

Effects of a preventive mindfulness intervention on perceived stress and anticipatory anxiety before first clinical training in nursing students: A preregistered randomized controlled trial

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Abstract

Background

Clinical training is a significant stressor for nursing students, and those facing their first placement are particularly vulnerable. This preregistered randomized controlled trial (RCT) evaluated whether a 6-week mindfulness program delivered before first clinical training could prevent stress and anxiety.

Methods

Twenty-nine nursing students were randomly assigned to the intervention ($n = 15$) or control ($n = 14$) group; 27 completed the study (intervention: $n = 13$, control: $n = 14$). The intervention group received a 6-week mindfulness meditation program; controls received standard curriculum only. Perceived stress (PSS-10) was the primary outcome; anxiety (STAI), depression (BDI-II), sleep quality (PSQI), and mindful awareness (MAAS) were secondary outcomes, assessed at baseline, pre-, mid-, and post-clinical training. Each outcome was analyzed using two-way repeated measures analysis of variance, followed by Bonferroni-corrected between-group t-tests when the group $\times$ time interaction was significant.

Results

The primary outcome, perceived stress, did not show a significant intervention effect ($F(3, 75) = 0.41$, $p = .747$). Among secondary outcomes, a significant group $\times$ time interaction was observed for state anxiety ($F(3, 75) = 5.58$, $p = .002$, $\eta^2 = 0.182$). The control group showed a sharp increase in state anxiety from baseline to the pre-clinical assessment, indicating anticipatory anxiety before first clinical training. The intervention group showed no such increase, with significantly lower state anxiety than controls at the pre-clinical assessment ($d = 0.99$, one-tailed Bonferroni-corrected $p = .033$). No significant effects were observed for trait anxiety, depressive symptoms, sleep quality, or mindful awareness.

Conclusions

In this RCT, the primary outcome of perceived stress was not significantly reduced by the mindfulness intervention. However, the findings indicate that nursing students experience substantial anticipatory anxiety before first clinical placement and suggest that a preventive mindfulness program can attenuate this anticipatory state anxiety. Future research should examine booster sessions during clinical training and evaluate effects in more diverse populations.

Trial registration:

Japan Registry of Clinical Trials (jRCT), jRCT1040240204. Registered 25 March 2025.

Background

Nursing shortages and high turnover represent a persistent global challenge with direct consequences for patient care.[1] Nurses experience higher burnout rates than most other healthcare professionals,[2, 3] and this burden extends to nursing students: burnout during training can impair skill acquisition and increase the likelihood of leaving the profession after graduation.[4, 5] These patterns point to the importance of developing effective stress management skills early in nursing education.

Clinical training is among the most significant stressors nursing students face, with perceived stress during this period associated with adverse psychosocial outcomes and impaired clinical performance.[6–8] First-time clinical experiences are particularly demanding: students commonly report difficulties managing difficult patients and relatives, navigating the theory-practice gap, and adjusting to professional expectations.[9, 10] These concerns are not limited to the clinical period itself; students report that comparable psychological burdens arise in anticipation of placement, before they enter the ward.[11] Such challenges are especially acute for those entering clinical practice for the first time, suggesting a need for targeted preventive interventions before initial clinical exposure.

Mindfulness-based interventions, including Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT), share a common foundation in mindfulness meditation, defined as deliberate, non-judgmental attention to present-moment experience.[12, 13] These approaches have demonstrated effectiveness for stress, anxiety, depression, and sleep disturbance across both clinical and healthy populations.[14–16] Neurobiological evidence further suggests that regular practice modulates brain regions involved in emotional regulation and improves sleep quality,[17, 18] supporting their potential relevance for nursing students facing the psychological demands of clinical training.

Several RCTs have examined mindfulness interventions for nursing students in the context of clinical training. Programs ranging from 4 to 20 weeks have reported reductions in stress and anxiety,[19–22] though findings are inconsistent across studies. For example, Ratanasiripong et al. reported significant reductions in stress and anxiety following a 4-week program delivered during clinical training.[21] In contrast, Plummer et al. observed no significant effect on stress after a 20-week intervention, though mindfulness levels did improve.[20]

Despite this body of work, the preventive efficacy of these interventions remains insufficiently examined. Although some programs were implemented before clinical training began, no study tracked stress and anxiety continuously from the pre-clinical period through training completion. Because outcomes were typically assessed immediately after the intervention or at a single mid-practicum time point, it is unclear whether reductions reflected genuine prevention of stress escalation or the management of symptoms that had already developed. Whether pre-training mindfulness programs can specifically buffer anticipatory stress and anxiety before first clinical exposure therefore remains an open question.

A second limitation is the absence of preregistration. To our knowledge, no RCT of mindfulness interventions for nursing students has prospectively registered its hypotheses and analysis plan prior to data collection.[19–28] This observation is supported by Chen et al.'s systematic review, in which none of the 10 identified RCTs reported preregistration.[29] Non-preregistered studies are vulnerable to hypothesizing after the results are known (HARKing) and selective outcome reporting, practices that systematically distort the literature toward positive results.[30–33] Given that preregistration is increasingly regarded as a minimum standard for reproducible clinical research,[30, 31] its absence from this field warrants attention.

These two gaps informed the design of the present study. To address the first, we implemented a 6-week mindfulness program before first clinical training and assessed outcomes at four time points: at baseline, immediately before clinical training, mid-clinical training, and post-clinical training. To address the second, the trial was prospectively registered prior to recruitment. We hypothesized that the intervention would reduce stress and anxiety, improve sleep quality, and increase mindfulness compared to standard curriculum.

Methods

Study Design

The aim of this study was to examine whether a 6-week mindfulness program delivered before first clinical training could prevent stress and anxiety in second-year nursing students at a Japanese university. This preregistered, two-arm, parallel-group randomized controlled trial assigned participants to either a 6-week mindfulness meditation program delivered before first clinical training or a standard curriculum control condition. Ethical approval was granted by the Institutional Review Board of Hamamatsu University School of Medicine (approval number: 24–257; March 19, 2025). The trial was registered with the Japan Registry of Clinical Trials (jRCT1040240204, registered March 25, 2025), and the study protocol and analysis plan were preregistered on the Open Science Framework prior to recruitment (registered May 13, 2025; see the Section of Availability of data and materials). The study adhered to the Declaration of Helsinki and was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines[34] (Additional file 1). No patient or public involvement was incorporated in this study.

Participants

Participants were second-year nursing students at Hamamatsu University School of Medicine scheduled to undergo their first basic nursing clinical training involving direct patient assignment. Exclusion criteria were severe suicidal ideation or behavior and current psychiatric treatment. Students were recruited through self-selection via campus announcements and posters, with explicit clarification that

participation was voluntary and would not affect academic standing. Written informed consent was obtained prior to enrollment, and participants received compensation of 20,000 JPY.

Sample Size

Sample size was estimated based on a meta-analysis reporting a medium effect of mindfulness interventions on stress in nursing students (standardized mean difference (SMD) = - 0.50).[29] Assuming a medium effect size (Cohen's $f = 0.25$) and using G*Power (version 3.1.9.7) with $\alpha = 0.05$, power = 0.90, two groups, four time points, and a within-subjects correlation of 0.50, the minimum required sample size was 30 participants (15 per group). The target enrollment was set at 40 (20 per group) to accommodate an anticipated 20% dropout rate.

Randomization and Blinding

Participants were randomized using a concealed, computer-generated permuted block design with no stratification via the University Hospital Medical Information Network (UMIN) Internet Data and Information System. The first author enrolled participants and communicated allocations following informed consent.

Full blinding was not possible given the behavioral nature of the intervention; participants and the program implementer (first author) were aware of group assignment. The nursing faculty supervising clinical training (second and third authors) and all other team members remained blinded throughout the study. Statistical analyses were conducted by the last author, who was blind to allocation. No unintended unblinding occurred.

Intervention

A 6-week mindfulness meditation program was delivered face-to-face in group format in university classrooms, with individual or small-group make-up sessions provided as needed. The program was grounded in MBSR principles[12] and incorporated multiple mindfulness modalities, as evidence supports the effectiveness of multicomponent approaches.[35] A 6-week format was adopted to reduce burden on nursing students, consistent with research demonstrating the efficacy of shorter programs in university populations.[35, 36] The program was facilitated by the first author, a clinical psychologist with nine years of experience who has completed training in MBSR, MBCT-D (Mindfulness-Based Cognitive Therapy for Depression), and BW-S (Breathworks for Stress) through the International Mindfulness Center Japan.

The program content progressed over six weeks as follows. Week 1 introduced mindfulness concepts with practices including mindful eating, breathing, and body scan. Week 2 addressed stress with reflection on daily pleasant experiences and continued breathing and body scan practice. Week 3

focused on unpleasant experiences with sitting and walking meditation. Week 4 covered stress responses with mindful hatha yoga. Week 5 addressed challenges specific to nursing clinical training[9, 10] with STOP[37] and RAIN[38] practices. Week 6 consolidated learning through sitting meditation and program reflection. Following the 2-week clinical training period, a follow-up session was held to support application of skills. Throughout the intervention period, participants were instructed to practice mindfulness independently for 10–15 minutes daily. Participants were also asked to refrain from engaging in other psychological therapies during the study period.

Outcome Measures

All outcomes were self-reported. The primary outcome was perceived stress, assessed using the Perceived Stress Scale (PSS-10),[39, 40] a 10-item measure of stress appraisal over the past month rated on a 5-point Likert-type scale, with the Japanese instructional statements from Mimura et al.[41] Secondary outcomes were anxiety, assessed using the State-Trait Anxiety Inventory (STAI Form X),[42, 43] a 40-item scale assessing both state and trait anxiety on a 4-point Likert-type scale; depressive symptoms, assessed using the Beck Depression Inventory-II (BDI-II),[44, 45] a 21-item measure rated on a 0–3 scale; sleep quality, evaluated using the Pittsburgh Sleep Quality Index (PSQI),[46, 47] a 9-item measure of sleep quality over the past month, with higher scores indicating poorer sleep; and mindful awareness, assessed using the Mindful Attention Awareness Scale (MAAS),[48, 49] which measures dispositional mindfulness on a 6-point Likert-type scale.

Procedures

After obtaining written informed consents, participants completed measures of demographic and background characteristics, including age, sex, nursing career motivation, prior meditation experience, and psychiatric history. Autism-spectrum traits were assessed using the Autism-Spectrum Quotient, Japanese version (AQ-J).[50, 51]

All participants completed self-report measures at four time points: baseline (T0), before the intervention began; pre-clinical training (T1), immediately after the 6-week program, which coincided with the period shortly after notification of clinical training ward and group assignments; mid-clinical training (T2), during the first week of clinical training; and post-clinical training (T3), immediately after completing the 2-week clinical training.

Statistical Analysis

Baseline demographic and clinical characteristics were summarized as means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Group differences at baseline were assessed using independent t-tests for continuous variables and chi-square tests or Fisher's exact test for categorical variables.

For all outcome measures (PSS-10, STAI State, STAI Trait, BDI-II, PSQI, and MAAS), two-way repeated measures analysis of variance (ANOVA) was conducted with group (intervention vs. control) as a between-subjects factor and time (T0–T3) as a within-subjects factor, with each measure analyzed separately. All ANOVA tests used two-tailed significance tests. When a significant time $\times$ group interaction was identified, between-group comparisons at each time point were conducted using independent samples t-tests with one-tailed tests, as prespecified in the trial registration, consistent with the directional hypotheses predicting lower scores in the intervention group. Bonferroni correction was applied across the four time points. Effect sizes were calculated as η^2 for ANOVA, with values of 0.01, 0.06, and 0.14 interpreted as small, medium, and large, and as Cohen's d for t-tests, with values of 0.2, 0.5, and 0.8 interpreted as small, medium, and large, respectively. All analyses were conducted using SPSS version 28 and Stata version 19. Statistical significance was set at $\alpha = .05$.

Although the preregistered protocol specified an intention-to-treat (ITT) analysis, data from two participants who withdrew were deleted at their request in accordance with the informed consent agreement. Because no data were available for imputation, the analysis was conducted as a complete case analysis restricted to the 27 participants who completed all four assessments.

Assessment of Adverse Events

Adverse events were defined as unfavorable physical or psychological symptoms occurring during the study period, including discomfort, excessive fatigue, worsening anxiety or depression, or any event requiring medical intervention. The first author assessed adverse events at each time point. Events were classified as serious if they resulted in hospitalization, permanent impairment, or were otherwise deemed medically significant; all other events were classified as non-serious.

Use of Large Language Models

Claude Opus 5 (Anthropic, San Francisco, CA, USA) were used for English language editing, formatting to journal requirements, and consistency checks of reported statistics. The authors reviewed and revised all text and take full responsibility for the content of the manuscript.

Results

Participant Flow and Sample Characteristics

Participant recruitment took place from May 15 to June 25, 2025. The 6-week mindfulness intervention was delivered from late August through early October 2025, followed by 2 weeks of clinical training, with final follow-up assessments completed in late October 2025.

Figure 1 shows the CONSORT flow diagram. A total of 46 students expressed interest following post-lecture announcements and were invited to an information session via email. Of these, 31 attended and were assessed for eligibility; 2 were excluded: 1 for meeting an exclusion criterion and 1 for declining to provide informed consent. Twenty-nine eligible students were randomly assigned to the intervention

group (n = 15) or control group (n = 14). Two participants from the intervention group subsequently withdrew: one before the first session due to scheduling conflicts, and one after the first session due to discomfort during home meditation practice. In accordance with the informed consent agreement, all data from these participants were deleted upon withdrawal. The final analytical sample comprised 27 participants (intervention: n = 13; control: n = 14). All 27 completed assessments at all four time points, yielding 100% retention and no missing data.

The protocol prespecified that enrollment would continue across successive academic years (2025, 2026, and 2027) until the target of 40 participants was reached, given that the clinical training placement occurs once annually for second-year students. However, recruitment was discontinued after the 2025 cohort due to an unforeseen personal circumstance affecting a key member of the research team. The enrolled sample of 27 fell marginally short of the a priori minimum of 30 (prior to dropout adjustment). A post-hoc sensitivity analysis indicated that the achieved sample was sufficient to detect interaction effects of $f \geq 0.23$ with 80% power and $f \geq 0.26$ with the 90% power assumed in the a priori calculation.

Adverse Events

One participant withdrew from the study after experiencing discomfort during home meditation practice following the first intervention session. This event was classified as a non-serious adverse event, as it resolved spontaneously without requiring medical intervention. The other participants reported no adverse events.

Baseline Characteristics

Baseline characteristics are presented in Table 1. The groups showed no significant differences in any outcome measure at baseline (all $p > .05$). A statistically significant difference in age was observed ($t(25) = -2.80$, $p = .010$), with the intervention group slightly older than the control group (19.6 ± 0.5 vs. 19.1 ± 0.4 years); however, this difference of 0.5 years is unlikely to be clinically meaningful given that both groups comprised second-year nursing students of similar age.

Table 1
Baseline Characteristics of Participants.

Characteristics	Intervention (N = 13) Mean (SD)	Control (N = 14) Mean (SD)	p-value
Age	19.6 (0.5)	19.1 (0.4)	.010*
Female, n (%)	13 (100.0%)	14 (100.0%)	—†
Prior meditation experience, n (%)	1 (7.7)	2 (14.3)	.586
Nursing career motivation			
High, n (%)	3 (23.1)	4 (28.6)	.560
Moderate, n (%)	10 (76.9)	9 (64.3)	
Low, n (%)	0 (0.0)	1 (7.1)	
AQ total score	16.3 (5.9)	14.9 (5.9)	.529
PSS-10	18.3 (4.4)	17.4 (5.6)	.656
STAI Trait	44.6 (8.5)	40.9 (8.8)	.270
STAI State	39.2 (6.6)	35.1 (7.2)	.140
BDI-II	6.8 (4.5)	5.4 (3.1)	.319
PSQI	6.2 (2.2)	5.3 (2.3)	.326
MAAS	67.8 (6.2)	68.9 (8.5)	.708

Values are mean (SD) unless otherwise indicated. Continuous variables were compared using independent t-tests; categorical variables were compared using chi-square tests or Fisher's exact test. *p < .05. †Statistical test not performed because all participants were female. Abbreviations: SD, standard deviation; PSS-10, Perceived Stress Scale; STAI, State-Trait Anxiety Inventory; BDI-II, Beck Depression Inventory-II; PSQI, Pittsburgh Sleep Quality Index; MAAS, Mindful Attention Awareness Scale; AQ, Autism-Spectrum Quotient.

Intervention Delivery and Adherence

All six sessions were delivered by the first author as planned, and all 13 intervention group participants attended all sessions. Make-up sessions were provided individually or in small groups as needed due to scheduling conflicts or illness. All sessions followed the pre-planned protocol and session outlines, and adherence was monitored by the session facilitator. However, independent assessment of intervention fidelity and systematic monitoring of daily home practice were not conducted.

Perceived Stress (PSS-10)

Two-way repeated measures ANOVA revealed no significant main effect of time ($F(3, 75) = 1.58, p = .202, \eta^2 = 0.059$), group ($F(1, 25) = 0.14, p = .710, \eta^2 = 0.006$), or time $\times$ group interaction ($F(3, 75) = 0.41, p = .747, \eta^2 = 0.016$), indicating that perceived stress did not change differentially between groups over time. Temporal patterns are illustrated in Fig. 2A and full statistics are presented in Table 2.

Mean scores ($\pm$ 95% confidence intervals (CI)) for all outcome measures in the intervention group (orange squares) and control group (blue circles) at four time points: T0 (baseline), T1 (pre-clinical training), T2 (mid-clinical training), and T3 (post-clinical training). Panels A through F show the six outcome measures: (A) Perceived Stress (PSS-10), (B) Trait Anxiety (STAI Trait), (C) State Anxiety (STAI State), (D) Depressive Symptoms (BDI-II), (E) Sleep Quality (PSQI), and (F) Mindful Awareness (MAAS). Error bars represent 95% CI. * $p < .05$ for the between-group comparison at T1 (one-tailed, Bonferroni-corrected).

Table 2
Results of Two-Way Repeated Measures ANOVA for All Outcome Measures.

Outcome Measure	Time			Group			Time $\times$ Group		
	F	p-value	η^2	F	p-value	η^2	F	p-value	η^2
PSS-10	1.58	.202	0.059	0.14	.710	0.006	0.41	.747	0.016
STAI Trait	6.69	< .001***	0.211	0.28	.598	0.011	1.27	.290	0.048
STAI State	22.72	< .001***	0.476	0.13	.721	0.005	5.58	.002**	0.182
BDI-II	3.15	.030*	0.112	0.11	.746	0.004	1.57	.204	0.059
PSQI	6.06	< .001***	0.195	2.19	.151	0.081	2.25	.090	0.083
MAAS	1.23	.301	0.047	0.01	.937	0.000	0.97	.392	0.037

Each outcome measure was analyzed in a separate model with group (intervention vs. control) as a between-subjects factor and time (T0–T3) as a within-subjects factor. F = F-statistic; η^2 = partial eta squared. Degrees of freedom: Time and Time $\times$ Group, $df = 3, 75$; Group, $df = 1, 25$. Greenhouse-Geisser correction applied for sphericity violation. * $p < .05$, ** $p < .01$, *** $p < .001$.

Trait Anxiety (STAI)

ANOVA revealed a significant main effect of time ($F(3, 75) = 6.69, p < .001, \eta^2 = 0.211$), but no significant main effect of group ($F(1, 25) = 0.28, p = .598, \eta^2 = 0.011$) or time $\times$ group interaction ($F(3, 75) = 1.27, p = .290, \eta^2 = 0.048$), indicating that trait anxiety changed over time across both groups without differential intervention effects (Fig. 2B).

State Anxiety (STAI)

ANOVA revealed a significant main effect of time ($F(3, 75) = 22.72, p < .001, \eta^2 = 0.476$) and a significant time $\times$ group interaction ($F(3, 75) = 5.58, p = .002, \eta^2 = 0.182$), but no significant main effect

of group ($F(1, 25) = 0.13$, $p = .721$, $\eta^2 = 0.005$). Between-group comparisons at each time point (two samples t-tests, one-tailed, Bonferroni-corrected) revealed a significant difference at T1, with the intervention group reporting significantly lower state anxiety than the control group (38.2 ± 10.9 vs. 48.8 ± 10.4 , $t(25) = 2.57$, $p = .033$, $d = 0.99$), representing a large effect. No significant differences were observed at other time points (Table 3). Within-group temporal patterns revealed distinct trajectories (Fig. 2C). The control group showed a sharp increase in state anxiety from baseline to T1, which remained elevated at T2 before declining at T3. The intervention group showed minimal change from baseline to T1, a moderate increase at T2, and a subsequent decline at T3.

Table 3
Between-Group Comparisons at Each Time Point for State Anxiety.

Time Point	Intervention M (SD)	Control M (SD)	t	p [¶]	Cohen's d
T0: Baseline	39.2 (6.6)	35.1 (7.2)	-1.53	1.000	-0.59
T1: Pre-clinical training	38.2 (10.9)	48.8 (10.4)	2.57	.033*	0.99
T2: Mid-clinical training	48.3 (11.9)	50.9 (11.6)	0.56	1.000	0.22
T3: Post-clinical training	35.5 (7.1)	30.2 (10.0)	-1.56	1.000	-0.60

Two samples t-tests were conducted at each time point for state anxiety (STAI State). T0 = Baseline; T1 = pre-clinical training; T2 = mid-clinical training; T3 = post-clinical training. * $p < .05$. Positive t and Cohen's d values indicate lower scores (reflecting better outcomes) in the intervention group. [¶]One-tailed in the preregistered direction (intervention < control) and Bonferroni-corrected for four time points; corrected values exceeding 1 are shown as 1.000.

Depressive Symptoms (BDI-II)

ANOVA revealed a significant main effect of time ($F(3, 75) = 3.15$, $p = .030$, $\eta^2 = 0.112$), but no significant main effect of group ($F(1, 25) = 0.11$, $p = .746$, $\eta^2 = 0.004$) or time $\times$ group interaction ($F(3, 75) = 1.57$, $p = .204$, $\eta^2 = 0.059$), indicating that depressive symptoms changed over time in both groups without differential intervention effects (Fig. 2D).

Sleep Quality (PSQI)

ANOVA revealed a significant main effect of time ($F(3, 75) = 6.06$, $p < .001$, $\eta^2 = 0.195$), but no significant main effect of group ($F(1, 25) = 2.19$, $p = .151$, $\eta^2 = 0.081$) or time $\times$ group interaction ($F(3, 75) = 2.25$, $p = .090$, $\eta^2 = 0.083$), indicating that sleep quality changed over time in both groups without differential intervention effects (Fig. 2E).

Mindful Awareness (MAAS)

ANOVA revealed no significant main effect of time ($F(3, 75) = 1.23$, $p = .301$, $\eta^2 = 0.047$), group ($F(1, 25) = 0.01$, $p = .937$, $\eta^2 = 0.000$), or time $\times$ group interaction ($F(3, 75) = 0.97$, $p = .392$, $\eta^2 = 0.037$), indicating

that mindful awareness did not change significantly over time in either group (Fig. 2F).

Discussion

This preregistered RCT evaluated a 6-week preventive mindfulness program delivered before nursing students' first clinical training. The primary outcome, perceived stress, was not significantly reduced by the intervention. Among the secondary outcomes, a significant effect was observed only for state anxiety, with the intervention group showing substantially lower anxiety than controls at the pre-clinical assessment ($d = 0.99$). No significant effects were found for trait anxiety, depressive symptoms, sleep quality, or mindful awareness.

This study offers three contributions to the existing literature. First, it documents a within-person rise in state anxiety from a pre-intervention baseline to the period immediately before first clinical placement. The control group's state anxiety rose sharply from baseline to T1 (35.1 to 48.8), quantifying the anticipatory burden described in qualitative research.[11] A previous study measured state anxiety before first clinical placement,[52] but only at a single pre-placement time point, so an anticipatory increase could not be examined. Second, it suggests that a preventive mindfulness intervention delivered before clinical training can specifically attenuate this anticipatory anxiety with a large between-group effect at T1 ($d = 0.99$). Third, to our knowledge, this is the first preregistered RCT of a mindfulness intervention for nursing students, enhancing transparency through prospective registration of hypotheses and analysis plans and reducing susceptibility to publication bias.

The significant reduction in state anxiety at T1 represents the central finding of this study. The T1 assessment coincided with the period immediately following notification of clinical ward and group assignments, a time when anticipatory anxiety would be expected to peak. Consistent with this, the control group showed a sharp rise in state anxiety from baseline to T1, confirming that this transitional period is particularly anxiety-provoking for students facing their first clinical placement. The intervention group, by contrast, showed no such increase, suggesting that mindfulness skills developed before clinical exposure can buffer anxiety during this vulnerable period. To our knowledge, this is the first RCT to show that a preventive mindfulness intervention specifically targeting the pre-clinical period can attenuate anticipatory anxiety before first clinical exposure.

Even in the absence of sustained effects, reducing anticipatory anxiety before first clinical exposure has distinct educational value. The pre-clinical transition is a critical juncture at which excessive anxiety can impair initial clinical learning, motivation, and contribute to avoidance of professional challenges; an intervention that moderates anxiety at this threshold may therefore support more adaptive engagement during the earliest and most formative stage of clinical education. That anxiety subsequently rose in both groups reflects the inherent demands of clinical training, but this should not obscure the value of ensuring students enter that environment in a less psychologically burdened state.

This elevation in anxiety during clinical training, observed in both groups, points to the limits of a pre-clinical intervention and raises the question of why its effects did not carry forward. One possible

explanation is that anticipatory anxiety before clinical training is driven primarily by uncertainty about an unfamiliar environment, a type of anxiety that mindfulness practice may be well-suited to address. Once students enter the clinical environment, however, the nature of their stressors changes fundamentally: rather than uncertainty about an unfamiliar situation, they face concrete and varied demands, including managing patient care, navigating professional relationships, and meeting clinical expectations, which may require different coping strategies than those cultivated in a pre-clinical mindfulness program. Additionally, the mindfulness techniques emphasized in the pre-clinical program, such as mindful eating, body scans, and breathing exercises, may have been less readily transferable to the clinical environment, where students face immediate and interpersonally demanding situations requiring real-time regulation. This pattern suggests that pre-clinical training alone may be insufficient to sustain benefits across the full arc of clinical education, and that brief booster sessions delivered during clinical training, targeting the specific stressors students encounter in that setting, may be necessary to extend the protective effects observed at T1.

The null effects on perceived stress, trait anxiety, depressive symptoms, sleep quality, and mindful awareness are broadly consistent with the existing literature: among the RCTs identified in Chen et al.'s meta-analysis, 71% of studies examining stress and 40% examining depression reported non-significant effects.[29] Inconsistencies across prior studies likely reflect differences in program duration, participant characteristics, and assessment timing. The absence of preregistration in prior work further complicates interpretation, as selective outcome reporting may have inflated the proportion of positive findings in the published literature.[30–33] As the first preregistered RCT in this area, the present study provides a more transparent estimate of intervention effects.

Several methodological factors may help explain the null results on specific outcomes. First, baseline BDI-II scores (mean 6.1) fell within the minimal range,[44] and baseline PSQI scores (mean 5.7) were close to the cutoff of the Japanese version (5.5),[46] suggesting limited room for improvement in this relatively healthy sample. Second, the retrospective time windows of the PSS-10 (past month), PSQI (past month), and BDI-II (past two weeks) may have diluted intervention effects at T1, as these windows partially overlapped with the pre-intervention period. State anxiety, which reflects the present moment, was not subject to this limitation and may therefore have been more sensitive to the immediate post-intervention effect. Finally, the absence of a significant effect on mindful awareness is consistent with Creswell's observation that approximately 50% of mindfulness intervention studies fail to detect significant changes on self-report mindfulness scales.[53]

Limitations

Several limitations of this study should be noted. First, the final sample size ($n = 27$) fell marginally short of the minimum of 30 specified by the a priori power analysis. As stated in the Results section, the achieved sample provided 90% power only for interaction effects of $f \geq 0.26$, slightly larger than the medium effect ($f = 0.25$) assumed a priori. The non-significant findings for perceived stress, sleep quality, and other outcomes may therefore partly reflect limited statistical power. The large between-group

difference observed for state anxiety ($d = 0.99$, $f \approx 0.50$) was well within the detectable range. Future trials should target larger samples to improve precision of effect estimates and power for smaller effects. Second, daily home practice was not monitored, limiting the assessment of intervention fidelity and dose-response relationships. Future studies should incorporate objective monitoring tools such as app-based practice logs to quantify home practice adherence. Third, the absence of structured booster sessions during clinical training represents a design limitation that future studies should address, ideally by testing whether brief, setting-specific sessions during clinical placement can sustain the pre-clinical gains documented here. Finally, all participants were female nursing students from a single Japanese institution, limiting the generalizability of findings to male students, other cultural contexts, and different educational settings.

Conclusions

This preregistered RCT demonstrates that nursing students experience substantial anticipatory anxiety before their first clinical placement. Although the primary outcome of perceived stress was not significantly reduced, a 6-week preventive mindfulness program effectively attenuated anticipatory state anxiety, a preregistered secondary outcome ($d = 0.99$). The results suggest that mindfulness functions most effectively as a situation-specific regulatory tool at critical transitions in nursing education. Future trials should examine whether booster sessions during clinical training can extend these gains.

Abbreviations

ANOVA

Analysis of variance

AQ-J

Autism-Spectrum Quotient, Japanese version

BDI-II

Beck Depression Inventory-II

BW-S

Breathworks for Stress

CI

Confidence interval

CONSORT

Consolidated Standards of Reporting Trials

HARKing

Hypothesizing after the results are known

IRB

Institutional Review Board

ITT

Intention-to-treat

jRCT

Japan Registry of Clinical Trials
MAAS
Mindful Attention Awareness Scale
MBCT
Mindfulness-Based Cognitive Therapy
MBCT-D
Mindfulness-Based Cognitive Therapy for Depression
MBSR
Mindfulness-Based Stress Reduction
PSQI
Pittsburgh Sleep Quality Index
PSS-10
Perceived Stress Scale, 10-item version
RCT
Randomized controlled trial
SD
Standard deviation
SMD
Standardized mean difference
STAI
State-Trait Anxiety Inventory
UMIN
University Hospital Medical Information Network

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Hamamatsu University School of Medicine (approval number: 24-257) and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment.

Consent for publication

Not applicable.

Availability of data and materials

The de-identified outcome data supporting the conclusions of this article are included in Additional file 2. Demographic data are not publicly available because of the risk of participant re-identification in this

small single-cohort sample, but are available from the corresponding author on reasonable request. The preregistered study protocol is available on the Open Science Framework (<https://doi.org/10.17605/OSF.IO/ZRQKD>). No custom code was developed for this study.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

HT, JI, and ST conceived and designed the study. HT, SN, and TM acquired the data. ST analysed the data. HT and ST drafted the manuscript. All authors critically revised the manuscript for important intellectual content. ST supervised the study. All authors read and approved the final manuscript.

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Figures

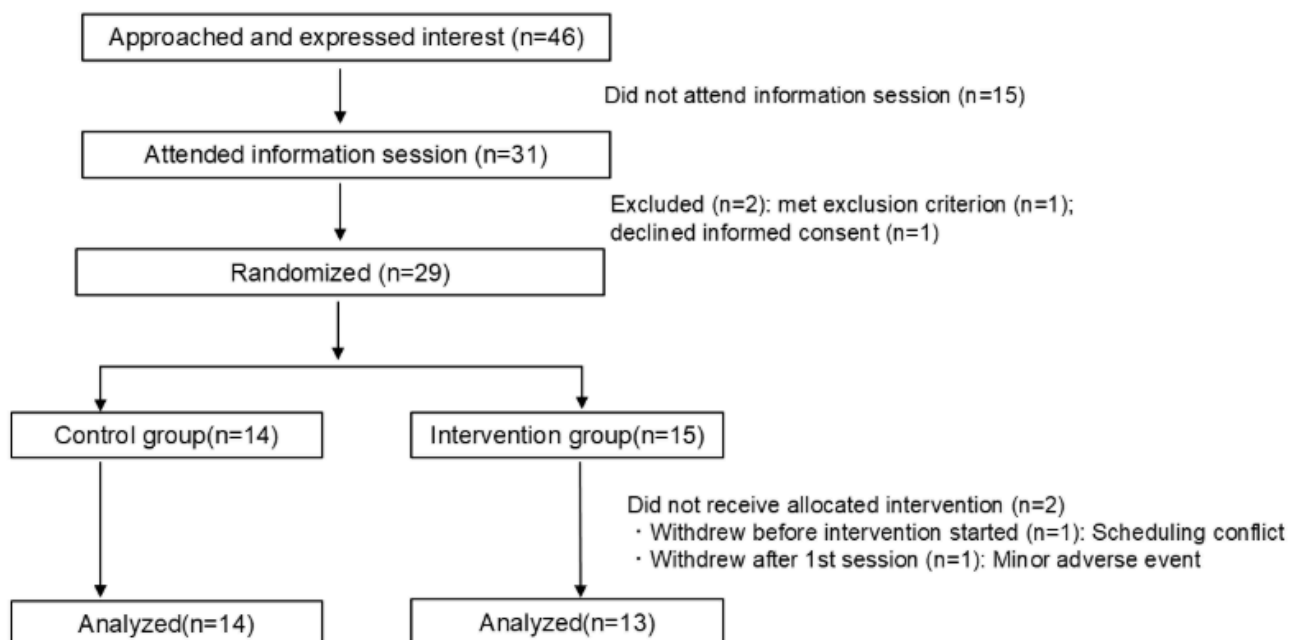


Figure 1

CONSORT Flow Diagram.

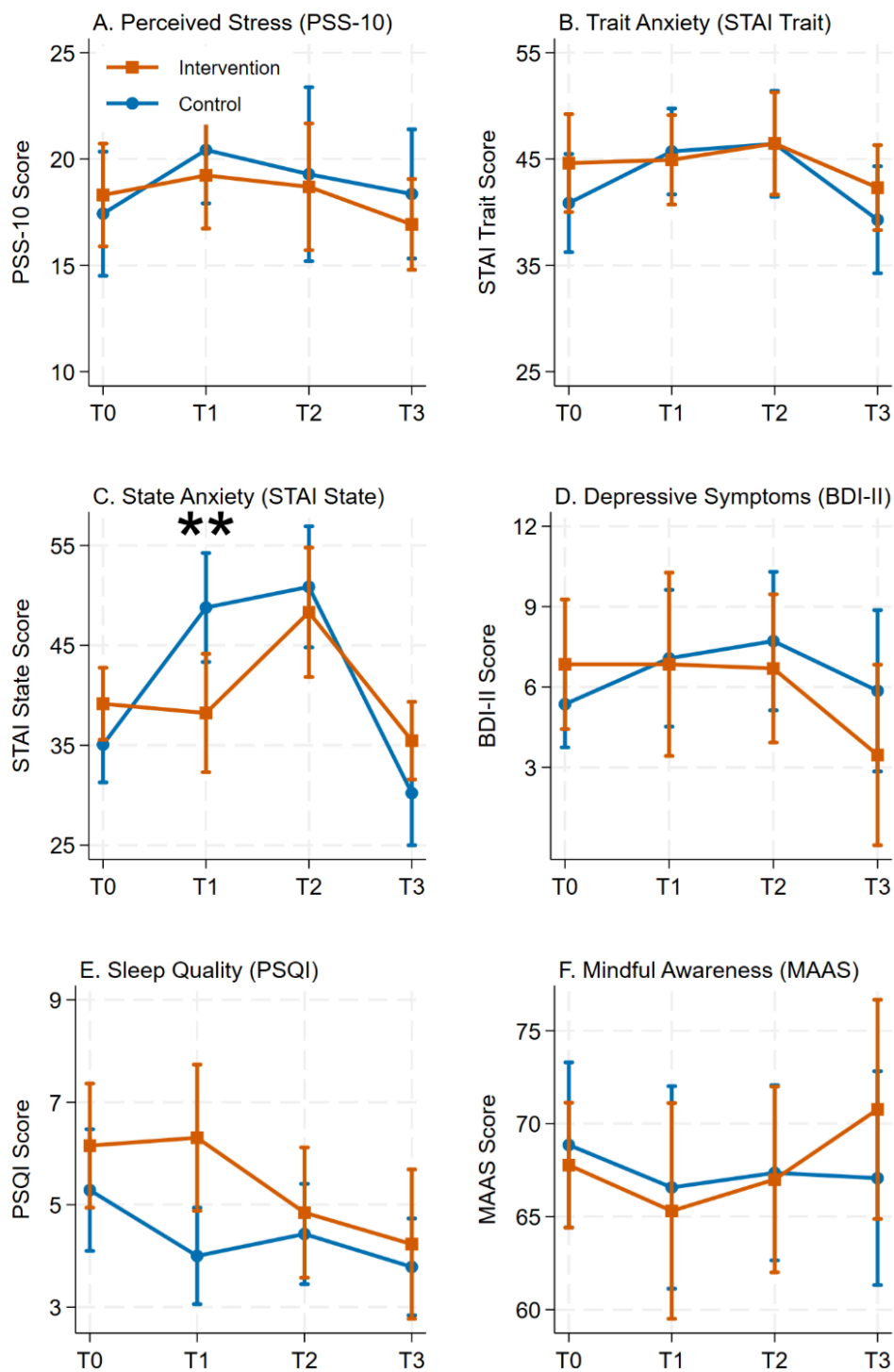


Figure 2

Changes in outcome measures over time.

Mean scores ($\pm 95\%$ confidence intervals (CI)) for all outcome measures in the intervention group (orange squares) and control group (blue circles) at four time points: T0 (baseline), T1 (pre-clinical training), T2 (mid-clinical training), and T3 (post-clinical training). Panels A through F show the six

outcome measures: (A) Perceived Stress (PSS-10), (B) Trait Anxiety (STAI Trait), (C) State Anxiety (STAI State), (D) Depressive Symptoms (BDI-II), (E) Sleep Quality (PSQI), and (F) Mindful Awareness (MAAS). Error bars represent 95% CI. * $p < .05$ for the between-group comparison at T1 (one-tailed, Bonferroni-corrected).