stress self-management health education program will remain accessible to participants following the trial's conclusion.

Relevant concomitant care permitted or prohibited during the trial [11d]

Participants who have previously taken part in other psychological intervention programs are excluded from the study to preserve the internal validity of the intervention's effects. Furthermore, all enrolled participants are explicitly informed that they may not engage in any other research-based psychological interventions or treatments during the trial. However, participants are allowed to continue their routine medical care and daily health activities (e.g., regular exercise, campus health lectures, or previously prescribed medications).

Outcomes [12]

The primary outcome of this trial is stress, measured by the stress subscale of the Depression Anxiety Stress Scale (DASS-21). Secondary outcomes include stress knowledge (Stress Knowledge Questionnaire—SKQ-5), general stress mindset (Stress Mindset Measurement-General—SMM-G), perceived social support (Multidimensional Scale of Perceived Social Support—MSPSS), self-compassion (Self-Compassion Scale-Short Form—SCS-SF), and resilience (Conner–Davidson Resilience Scale—CD-RISC).

All outcomes are self-reported and administered online via the Wenjuanxing platform by trained personnel (Guo). Validated Chinese versions are used, except for SKQ-5, which underwent a rigorous translation and back-translation process.

Outcomes are assessed at five time points: baseline, immediately post-intervention, 1 month post-intervention, 3 months post-intervention, and 6 months post-intervention. The primary outcome will be analyzed across these time points using a generalized linear mixed model (GLMM), which accounts for repeated measures.

Stress

The stress subscale of the DASS-21, developed by Lovibond and Lovibond [50], will be used to assess stress. This self-reported tool comprises 21 items designed to evaluate an individual's treatment response over the past week. Items 1, 6, 8, 11, 12, 14, and 18 of the DASS-21 assess stress, with each item scored from 0 ("did not apply to me at all") to 3 ("applied to me very much, or

most of the time"). The total score of the stress subscale is calculated by doubling the sum of these 7-item scores, yielding a range of 0 to 42. Stress levels are categorized into five groups based on total scores: normal (14 or below), mild [15–18], moderate [19–25], severe [27–34], and extremely severe (34 or above). Higher scores reflect greater stress, while lower scores indicate less stress.

Stress knowledge

This study utilizes the Chinese translated version of the SKQ. The original SKQ, developed by Joyce in 2008, comprised seven items; two items were subsequently removed by Alshahrani [51] due to potential conceptual ambiguity and participant confusion. The Chinese SKQ-5 demonstrated acceptable internal consistency and test–retest reliability (intraclass correlation coefficient = 0.735). Items were presented in a yes/no/unclear format, with correct responses scored as one and incorrect or unclear responses scored as zero, yielding a total score range of 0–5. Higher scores indicate greater knowledge of stress.

Stress mindset

The SMM-G is used to assess participants' beliefs about stress [33]. This self-reported tool comprises eight 5-point Likert items, each with five options ranging from "strongly disagree" to "strongly agree," scored from 0 to 4, respectively. Items 1, 3, 5, and 7 are negatively worded, while items 2, 4, 6, and 8 are positively worded. The SMM-G score is the average score of eight items, ranging from 0 to 4, with the negatively worded items reverse-scored. Higher scores reflect a more "stress-is-enhancing" mindset, while lower scores reflect a more "stress-is-debilitating" mindset.

Perceived social support

The MSPSS is used to evaluate perceived social support from family, friends, and significant others [52]. This self-reported questionnaire uses a 7-point Likert scale for each item, ranging from "extremely disagree" to "extremely agree." The mean score of all items in the MSPSS, ranging from 0 to 7, represents the extent of perceived social support, with higher scores indicating greater perceived support. Higher scores indicate greater perceived social support.

Self-compassion

The self-reported 12-item SCS-SF is commonly used to measure how often individuals treat themselves with kindness and care during difficult times [53]. It is a condensed version of Neff's 26-item SCS, adapted by Gong et al. [54]. Each question is rated on a 5-point Likert scale, ranging from 0 to 5, representing "almost never" to

“almost always.” The mean score of all items is calculated, ranging from 0 to 5, with higher mean scores indicating greater self-compassion.

Resilience

The CD-RISC is a self-report tool consisting of 10 items, adapted by Campbell-Sills et al. [55] from the original 26-item version created by Connor and Davidson [56]. It is primarily used to assess how well individuals handle challenging situations, such as illness, stress, or failure. The scale uses a 5-point Likert format, with responses ranging from 0 (“not true at all”) to 4 (“true nearly all the time”). The total score is calculated by summing the scores of each item, resulting in a range of 0 to 40. Higher scores indicate a higher degree of resilience.

Feasibility data are collected to assess the implementation of the program, including recruitment, eligibility, and retention rates, demographic characteristics to evaluate the effectiveness of randomization, and task completion rates to gauge participant engagement.

Participant timeline {13}

Participants will participate in the IMB-based stress self-management health education program once a week for 8 weeks (see Table 2).

Sample size {14}

Because of within-cluster correlation, the required sample size was adjusted using the design effect ($DE = 1 + (n-1)\rho$) [57], where n is the average cluster size

and ρ is the intracluster correlation coefficient (ICC). For this study, the cluster size was set at $n=5$, reflecting the dormitory composition and anticipated participation, and the intra-cluster correlation coefficient was specified as $\rho=0.05$, consistent with median estimates from the CLustered OUtcome Dataset (CLOUD) bank [58]. The initial sample size per group was calculated using the standard formula for comparing two means under individual randomization [59]:

$$m = \frac{(Z_{(1-\alpha/2)} + Z_{1-\beta})^2 2\sigma^2}{\Delta^2} (1 + (n-1)\rho)$$

This calculation incorporated a two-sided α of 0.05, 80% power, a pooled standard deviation of 11.77, and an expected mean difference (Δ) of 7.94, derived from stress scores reported by Günaydin [60]. As a result, this yielded 42 participants per group, which was then inflated by the design effect and further adjusted for an anticipated 20% attrition rate, resulting in a final requirement of 53 participants per group or a total of 106 participants. With an average of 5 students per cluster, 22 clusters were therefore required to achieve adequate statistical power.

Recruitment {15}

In the fall of 2024, Changzhi Medical College enrolled approximately 316 first-semester undergraduate nursing students, distributed across 53 dormitories. During recruitment, researchers held brief meetings to provide a concise overview of the study. They explained the eligibility criteria, guided students on how to fill out the

Table 2 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) enrollment schedule, interventions, and assessments

Timepoints	Study period							
	Enrollment Screening	Allocation Randomization	Intervention Pretest	Intervention implementation	Posttest	Follow-up 1 month	3 months	6 months
Enrollment	X							
Eligibility screen	X							
Informed consent	X							
Allocation		X						
Interventions								
IMB health education				X				
Waitlist				X				
Assessments								
Demographics			X					
SKQ			X		X	X	X	X
SMM-G			X		X	X	X	X
MSPSS			X		X	X	X	X
SCS-SF			X		X	X	X	X
CD-RISC			X		X	X	X	X

registration form, and distributed the registration link. All students interested in participating in the intervention were invited to complete the form. The recruitment period lasted from September 2024 to October 2024.

To ensure the calculated sample size is met, the number of eligible participants in each dormitory was counted. Dormitories with four or more eligible participants were selected for random sampling and allocation. Ultimately, 24 dormitories met the eligibility criteria. Due to the limited number of male dormitories, all four were included in the study. For the remaining 20 female dormitories, simple random sampling was used to select 18 dormitories for inclusion. As a result, the study included four male dormitories and 18 female dormitories. These dormitories were randomly assigned to intervention and control arms based on gender, resulting in two male dormitories and nine female dormitories in both the intervention group and the waitlist control group.

Assignment of interventions: allocations

Sequence generation {16a}

Randomization was performed at the cluster (dormitory) level, stratified by sex to account for potential gender-related differences. Each dormitory was assigned a unique identifier to maintain allocation integrity. For female dormitories, all 20 eligible units were coded, and 18 were randomly selected using the Research Randomizer website (Urbaniak and Plous, 2007) before being allocated to the intervention or control group. For male dormitories, all four eligible units were directly randomized to either group.

Concealment mechanism {16b}

A “third-party” allocation method was applied to ensure allocation concealment. After participant recruitment and the identification of eligible dormitories, the researcher and research assistant A coded all eligible dormitories. The codes were known only to the researcher and research assistant A. Subsequently, the researcher placed the codes into opaque, sealed envelopes and handed them to research assistant B, who conducted the random selection and allocation of these codes. During this process, research assistant B was blinded to the significance of the codes. The randomly generated sequence was then placed into opaque, sealed envelopes by research assistant B and returned to the researcher. To prevent tampering, a second person was required to be present when the researcher or research assistant opened the sealed envelope, checking for any signs of tampering.

Implementation {16c}

Research assistant A created the randomization sequence, the first author and research assistant A

handled participant enrollment, and research assistant B was responsible for assigning interventions to the participants.

Assignment of interventions: masking

Who will be masked? {17a}

Throughout the trial, the outcome assessor (Guo) and trial statisticians (He) remain masked to treatment allocation to ensure unbiased data collection and analysis. Participants, research assistant A, and the researcher are not masked. To maintain participant anonymity, each participant is required to create a personal code during the baseline survey, which serves as their anonymized ID for the study. This code is known only to the participants to prevent accidental unmasking.

Procedure for unmasking if needed {17b}

Strict standard operating procedures have been implemented to avoid unmasking. If a participant's masking is inadvertently compromised during outcome evaluation, the evaluation process will be immediately halted. An independent assessor, who remains unaware of the participant's treatment allocation, will then complete the remaining evaluations with the participant to preserve the integrity of the data.

Data collection and management

Plans for assessment and collection of outcomes {18a}

The primary and secondary outcomes will be assessed by the outcome assessor (Guo) via online questionnaires at five time points: baseline, immediately post-intervention, and at 1 month, 3 month, and 6 months post-intervention. Baseline assessment will also include demographic information. Questionnaires were administered through Wenjuanxing, a widely used online survey platform, and WeCom (WeChat Work), the university's enterprise communication system.

Plans to promote participant retention and complete follow-up {18b}

To maximize participant retention and ensure the completeness of follow-up data, a structured strategy is employed, focusing on participants' continued engagement and adherence to scheduled assessments. Participation in the study will be entirely voluntary and free of charge, minimizing financial burden and promoting equitable access. To encourage the completion of follow-up measures, participants will receive a monetary incentive of 10 Chinese yuan for each valid questionnaire they complete. Participants' responsibilities to complete all scheduled modules and outcome evaluations will be explicitly outlined in the informed consent form, and written consent will be obtained to ensure voluntary

agreement. To further support follow-up completion, the research team will establish groups on the WeCom platform to facilitate timely reminders and notifications regarding upcoming or missed assessments. These combined measures aim to safeguard ethical compliance, reduce attrition, and promote the completeness of collected data throughout the study.

Data management {19}

Upon completion of data collection and the trial, paper records will be stored in designated file folders, while electronic files will be saved on a secure, password-protected hard drive. Access will be restricted to the researcher only.

Confidentiality {27}

All data collected will be handled with strict confidentiality and stored and managed securely in full compliance with the legal and ethical requirements of Changzhi Medical College. Each participant will be assigned a unique identification code, and no personally identifiable information will be linked to the research dataset. All electronic data will be stored on a dedicated, encrypted universal serial bus (USB) device under the custody of a designated data manager (He). At the same time, any hard-copy materials will be securely kept in locked cabinets. Access to the data will be restricted to the principal investigator and authorized research team members only. In all reports, presentations, and publications, only aggregated findings will be presented, ensuring that no individual participant can be identified.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

No biological specimens will be collected in this study because its primary focus is on assessing psychological and behavioral outcomes rather than genetic or molecular factors.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

An intention-to-treat (ITT) analysis will be conducted to evaluate the program's effectiveness. IBM SPSS Statistics 27.0 software will be used to perform the statistical analysis.

Descriptive statistics will be used to compare baseline characteristics, including sex, perceived family economic status, father's educational level, mother's educational level, reasons for choosing nursing, and liking for the nursing profession across groups. These characteristics will be presented as frequencies,

percentages, or proportions. Outcomes comprising age, DASS-21 Stress subscale, SKQ, SMM-G, MSPSS, SCS-SF, and CD-RISC will be summarized using means and standard deviations for normally distributed data or medians and interquartile ranges for non-normally distributed data.

A GLMM will be used to evaluate the effectiveness of the IMB-based stress self-management health education program on the SKQ, SMM-G, MSPSS, SCS-SF, CD-RISC, and stress (as measured by the stress subscale of the DASS-21). For each outcome, group (intervention vs. control), time (baseline, immediate post-intervention, 1-month, 3-month, and 6-month follow-ups), and their interaction will be included as fixed effects. Participants nested within dormitory clusters will be modeled as random effects to account for repeated measurements and cluster-level correlations.

Interim analyses {21b}

No interim analyses or stopping rules are included in this study, as the trial is designed to proceed to completion without modifications based on interim results.

Methods for additional analyses {20b}

Additional analyses are planned as exploratory post hoc comparisons to further examine potential trends in the outcomes. The primary analysis uses GLMM, which accounts for repeated measures across time and evaluates overall fixed effects (e.g., group, time, and group $\times$ time interaction). Exploratory analyses include pairwise comparisons between groups at each time point and within-group comparisons across time points. Appropriate adjustments for multiple testing (e.g., Bonferroni correction) will be applied only in these exploratory analyses to control type I error.

Methods in analysis to handle protocol nonadherence and any statistical methods to handle missing data {20c}

Protocol nonadherence will be addressed using both intention-to-treat (ITT) and per-protocol (PP) analyses. ITT includes all randomized participants in their assigned groups, whereas PP includes only participants who completed at least 7 of 8 modules ($\approx 80\%$) and all primary outcome assessments. Missing data will be handled using GLMMs under the missing-at-random (MAR) assumption, which allows for valid inference using all observed data without requiring imputation. If data are suspected to be missing not at random (MNAR), missing values will be supplemented using the last observation carried forward (LOCF) as a conservative approach.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

The study does not intend to make participant-level datasets or statistical codes publicly available because of concerns regarding participant confidentiality and data privacy.

Oversight and monitoring

Composition of the coordinating center and trial steering committee (5d)

This study does not include a central coordinating body or trial steering committee because the scale and complexity of the trial do not necessitate such structures.

Composition of the data monitoring committee and its role and reporting structure {21a}

No formal data monitoring committee is included in the study because the trial is considered to have minimal risks to participants and is of relatively short duration. Additionally, the research team is deemed capable of overseeing data management and safety monitoring effectively.

Adverse event reporting and harms {22}

Although the intervention is considered low risk, safeguarding participants' psychological well-being is a core ethical priority. Psychological outcomes will be systematically assessed at baseline, immediately post-intervention, and at 1-, 3-, and 6-month follow-ups using validated measures, including the stress subscale of the DASS-21, providing continuous monitoring of participants' psychological status. Participants are informed in the consent form that they may contact the research team or a designated mental health professional at any time if they experience psychological distress or emergent issues.

In case of severe distress or other emergent situations, the research team will implement the Safety and Emergency Plan (see supplementary material), which specifies procedures for immediate support, referral to qualified mental health professionals, and, if necessary, temporary suspension or termination of the intervention. All incidents will be meticulously documented and reported to the principal investigator, the institutional ethics committee, and the participant's academic counselor in accordance with the study protocol.

Frequency and plans for auditing trial conduct {23}

There are no plans for auditing the trial as the study is low risk and will be conducted in accordance with established institutional protocols and ethical guidelines.

Plans for communicating important protocol amendments to relevant parties {25}

No amendments to the protocol have been made, as the trial remains in its initial implementation phase and the current protocol is considered adequate to guide all planned procedures.

Dissemination plans {31a}

The study findings will be disseminated in peer-reviewed journal publications.

Discussion

This study aims to evaluate the effectiveness of a stress self-management health education program, grounded in the IMB model, through a cluster-randomized controlled trial among bachelor's degree nursing students at a college in Shanxi Province, China. Guided by the IMB framework, the program aims to enhance students' knowledge about stress, foster a stress-enhancing mindset, increase perceived social support, and develop practical stress management skills, including self-compassion and resilience.

If proven effective, the program has the potential to enhance the mental health of nursing students and demonstrate scalability for broader application among other student populations. Furthermore, it provides novel evidence supporting the application of the IMB theory in stress intervention research, highlighting its innovative use in addressing stress among nursing students. The program could also serve as an effective early intervention or complementary strategy to reduce stress and prevent the onset of more serious mental health conditions. Notably, it is well-suited for delivery by nonmental-health professionals, such as nursing educators, academic counselors, or workplace supervisors, offering a preventive alternative that may help address gaps in mental health education accessibility, particularly in settings such as China, where the availability of trained mental health professionals remains limited.

Trial status

This study, initiated in October 2021, adheres to a single protocol version. Participant recruitment and randomization were completed in October 2024, and the intervention phase is currently in progress. Baseline data has already been collected. An immediate post-intervention test will be conducted from December 2024 to January 2025, followed by the final follow-up in June–July 2025.

Abbreviations

CD-RISC	Connor-Davidson Resilience Scale
CLOUD	CLustered OUtcome Dataset
DASS	Depression Anxiety Stress Scale
DE	Design effect

GLMM	Generalized linear mixed model
ICC	Intraclass correlation coefficient
IMB	Information-motivation-behavioral skills
ITT	Intention to treat
LOCF	Last observation carried forward
MAR	Missing at random
MNAR	Missing not at random
MSPSS	Multidimensional Scale of Perceived Social Support
PP	Per protocol
RA	Research assistant
RCT	Randomized controlled trial
SKQ	Stress knowledge questionnaire
SCS	Self-compassion scale
SF	Short form
SMM-G	Stress Mindset Measure-General
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
USB	Universal serial bus

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-026-09526-5>.

Supplementary material 1.

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Authors' contributions (31b)

D conceptualized the study, developed the protocol, and designed the online "IMB-based stress health education" course. A, T, Z, and L provided guidance on the development and content design of the intervention program. D, G, and H were responsible for participant recruitment, data collection, and data analysis. D and T drafted and revised the manuscript. All authors reviewed and approved the final manuscript.

Funding (4)

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Data availability (29)

De-identified datasets generated and analyzed during the current study may be made available upon reasonable request to the first author and subject to approval by the institutional ethics committee. Due to participant confidentiality considerations and institutional policies, the full datasets are not publicly available.

Declarations

Ethics approval and consent to participate (24)

Ethical approval for this study was obtained from the Research Ethics Committee of Changzhi Medical College (RT20240010). All participants provided written informed consent prior to participation.

Consent for publication (32)

Not applicable, as the study does not involve the publication of identifiable personal data or images, nor does it include any individual information or case reports requiring separate consent for publication.

Competing interests (28)

The authors declare that they have no competing interests.

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