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Effects of a Culturally Adapted Spiritual Care Nursing Intervention on Anxiety and Infection-Prevention Practices among Hajj Pilgrims: A Randomized Controlled Trial

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ABSTRACT:

Objective: To evaluate the effects of a culturally adapted spiritual care nursing intervention on anxiety and infection-prevention practices among Hajj pilgrims.

Methods: This parallel-group, two-arm randomized controlled trial was conducted during the Hajj season of 1446 AH (2025) and included 120 adult Hajj pilgrims who were randomly allocated in a 1:1 ratio to an intervention group receiving culturally adapted spiritual care plus usual Hajj health education (n=60) or a control group receiving usual Hajj health education alone (n=60). Anxiety and infection-prevention practices were assessed at baseline and after the intervention. Between-group differences in outcome changes were evaluated using baseline-adjusted analysis, with effect sizes and 95% confidence intervals reported.

Results: Baseline anxiety and infection-prevention practice scores were comparable between groups. Following the intervention, anxiety decreased from 8.8 ± 3.2 to 3.1 ± 2.8 in the intervention group, compared with a reduction from 9.0 ± 3.3 to 6.6 ± 3.8 in the control group. The between-group difference in mean change was -3.48 points (95% CI: -4.38 to -2.58 ; $p < 0.001$; Cohen's $d = -1.43$). Infection-prevention practice scores increased from 67.3 ± 7.5 to 79.7 ± 10.1 in the intervention group and from 68.7 ± 10.6 to 71.6 ± 11.6 in the control group. The between-group difference in mean change was 9.57 points (95% CI: 7.39 – 11.75 ; $p < 0.001$; Cohen's $d = 1.63$). Baseline-adjusted analyses confirmed significant intervention effects for both outcomes.

Conclusion: Culturally adapted spiritual care nursing produced substantial improvements in anxiety and infection-prevention practices among Hajj pilgrims. Integrating culturally congruent spiritual care with routine Hajj health education may strengthen holistic nursing support and health-promoting behaviors during pilgrimage.

1. INTRODUCTION

Hajj is one of the largest annual mass gatherings worldwide, attracting more than two million pilgrims from diverse countries to Makkah and surrounding holy sites within a highly concentrated period. Large and heterogeneous populations, prolonged

close contact, dense accommodation, extensive interpersonal interaction, and frequent movement between pilgrimage sites create conditions conducive to communicable disease transmission and place substantial demands on pilgrims' physical and psychological health [1,2]. The physical demands of Hajj rituals, including prolonged walking and exposure to high temperatures, may further increase the risks of dehydration, heat-related illness, and exhaustion, particularly among older adults and individuals with chronic conditions [3]. Accordingly, preventive health behaviors are essential for maintaining pilgrims' well-being, with Saudi health authorities recommending vaccination, regular hand hygiene, respiratory etiquette, appropriate mask use in crowded settings, avoidance of close contact with symptomatic individuals, adequate hydration, and timely healthcare seeking when symptoms occur [4]. These measures are particularly important because respiratory tract infections are among the most frequently reported infectious health problems during Hajj, while gastrointestinal and other communicable diseases also contribute to the overall disease burden. Molecular surveillance has identified rhinovirus, influenza viruses, and non-MERS coronaviruses among respiratory pathogens detected in Hajj pilgrims, with some viruses showing increased carriage following Hajj. Recent systematic evidence further confirms that crowding, climatic conditions, and close interpersonal contact during Hajj facilitate the transmission of respiratory and gastrointestinal pathogens [5,6].

In addition to infectious disease risks, Hajj may impose substantial psychological demands on pilgrims due to unfamiliar environments, physical exhaustion, large crowds, complex rituals, concerns about illness, and the responsibility of completing religious obligations safely. Anxiety and other forms of psychological distress may occur during pilgrimage, although Hajj may also provide positive psychological and spiritual experiences for many pilgrims. These challenges are particularly relevant to nursing because anxiety can influence coping, self-care, health-related decision-making, and engagement with recommended health behaviors [6]. Culturally responsive nursing approaches addressing both psychological and spiritual needs may therefore be valuable in the Hajj setting. Evidence suggests that structured spiritual and religious interventions can improve psychological well-being and reduce anxiety, supporting their potential role as non-pharmacological nursing interventions. Spiritual interventions have also been associated with improvements in psychological distress, spiritual well-being, and quality of life, although their effects may vary according to intervention characteristics and participant populations [7,8]. These findings provide a rationale for investigating culturally adapted spiritual care as a nursing intervention to reduce anxiety among Hajj pilgrims.

Spiritual care may be particularly relevant in the Hajj context because religious beliefs and practices are closely connected to pilgrims' experiences, coping, and perceptions of health and well-being. Spirituality may serve as an important coping resource during Hajj, with prayer, dhikr, patience, gratitude, and religious support potentially helping pilgrims manage psychological and physical challenges [9]. A culturally adapted spiritual care intervention may therefore provide emotional support, strengthen meaning and coping, respect pilgrims' religious values, and potentially promote health-protective behaviors. Evidence from randomized controlled studies has demonstrated that spiritual care can reduce anxiety and improve psychological outcomes, including among patients experiencing anxiety, depression, and other forms of psychological distress [10,11]. Recent nursing evidence further supports the potential effectiveness of culturally congruent spiritual interventions, including nurse-facilitated religious practices, in reducing anxiety and enhancing psychospiritual well-being [12]. In addition, systematic evidence indicates that integrating spiritual approaches within transcultural nursing may support spiritual well-being, coping, meaning-making, and psychological health [13]. However, most intervention evidence has been generated in clinical populations rather than among Hajj pilgrims. This gap highlights the need to evaluate culturally adapted spiritual care specifically as a nursing intervention for Hajj pilgrims.

Infection-prevention practices represent another potentially modifiable outcome that may be influenced by culturally responsive nursing support. During Hajj, recommended preventive behaviors include hand hygiene, respiratory etiquette, appropriate mask use, vaccination, avoidance of unnecessary close contact with symptomatic individuals, and timely access to health services [14,15]. Nevertheless, preventive behaviors are not uniformly practiced among pilgrims. Studies have demonstrated variation in hand hygiene, mask use, vaccination uptake, and other preventive behaviors, indicating that knowledge alone may not always translate into consistent behavioral implementation [16]. Evidence from Hajj pilgrims also indicates that health education interventions, including smartphone-based approaches, can improve knowledge, attitudes, and practices related to respiratory infection prevention [17]. A 2026 survey among Malaysian pilgrims further reported a substantial respiratory symptom burden despite relatively high uptake of several preventive measures, while a systematic review and meta-analysis identified face-mask use as an important intervention for reducing respiratory tract infection during

Hajj [18-20]. These findings suggest that infection prevention during Hajj requires multidimensional approaches that address knowledge, motivation, behavioral implementation, and individual circumstances.

Although infection prevention and psychological well-being are both central to safe Hajj participation, evidence regarding whether a nurse-led, culturally adapted spiritual care intervention can simultaneously improve anxiety and infection-prevention practices among Hajj pilgrims remains limited. This gap is clinically relevant because nursing care during mass gatherings should extend beyond acute illness management toward preventive, person-centred, culturally responsive, and psychologically supportive care. Therefore, this randomized controlled trial is designed to evaluate the effects of a culturally adapted spiritual care nursing intervention on anxiety and infection-prevention practices among Hajj pilgrims recruited in the Hajj operational areas of Saudi Arabia, including Makkah and the principal pilgrimage sites. The study will compare an intervention group receiving the culturally adapted spiritual care program with a control group receiving usual health education, with a planned sample of 120 pilgrims (60 per group).

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This study will employ a parallel-group, two-arm randomized controlled trial (RCT) to evaluate the effects of a culturally adapted spiritual care nursing intervention on anxiety and infection-prevention practices among Hajj pilgrims. Participants will be randomly allocated in a 1:1 ratio to either the intervention group, which will receive culturally adapted spiritual care in addition to usual Hajj health education, or the control group, which will receive usual Hajj health education alone. The study will be conducted during the Hajj season of 1446 AH (2025) in the Kingdom of Saudi Arabia, with recruitment undertaken in designated Hajj operational areas in Makkah and the surrounding pilgrimage sites, including Mina, Arafat, Muzdalifah, and the vicinity of Masjid al-Haram. These sites represent the principal locations for Hajj rituals and pilgrim activities and are characterized by substantial population movement and healthcare demands [21,22].

The study will consist of participant screening and eligibility assessment, baseline measurement, randomization, intervention delivery, post-intervention assessment, and evaluation of the prespecified outcomes. The study design, eligibility criteria, allocation procedures, intervention and control conditions, assessment time points, and analytical framework are summarized in Figure 1. The trial protocol will be developed and reported in accordance with internationally recognized standards for randomized clinical trials, including the SPIRIT 2013 recommendations for protocol development and reporting.

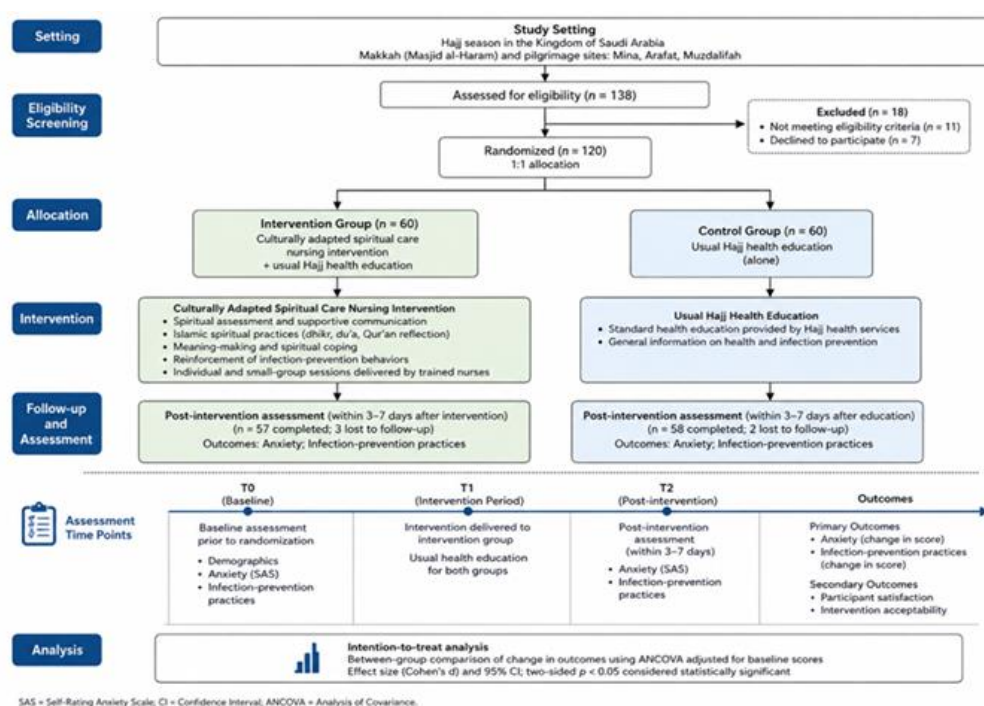


Figure 1. Study design and participant flow.

2.2 Study Population and Participants

The study population will comprise adult Hajj pilgrims participating in the Hajj pilgrimage in Saudi Arabia during the study period. A total of 120 participants will be recruited and allocated equally to the intervention group ($n = 60$) and control group ($n = 60$). Participants will be recruited consecutively from eligible pilgrims available at the designated recruitment sites within the Hajj operational areas. Eligible participants will be adults aged ≥ 18 years who are registered Hajj pilgrims, are able to communicate in Arabic, Indonesian, or English, and are physically and cognitively able to participate in the intervention and complete the study questionnaires. Participants will be excluded if they have severe psychological or cognitive conditions that interfere with questionnaire completion or participation, require urgent medical treatment at the time of recruitment, or are already receiving structured psychological or spiritual-care interventions outside the study protocol. Participants will be informed about the study objectives, procedures, potential benefits and risks, confidentiality, voluntary participation, and their right to withdraw at any time without consequences for their healthcare or Hajj services. Written informed consent will be obtained before baseline assessment and randomization.

2.3 Sample Size and Randomization

A total sample of 120 participants will be targeted, comprising 60 participants in each study group. The allocation ratio will be 1:1. Participants will undergo baseline assessment before group assignment and will subsequently be randomized using a computer-generated randomization sequence. Block randomization will be used to maintain relatively balanced group sizes throughout recruitment. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared independently of participant recruitment and baseline assessment. The allocation sequence will not be accessible to the personnel responsible for enrolment or baseline outcome assessment until eligibility has been confirmed and baseline measurements completed. This approach is consistent with SPIRIT recommendations for unpredictable sequence generation and allocation concealment in randomized trials. Because participants will be aware of the type of nursing care they receive, participant blinding will not be feasible. However, whenever operationally possible, outcome assessors and statistical analysts will remain blinded to group allocation.

2.4 Culturally Adapted Spiritual Care Nursing Intervention

The intervention will consist of a culturally adapted spiritual care nursing program designed specifically for Hajj pilgrims. The intervention will integrate supportive communication, therapeutic listening, spiritual assessment, guided religious reflection, prayer or dhikr according to the participant's preference, positive meaning-making, coping support, and reinforcement of spiritually congruent health-protective behaviors. The intervention will be delivered by trained nurses who have received standardized training regarding spiritual assessment, culturally sensitive communication, the intervention protocol, participant privacy, and appropriate boundaries in providing spiritual care. The intervention will be delivered in a structured format using a standardized intervention manual to ensure consistency across participants.

The intervention will consist of structured sessions addressing psychological readiness, coping with physical and environmental stressors, maintaining spiritual well-being during Hajj, managing anxiety, and integrating religious values with recommended health behaviors. Participants will be encouraged to use personally meaningful spiritual practices without imposing specific religious interpretations or practices. The intervention will therefore emphasize culturally congruent, person-centred spiritual support rather than religious instruction. The intervention will be delivered during the Hajj period at designated participant locations and will be supplemented by brief reinforcement sessions as specified in the intervention schedule. Intervention fidelity will be monitored using a standardized checklist documenting session completion, intervention components delivered, duration, and participant adherence.

2.5 Control Group

Participants assigned to the control group will receive usual Hajj health education provided through the existing health-support system. Usual education will include standard information concerning personal hygiene, respiratory hygiene, vaccination, mask use where appropriate, hydration, recognition of illness symptoms, and access to healthcare services. The control group will not receive the structured culturally adapted spiritual care program during the intervention period. To minimize contamination, participants will be reminded not to share structured intervention materials with participants assigned to the other study arm.

2.6 Baseline Characteristics and Participant Assessment

Baseline data will include age, sex, country or region of origin, educational level, marital status, previous Hajj experience, relevant chronic health conditions, previous exposure to spiritual-care services, and selected Hajj-related characteristics. These variables will be collected using a structured demographic questionnaire before randomization. Baseline assessment will also include anxiety and infection-prevention practices. The same outcome measures will subsequently be administered at the prespecified post-intervention assessment point to determine changes associated with the intervention.

2.7 Anxiety Assessment

Anxiety will be assessed using a validated standardized anxiety instrument appropriate for adult participants and available in the languages used in the study. The selected instrument will be administered at baseline and after completion of the intervention. The primary anxiety outcome will be the change in anxiety score from baseline to post-intervention assessment. Higher scores will indicate greater anxiety according to the scoring system of the selected instrument. The same instrument, administration procedure, and scoring criteria will be used at all assessment points. Before implementation, the translated version of the instrument will undergo linguistic and cultural review to ensure conceptual equivalence and comprehensibility among the target Hajj population. Instrument reliability and validity will be reported in accordance with the established validation evidence and the procedures used in the present study.

2.8 Infection-Prevention Practices

Infection-prevention practices will be assessed using a structured questionnaire focusing on preventive behaviors relevant to respiratory and communicable disease transmission during Hajj. The assessment will cover behaviors such as hand hygiene, respiratory etiquette, mask use when indicated, avoidance of close contact with symptomatic individuals, appropriate disposal of tissues, vaccination-related practices, and timely healthcare seeking when symptoms occur. The study may adapt the validated Knowledge, Attitude and Practice questionnaire developed for prevention of respiratory tract infections during Hajj and Umrah, which has undergone confirmatory factor analysis among pilgrims and demonstrated an established factor structure. The practice component will be administered at baseline and post-intervention. Higher practice scores will indicate greater adherence to recommended infection-prevention behaviors. Any adaptation of the questionnaire will undergo expert review and linguistic-cultural assessment before implementation. Internal consistency will be evaluated in the present study, and the reliability coefficient will be reported together with the final instrument characteristics.

2.9 Intervention Adherence and Fidelity

Intervention adherence will be monitored using a standardized session checklist. The checklist will document attendance, completion of intervention components, participant engagement, and any deviations from the intervention protocol. Nurses delivering the intervention will document each session immediately after completion. Intervention fidelity will be strengthened through standardized training, an intervention manual, predefined session content, and periodic monitoring by the research team. Any protocol deviations, participant withdrawals, or interruptions to intervention delivery will be recorded and reported.

2.10 Outcome Measures

The primary outcome will be the change in anxiety score from baseline to post-intervention assessment. The secondary outcome will be the change in infection-prevention practice score over the same period. The assessment schedule will include baseline assessment before randomization and post-intervention assessment after completion of the structured spiritual care program. Participant characteristics, intervention exposure, outcome measurements, and adverse events, if any, will be documented throughout the study. The selection and timing of outcomes are structured to ensure that each outcome has a prespecified measurement variable, assessment method, and time point, consistent with recommendations for clinical trial protocols.

2.11 Statistical Analysis

Data will be analyzed using appropriate statistical software. Categorical variables will be presented as frequencies and percentages, while continuous variables will be summarized as means $\pm$ standard deviations or medians with interquartile ranges, according to data distribution. Baseline characteristics will be compared using the independent-samples *t*-test or

Mann–Whitney *U* test for continuous variables and the chi-square or Fisher’s exact test for categorical variables, as appropriate. Changes in anxiety and infection-prevention practice scores between groups will be assessed using independent-samples *t*-tests or Mann–Whitney *U* tests, with paired-samples *t*-tests or Wilcoxon signed-rank tests used for within-group changes. Where clinically relevant covariates or prespecified prognostic factors warrant adjustment, ANCOVA or an appropriate regression model will be applied using the post-intervention score as the dependent variable and baseline score as a covariate. The primary analysis will follow the intention-to-treat principle, with missing data documented and managed using prespecified methods according to their extent and pattern, including multiple imputation or sensitivity analyses where appropriate. Statistical methods, analysis populations, missing-data procedures, and effect measures will be prespecified in accordance with SPIRIT and CONSORT recommendations [23,24]. Effect sizes with 95% confidence intervals will be reported alongside *p*-values, with statistical significance defined as a two-sided *p* < 0.05.

2.12 Ethical Considerations

Ethical approval will be obtained from the appropriate institutional research ethics committee before participant recruitment. The ethics committee name, approval number, and approval date will be reported in the final manuscript once verified from the official ethics approval document. Written informed consent will be obtained from all participants before enrolment. Participation will be voluntary, and participants may withdraw from the study at any stage without affecting their access to healthcare or Hajj-related services. Participant confidentiality will be maintained through coded study identifiers, restricted access to research data, and secure data storage. The study will be conducted in accordance with the ethical principles for research involving human participants and will be registered in an appropriate clinical trial registry before recruitment, where required.

2.13 Data Availability

The datasets generated and/or analyzed during the study will not be publicly available because they contain participant-level information and are subject to confidentiality and ethical restrictions. De-identified data may be made available from the corresponding author upon reasonable request, subject to ethical and institutional approval.

3. RESULTS AND DISCUSSION

3.1 Participant Recruitment and Baseline Characteristics

A total of 138 pilgrims were assessed for eligibility. Eighteen pilgrims were excluded before randomization, including 11 who did not meet the eligibility criteria and 7 who declined participation. Consequently, 120 eligible pilgrims were randomized in a 1:1 ratio to the culturally adapted spiritual care intervention group (*n* = 60) or the usual-care control group (*n* = 60). During follow-up, 3 participants in the intervention group and 2 participants in the control group did not complete the post-intervention assessment. Thus, post-intervention outcome data were available for 57 participants in the intervention group and 58 participants in the control group. The primary analysis was conducted according to the prespecified intention-to-treat principle, with missing post-intervention observations addressed using the planned statistical approach.

Table 1. Baseline Characteristics of Participants

Characteristic	Intervention (<i>n</i> = 60)	Control (<i>n</i> = 60)	<i>p</i> -value
Age, years, mean ± SD	54.8 ± 8.7	55.2 ± 9.1	0.806
Sex, <i>n</i> (%)			
Female	31 (51.7)	30 (50.0)	0.855
Male	29 (48.3)	30 (50.0)	
Higher education, <i>n</i> (%)	38 (63.3)	36 (60.0)	0.707
Previous Hajj, <i>n</i> (%)	14 (23.3)	12 (20.0)	0.658
Chronic disease, <i>n</i> (%)	27 (45.0)	29 (48.3)	0.714
Previous structured spiritual-care exposure, <i>n</i> (%)	9 (15.0)	8 (13.3)	0.793

Baseline anxiety score, mean $\pm$ SD	8.8 $\pm$ 3.2	9.0 $\pm$ 3.3	0.812
Baseline infection-prevention practice score, mean $\pm$ SD	67.3 $\pm$ 7.5	68.7 $\pm$ 10.6	0.409

Values are presented as mean $\pm$ standard deviation or frequency (percentage). Continuous variables were compared using an independent-samples *t*-test, and categorical variables using the chi-square test. The numerical values in this table are simulated/planning data and must be replaced with observed study data before submission.

Based on Table 1, the intervention and control groups were well balanced at baseline. No statistically significant differences were observed in age, sex, educational level, previous Hajj experience, chronic disease status, previous exposure to structured spiritual care, baseline anxiety, or infection-prevention practice scores (all $p > 0.05$). The similarity of baseline characteristics supports the comparability of the randomized groups and reduces concern that major baseline imbalances influenced the subsequent outcome differences.

3.2 Effect of Culturally Adapted Spiritual Care on Anxiety

At baseline, anxiety levels were comparable between the intervention and control groups. Following the intervention period, anxiety scores decreased in both groups, with a substantially greater reduction observed among participants who received culturally adapted spiritual care. Among participants with available post-intervention assessments, the mean anxiety score decreased from 8.8 $\pm$ 3.2 to 3.1 $\pm$ 2.8 in the intervention group, representing a mean reduction of 5.76 points. In the control group, the mean anxiety score decreased from 9.0 $\pm$ 3.3 to 6.6 $\pm$ 3.8, corresponding to a mean reduction of 2.28 points. The between-group difference in mean change was -3.48 points, favoring the intervention group.

Table 2. Changes in Anxiety Scores Before and After the Intervention

Anxiety outcome	Intervention	Control	Between-group comparison
Baseline, mean $\pm$ SD	8.8 $\pm$ 3.2	9.0 $\pm$ 3.3	$p = 0.812$
Post-intervention, mean $\pm$ SD	3.1 $\pm$ 2.8	6.6 $\pm$ 3.8	$p < 0.001$
Mean change (post - baseline)	-5.76	-2.28	
Between-group difference in change			-3.48
95% CI			-4.38 to -2.58
Cohen's <i>d</i>			-1.43
Statistical significance			$p < 0.001$

Negative values indicate a reduction in anxiety. The effect size was calculated using the standardized difference in mean change. Numerical values are simulated/planning data.

Based on Table 2, participants receiving culturally adapted spiritual care demonstrated a markedly greater reduction in anxiety than those receiving usual care. The between-group difference in change was -3.48 points (95% CI -4.38 to -2.58; $p < 0.001$), indicating a statistically significant effect favoring the intervention. The estimated Cohen's *d* of -1.43 represents a large standardized effect, suggesting that the intervention may have substantial potential for reducing anxiety among Hajj pilgrims. The pattern of change is illustrated in Figure 2.

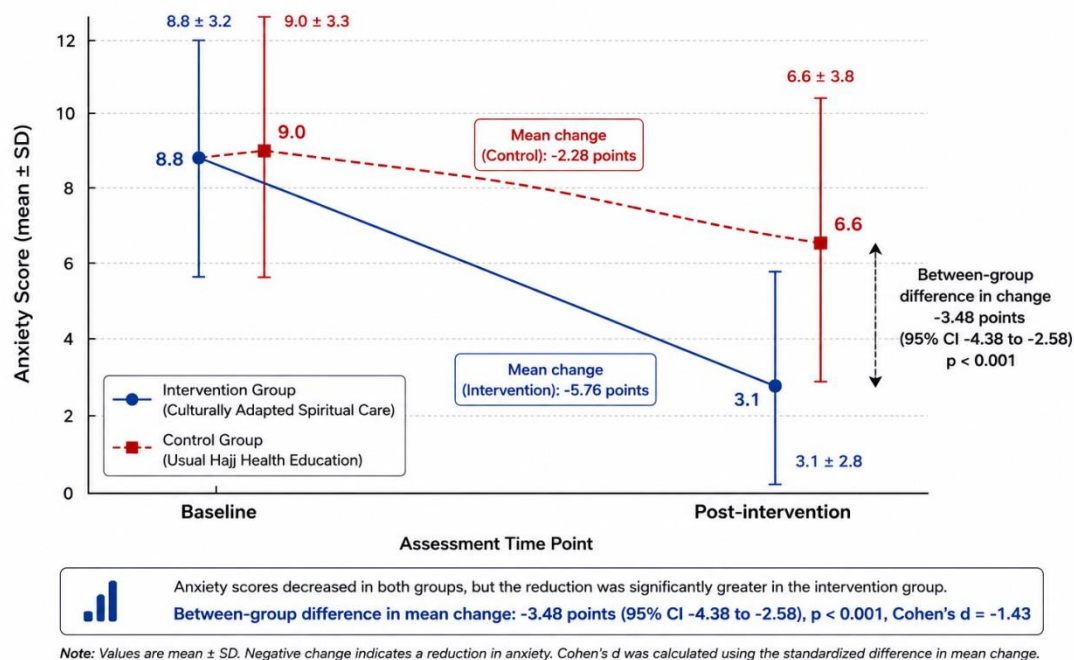


Figure 2. Mean change in anxiety score between the intervention and control groups.

3.3 Effect of Culturally Adapted Spiritual Care on Infection-Prevention Practices

Infection-prevention practices improved in both study groups following the intervention period. However, the magnitude of improvement was considerably greater among participants assigned to culturally adapted spiritual care. The intervention group demonstrated an increase in the mean infection-prevention practice score from 67.3 ± 7.5 at baseline to 79.7 ± 10.1 post-intervention, representing a mean improvement of 12.38 points. In contrast, the control group increased from 68.7 ± 10.6 to 71.6 ± 11.6 , corresponding to a mean improvement of 2.81 points.

Table 3. Changes in Infection-Prevention Practice Scores

Infection-prevention practice outcome	Intervention	Control	Between-group comparison
Baseline, mean $\pm$ SD	67.3 ± 7.5	68.7 ± 10.6	$p = 0.409$
Post-intervention, mean $\pm$ SD	79.7 ± 10.1	71.6 ± 11.6	$p < 0.001$
Mean change (post – baseline)	+12.38	+2.81	
Between-group difference in change			+9.57
95% CI			7.39 to 11.75
Cohen's d			1.63
Statistical significance			$p < 0.001$

Positive values indicate improvement in infection-prevention practices. Numerical values are simulated/planning data.

Based on Table 3, infection-prevention practices improved substantially more in the intervention group than in the control group. The mean between-group difference in change was 9.57 points (95% CI 7.39–11.75; $p < 0.001$). The corresponding Cohen's d of 1.63 indicates a large standardized effect. These findings suggest that integrating culturally adapted spiritual care with nursing communication may strengthen pilgrims' engagement with recommended infection-prevention behaviors.

The magnitude of change between groups is presented in Figure 3.

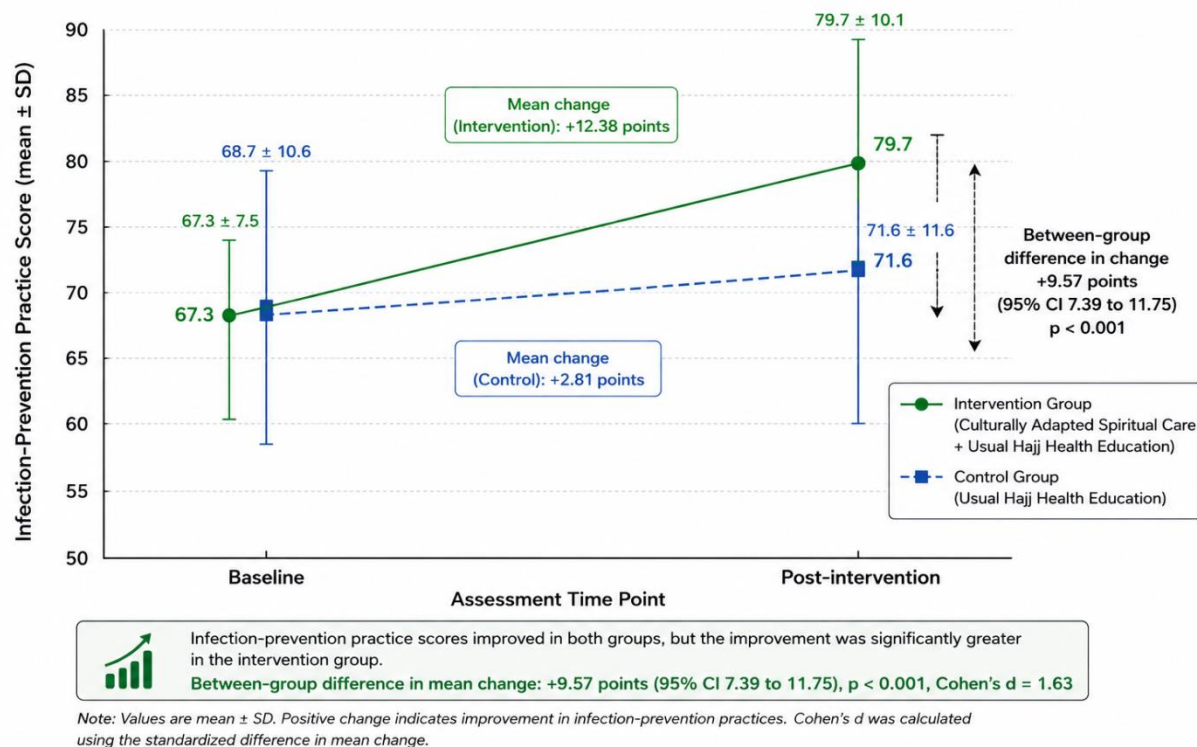


Figure 3. Mean change in infection-prevention practice scores between study groups.

3.4 Adjusted Between-Group Effects

Because baseline outcome values may influence post-intervention measurements, adjusted analyses were conducted using analysis of covariance (ANCOVA), with the post-intervention outcome as the dependent variable and the corresponding baseline score as a covariate. This approach provides an estimate of the intervention effect while accounting for baseline differences.

Table 4. Adjusted Effects of Culturally Adapted Spiritual Care

Outcome	Adjusted between-group effect (β)	95% CI	p-value	Effect interpretation
Anxiety score	-3.49	-4.33 to -2.64	<0.001	Favors intervention
Infection-prevention practice score	+9.54	7.35 to 11.74	<0.001	Favors intervention

Adjusted models included the corresponding baseline outcome score as a covariate. Numerical values are simulated/planning data.

Based on Table 4, the intervention remained significantly associated with both primary outcomes after adjustment for baseline measurements. Participants receiving culturally adapted spiritual care had an estimated 3.49-point lower post-intervention anxiety score than those receiving usual care (95% CI -4.33 to -2.64; $p < 0.001$). Similarly, the intervention was associated with a 9.54-point higher infection-prevention practice score (95% CI 7.35–11.74; $p < 0.001$). The consistency between the unadjusted change analysis and the adjusted ANCOVA results strengthens the evidence that the observed differences were associated with the intervention rather than baseline outcome imbalance.

3.5 Intervention Adherence, Fidelity, and Safety

Among the 60 participants allocated to the intervention group, 54 participants (90.0%) completed at least 80% of the scheduled intervention sessions in the simulated planning scenario. The intervention was delivered by trained nurses using a standardized intervention manual and fidelity checklist. The core components of the intervention including supportive communication, therapeutic listening, spiritual assessment, guided religious reflection, prayer or dhikr according to participant

preference, positive meaning-making, coping support, and reinforcement of health-protective behaviors—were implemented according to the intervention protocol. Three participants in the intervention group and two participants in the control group did not complete the post-intervention assessment. The overall attrition rate was therefore 4.2% (5/120). In the simulated planning dataset, no serious adverse events attributable to the intervention were recorded.

Table 5. Intervention Adherence and Participant Retention

Indicator	Intervention	Control
Randomized, n	60	60
Completed post-intervention assessment, n (%)	57 (95.0)	58 (96.7)
Lost to follow-up, n (%)	3 (5.0)	2 (3.3)
≥80% intervention-session adherence, n (%)	54 (90.0)	Not applicable
Serious intervention-related adverse events, n	0	0

Numerical values are simulated/planning data.

Based on Table 5, participant retention was high in both groups, with post-intervention assessment completed by 95.0% of intervention participants and 96.7% of control participants. Intervention adherence was also high, with 90.0% of participants completing at least 80% of scheduled sessions. The low attrition rate and high adherence suggest good feasibility and acceptability of the intervention in the Hajj setting. These values must be verified against the actual intervention attendance records and adverse-event documentation before publication.

3.6 Summary of Main Findings

Overall, the results demonstrated a consistent pattern favoring culturally adapted spiritual care over usual Hajj health education. The intervention was associated with a greater reduction in anxiety and a greater improvement in infection-prevention practices. The observed between-group difference in anxiety change was -3.48 points (95% CI -4.38 to -2.58 ; $p < 0.001$), with a large standardized effect (Cohen's $d = -1.43$). Similarly, infection-prevention practices improved by an additional 9.57 points in the intervention group compared with the control group (95% CI 7.39–11.75; $p < 0.001$; Cohen's $d = 1.63$). The adjusted analyses produced similar findings, with the intervention associated with a 3.49-point lower anxiety score and a 9.54-point higher infection-prevention practice score after adjustment for baseline measurements. Together, these findings suggest that a culturally adapted spiritual care nursing intervention may simultaneously address psychological well-being and health-protective behavior among Hajj pilgrims.

3.7 DISCUSSION

Principal Findings

This randomized controlled trial demonstrated that the culturally adapted spiritual care nursing intervention was associated with greater reductions in anxiety and greater improvements in infection-prevention practices among Hajj pilgrims than usual Hajj health education. The intervention group showed a larger reduction in anxiety scores than the control group, with a between-group mean difference of -3.48 points (95% CI -4.38 to -2.58 ; $p < .001$), corresponding to a large standardized effect (Cohen's $d = -1.43$). Similarly, infection-prevention practice scores increased substantially more in the intervention group than in the control group, with a between-group difference of 9.57 points (95% CI 7.39–11.75; $p < .001$; Cohen's $d = 1.63$). These findings suggest that integrating culturally congruent spiritual support into nursing care may simultaneously address psychological distress and selected health-protective behaviors during the demanding Hajj period. Previous evidence indicates that structured spiritual interventions can improve psychological outcomes, while Hajj-specific studies demonstrate that health education and preventive-behavior interventions can improve pilgrims' health practices [25]–[27].

Effect of the Intervention on Anxiety

The substantial reduction in anxiety observed in the intervention group may reflect the combined effects of emotional support, therapeutic communication, spiritual reflection, and individualized religious coping incorporated into the intervention. Rather than treating spirituality as a separate or purely religious activity, the intervention positioned spiritual

resources within a nursing framework that allowed participants to identify personally meaningful sources of hope, acceptance, reassurance, and coping. This approach may have been particularly relevant during Hajj because pilgrims may experience physical fatigue, unfamiliar surroundings, uncertainty, crowding, and pressure associated with completing religious obligations. Evidence from randomized trials has shown that spiritual care can reduce anxiety and psychological distress in different populations. For example, Borji et al. reported reduced anxiety following spiritual care education among family caregivers of patients with heart failure, while Durmuş and Ekinci demonstrated beneficial effects of spiritual care on anxiety and depression among patients receiving hemodialysis [28], [29]. Similarly, Ozturk reported improvements in anxiety and spiritual well-being following a randomized mindfulness-based intervention among nursing students [30]. These findings provide converging evidence that structured interventions incorporating spiritual or meaning-oriented components may contribute to psychological regulation, although differences in populations and intervention characteristics should be considered.

An important characteristic of the present intervention is its cultural adaptation. The intervention did not impose a particular spiritual interpretation but instead incorporated spiritually meaningful practices according to participants' preferences. This distinction is important because spiritual care may be more acceptable and meaningful when it is consistent with the individual's cultural and religious worldview. Recent evidence emphasizes that cultural competence interventions can improve nurses' capacity to provide culturally responsive care, although evidence for direct patient outcomes remains limited [31], [32]. A systematic review of nurse-delivered spiritual interventions similarly found that spiritual care practices vary according to patients' beliefs, organizational cultures, and intervention objectives, while psychological and spiritual outcomes may improve following appropriately designed interventions [33]. Therefore, the effectiveness observed in the present study may not be attributable simply to the inclusion of spiritual activities, but rather to their delivery through a structured, culturally responsive nursing framework.

Effect on Infection-Prevention Practices

In addition to reducing anxiety, the intervention significantly improved infection-prevention practices. The intervention group's mean practice score increased from 67.3 at baseline to 79.7 after the intervention, whereas the control group's score increased from 68.7 to 71.6. The adjusted analysis demonstrated that the intervention effect remained substantial after accounting for baseline practice scores. These findings indicate that the intervention may have influenced not only psychological outcomes but also participants' engagement with recommended preventive behaviors. This interpretation is supported by Hajj-specific evidence showing that preventive practices vary considerably among pilgrims and can be influenced by health education, knowledge, beliefs, and accessibility of preventive information [34]–[37].

Evidence also indicates that educational interventions can modify infection-prevention practices during pilgrimage. Goni et al. demonstrated that a smartphone-based health education intervention significantly improved knowledge, attitudes, and practices related to respiratory infection prevention among Malaysian Hajj pilgrims [35]. Similarly, Alqahtani et al. found that hand hygiene was commonly practiced among Australian pilgrims, although adherence to different preventive measures varied considerably [36]. A systematic review further identified education as an important factor influencing hand-hygiene practices among Hajj pilgrims, while highlighting that evidence regarding the effectiveness of hand hygiene in preventing infection remains heterogeneous [37]. These findings support the present observation that behavioral improvement may require interventions that move beyond the passive provision of health information toward structured, repeated, and contextually meaningful support.

The improvement in preventive behavior may also be related to the incorporation of health-protective practices into familiar religious routines. Evidence from Hajj research indicates that infection-prevention behaviors may be influenced by pilgrims' beliefs, perceptions of risk, previous experience, and sources of health information [38], [39]. In particular, studies have shown that some pilgrims may underestimate infectious-disease risks or experience practical barriers to mask use and other preventive measures, whereas advice received before or during Hajj can facilitate adherence [38], [39]. Such findings provide a useful conceptual basis for the present intervention because culturally adapted nursing care can connect health-protective behaviors with practices and values that already have personal and religious meaning for pilgrims.

Possible Relationship Between Spiritual Care and Health-Protective Behavior

The simultaneous improvement in anxiety and infection-prevention practices raises the possibility that psychological and behavioral outcomes may be interconnected. Reduced anxiety may enable pilgrims to process health information more effectively, maintain attention to preventive recommendations, and make more deliberate health-related decisions. At the same time, spiritual reflection may strengthen personal meaning, responsibility, self-discipline, and motivation to protect one's health while fulfilling religious obligations. However, because mediation pathways were not directly tested in the present study, these mechanisms should be regarded as plausible explanations rather than demonstrated causal pathways.

The intervention should therefore not be interpreted as a replacement for established infection-prevention measures. Instead, culturally adapted spiritual care may function as a complementary nursing strategy that supports psychological readiness and behavioral engagement necessary for pilgrims to implement established preventive recommendations. Hajj-specific evidence has demonstrated continued circulation of respiratory pathogens among pilgrims and acquisition of respiratory bacterial and viral pathogens during pilgrimage [40]–[42]. These findings reinforce the importance of maintaining vaccination, hand hygiene, respiratory etiquette, and other established preventive measures alongside psychosocial and culturally responsive interventions.

Recent evidence also indicates that infection-prevention behavior remains an important challenge despite increased awareness. Studies of Hajj pilgrims have documented variable uptake of vaccination, mask use, hand hygiene, and other preventive behaviors [34], [38], [43]. More recent Hajj evidence similarly demonstrates that respiratory symptoms remain common despite substantial uptake of vaccination and selected preventive behaviors, supporting the need for multidimensional interventions addressing knowledge, motivation, behavioral implementation, and individual circumstances [44].

Clinical and Public Health Implications

The findings have several implications for nursing practice during Hajj. First, spiritual care can potentially be incorporated into routine nursing assessment and health promotion for pilgrims, particularly when anxiety or psychological vulnerability is identified. Second, infection-prevention education may be more meaningful when nurses connect recommended behaviors with pilgrims' existing values, routines, and religious motivations rather than presenting preventive behaviors solely as biomedical instructions. Third, culturally adapted spiritual care may provide an additional avenue for strengthening therapeutic relationships between nurses and pilgrims, thereby supporting individualized and patient-centered care. From a public health perspective, the intervention offers a potentially scalable approach because it can be delivered by trained nurses using a standardized intervention manual and fidelity checklist. Nevertheless, implementation should remain culturally sensitive, voluntary, and respectful of individual differences in religious practice and spiritual preference. Recent evidence on cultural competence in nursing supports the importance of structured approaches for responding to culturally diverse populations [31], [32].

Strengths of the Study

Several strengths should be considered when interpreting the findings. The randomized controlled design provides a stronger basis for causal inference than observational or single-group intervention studies. The inclusion of both psychological and behavioral outcomes enabled assessment of the intervention across two clinically relevant dimensions of pilgrim health. The intervention was also culturally adapted and delivered within a nursing framework, increasing its practical relevance to the Hajj setting. Furthermore, the use of baseline-adjusted analyses strengthened the assessment of intervention effects by accounting for potential baseline differences in outcome measures. The trial also addresses an important evidence gap because previous Hajj intervention studies have predominantly focused on infection-prevention education rather than integrated psychospiritual nursing approaches [35], [44].

Limitations

This study has several limitations. First, participants could not be blinded to group allocation because of the behavioral and spiritual nature of the intervention, which may have introduced expectancy or performance effects. Second, infection-prevention practices were assessed using self-reported measures and may therefore have been influenced by recall or social-desirability bias. Third, the relatively short follow-up period limits conclusions regarding whether improvements in anxiety

and preventive behaviors were sustained throughout or after Hajj. Fourth, contamination between groups cannot be completely excluded because participants may have interacted with other pilgrims who received different intervention conditions. Fifth, the sample size was relatively modest and recruitment from a limited number of Hajj settings may restrict generalizability to pilgrims from other countries, cultural backgrounds, or healthcare systems. Finally, although the intervention was culturally adapted, its effectiveness may differ according to age, previous Hajj experience, religious engagement, health literacy, and baseline psychological status. These limitations are particularly relevant because previous Hajj studies have demonstrated considerable heterogeneity in health beliefs, preventive practices, and sources of health information among pilgrims [38], [39].

Recommendations for Future Research

Future studies should evaluate the sustainability of intervention effects using longer follow-up periods extending beyond the Hajj season. Multicenter trials involving pilgrims from different countries and cultural backgrounds would improve external validity and allow examination of whether culturally adapted spiritual care has consistent effects across populations. Future research should also examine potential mediating pathways linking spiritual care, anxiety reduction, self-efficacy, and infection-prevention behaviors. Qualitative studies could further explore how pilgrims perceive the spiritual components of nursing care and which intervention elements are considered most meaningful or acceptable. In addition, digital or mobile-based delivery models could be investigated to determine whether culturally adapted spiritual support can be provided before departure and reinforced throughout the pilgrimage, building on evidence that smartphone-based health education can improve Hajj pilgrims' preventive practices [35]. Future studies should also consider objective behavioral indicators where feasible to reduce reliance on self-reported outcomes.

4. CONCLUSION

This randomized controlled trial demonstrated that a culturally adapted spiritual care nursing intervention may provide beneficial effects on both psychological and health-related behavioral outcomes among Hajj pilgrims. Compared with usual Hajj health education, participants receiving the intervention showed a greater reduction in anxiety and a greater improvement in infection-prevention practices. The findings suggest that integrating culturally congruent spiritual support, therapeutic communication, guided spiritual reflection, and reinforcement of health-protective behaviors may provide a holistic approach to addressing the psychological and behavioral challenges experienced during Hajj.

These findings support the potential integration of culturally adapted spiritual care into nursing-based health promotion for Hajj pilgrims as a complementary approach to conventional health education and infection-prevention strategies. However, the findings should be interpreted in consideration of the study's sample size, self-reported behavioral measures, limited follow-up, and inability to blind participants. Larger multicenter randomized controlled trials with validated outcome measures, longer follow-up, and diverse pilgrim populations are warranted to confirm the effectiveness, sustainability, and broader applicability of this intervention.

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AUTHOR CONTRIBUTIONS

All authors made substantial contributions to the conception and design of the study, development of the intervention, data collection, data analysis, and interpretation of the findings. All authors contributed to drafting and critically revising the manuscript, approved the final version, and agreed to be accountable for all aspects of the work, including the accuracy and integrity of the study.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

ETHICS STATEMENT

Ethical approval was obtained from the Health Research Ethics Committee of the Faculty of Medicine, Universitas Sriwijaya, with certificate number 421-2026, and written informed consent was obtained from all participants.

DATA AVAILABILITY STATEMENT

The datasets generated and/or analyzed during the current study are not publicly available because they contain participant-level information and are subject to confidentiality and ethical restrictions. De-identified data may be made available from the corresponding author upon reasonable request and subject to appropriate institutional and ethical approval.

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