Development and Validation of a Culturally Competent Care Module (CCCM) and Its Efficacy on Nurses' Cultural Competence and Patient Satisfaction: A Randomized Controlled Trial in a Tertiary Care Hospital in India. Study Protocol

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Study Protocol

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Abstract

Background: Background
Cultural competence in nursing is defined, as the capacity to deliver care that is respectful of and responsive to, the cultural and linguistic needs of patients. It involves integrating cultural awareness, knowledge, and behaviors into clinical practice to promote effective cross-cultural interactions. This approach is increasingly recognized as critical to reducing health disparities, improving communication, fostering trust, and enhancing both patient satisfaction and clinical outcomes [1].
India's healthcare system operates within a highly diverse cultural landscape, further complicated by a growing internal migration from rural to urban areas driven by economic opportunities. Simultaneously, India continues to be a global hub for medical tourism, with over 2.1 million medical tourists recorded in 2024 alone. On a global scale, migration has reached unprecedented levels, with 304 million international migrants worldwide in mid-2024 [2]. These demographic shifts create urgent demands for culturally congruent care across all levels of healthcare delivery.
The importance of cultural integration extends beyond the clinical domain. In the information technology sector, for instance, cultural misalignment rather than technological or financial limitations has been identified as a major contributor to project failure. Organizations that proactively embed cultural integration into strategic planning report enhanced innovation, improved knowledge transfer, and more effective implementation [3]. These insights underscore the transferable value of cultural competence across sectors, including healthcare.
Evidence-based literature highlights that cultural competence training significantly improves nurse–patient communication and enhances culturally safe care [4]. In multicultural healthcare environments, such as those studied in Portugal, culturally competent nursing is positively associated with improved work environments and equitable patient outcomes [5]. Furthermore, cultural competence plays a vital role in addressing health inequities by ensuring inclusive and accessible healthcare services [6].
Despite its growing significance, cultural competence remains under-addressed within Indian nursing education and practice. There is a lack of standardized, context-specific training modules tailored to the Indian healthcare context. This study aims to bridge that gap by developing and evaluating a structured Culturally Competent Care Module (CCCM) for nurses. It will assess the impact of CCCM on the cultural competence of nurses and patient satisfaction compared to standard nursing care. The findings will inform clinical training strategies and contribute to policy frameworks supporting equitable, culturally responsive healthcare in India.

Objective: • To develop and validate a culturally tailored Culturally Competent Care Module (CCCM) and assess its effectiveness in enhancing the cultural competence of nurses and improving patient satisfaction in a tertiary care hospital setting.
• To evaluate the impact of a structured Culturally Competent Care Module (CCCM) on nurses' cultural competence and patient satisfaction compared to standard nursing care, using a randomized controlled trial design.

Methods: This study is a randomized, parallel group, pre-test post-test controlled trial, to be conducted in the medical-surgical wards of Acharya Vinoba Bhave Rural Hospital, Wardha District, Maharashtra. The intervention involves training registered nurses using a structured Culturally Competent Care Module (CCCM), while the comparator group will continue with standard nursing care. The primary hypothesis is that nurses who receive CCCM training will demonstrate a significantly higher level of cultural competence, and the patients under their care will report greater satisfaction, compared to those in the control group. Randomization will be employed to ensure group equivalence and minimize the risk of sample contamination.

Results: Its a protocol.

Conclusions: This study protocol outlines a rigorously designed randomized controlled trial aimed at addressing a critical gap in the integration of culturally competent nursing care within the Indian healthcare system. By developing, validating, and evaluating the Culturally Competent Care Module (CCCM), this research offers a scalable and evidence-informed intervention for improving nurse cultural competence and patient satisfaction. The findings are expected to inform curriculum development, institutional training programs, and national nursing policy, contributing to more inclusive and responsive healthcare delivery in India's increasingly multicultural clinical environments. Clinical Trial: CTRI/2025/06/088982.

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TITLE PAGE

Development and Validation of a Culturally Competent Care Module (CCCM) and Its Efficacy on Nurses' Cultural Competence and Patient Satisfaction: A Randomized Controlled Trial in a Tertiary Care Hospital in India.

Study Protocol

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MANUSCRIPT

Abstract:

Background:

Internal migration in India continues to be driven by economic opportunities, resulting in accelerated urbanization particularly in metropolitan hubs. As of mid-2024, global migration reached 304 million people, accounting for 3.7% of the global population (8.2 billion). Simultaneously, India has emerged as a prominent hub for medical tourism, hosting over 2.1 million international patients in 2024, including a significant number of non-resident Indians (NRIs) seeking affordable and advanced care for conditions such as cardiac diseases and cancer.

This evolving landscape has led to increasing cultural diversity among the patient population in Indian healthcare settings. Consequently, the ability of nurses to deliver culturally competent care has become critically important. However, despite the recognized relevance of cultural competence in improving patient outcomes and satisfaction, there remains a lack of standardized, context-specific training programs tailored to the Indian healthcare system.

This study aims to address this gap by developing and validating a Culturally Competent Care Module (CCCM) for nurses and to evaluate its effectiveness in enhancing nurses' cultural competence and improving patient satisfaction, compared to standard nursing practice.

Methods:

This three-phase, parallel-group randomized controlled trial will be conducted in a tertiary care hospital in Wardha, Maharashtra. In Phase 1, a Culturally Competent Care Module (CCCM) will be developed through stakeholder interviews and thematic analysis. Phase 2 will involve validation of the CCCM and a custom-developed patient satisfaction tool using the Delphi method. In Phase 3, registered nurses will be randomized into intervention (CCCM training) and control (standard care) groups. The intervention includes five one-hour sessions and refreshers on days 15 ,35 and 45. Cultural competence (CCT-I) and patient satisfaction (validated tool) will be assessed pre- and post-intervention. Comparative analysis will evaluate differences between groups.

Discussion

This study addresses a critical gap in culturally competent care and its impact on patient satisfaction by comparatively evaluating a structured Culturally Competent Care Module (CCCM) against standard nursing practice. By identifying effective strategies to enhance nurses' cultural competence, the findings contribute to the development of scalable and evidence-based interventions tailored to the Indian healthcare context. These results have the potential to inform policy frameworks, promote culturally congruent care, and support the integration of cultural competence training into nursing education and practice. Furthermore, structured interventions like CCCM are pivotal in reshaping healthcare delivery in culturally diverse environments, including those influenced by internal migration and international medical tourism. Empowering nurses with cultural competence not only improves patient satisfaction but also strengthens the healthcare system's readiness to meet the needs of a diverse and global patient population.

Clinical Trial Registry: **The Trail got registered in Clinical trial Registry of India--CTRI/2025/06/088982.Date of registration-17.05.2025**

ORCID ID: 0009-0009-4684-4181

Key words: Cultural competence, Nursing care, Patient satisfaction, Randomized controlled trial, Indian healthcare, Medical tourism, Transcultural nursing.

Background

Cultural competence in nursing is defined, as the capacity to deliver care that is respectful of and responsive to, the cultural and linguistic needs of patients. It involves integrating cultural awareness, knowledge, and behaviors into clinical practice to promote effective cross-cultural interactions. This approach is increasingly recognized as critical to reducing health disparities, improving communication, fostering trust, and enhancing both patient satisfaction and clinical outcomes [1].

India's healthcare system operates within a highly diverse cultural landscape, further complicated by a growing internal migration from rural to urban areas driven by economic opportunities. Simultaneously, India continues to be a global hub for medical tourism, with over 2.1 million

medical tourists recorded in 2024 alone. On a global scale, migration has reached unprecedented levels, with 304 million international migrants worldwide in mid-2024 [2]. These demographic shifts create urgent demands for culturally congruent care across all levels of healthcare delivery.

The importance of cultural integration extends beyond the clinical domain. In the information technology sector, for instance, cultural misalignment rather than technological or financial limitations has been identified as a major contributor to project failure. Organizations that proactively embed cultural integration into strategic planning report enhanced innovation, improved knowledge transfer, and more effective implementation [3]. These insights underscore the transferable value of cultural competence across sectors, including healthcare.

Evidence-based literature highlights that cultural competence training significantly improves nurse–patient communication and enhances culturally safe care [4]. In multicultural healthcare environments, such as those studied in Portugal, culturally competent nursing is positively associated with improved work environments and equitable patient outcomes [5]. Furthermore, cultural competence plays a vital role in addressing health inequities by ensuring inclusive and accessible healthcare services [6].

Despite its growing significance, cultural competence remains under-addressed within Indian nursing education and practice. There is a lack of standardized, context-specific training modules tailored to the Indian healthcare context. This study aims to bridge that gap by developing and evaluating a structured Culturally Competent Care Module (CCCM) for nurses. It will assess the impact of CCCM on the cultural competence of nurses and patient satisfaction compared to standard nursing care. The findings will inform clinical training strategies and contribute to policy frameworks supporting equitable, culturally responsive healthcare in India.

Methods/Design:

This study is a randomized, parallel group, pre-test post-test controlled trial, to be conducted in the medical-surgical wards of Acharya Vinoba Bhave Rural Hospital, Wardha District, Maharashtra. The

intervention involves training registered nurses using a structured Culturally Competent Care Module (CCCM), while the comparator group will continue with standard nursing care. The primary hypothesis is that nurses who receive CCCM training will demonstrate a significantly higher level of cultural competence, and the patients under their care will report greater satisfaction, compared to those in the control group. Randomization will be employed to ensure group equivalence and minimize the risk of sample contamination.

Aim:

- To develop and validate a culturally tailored Culturally Competent Care Module (CCCM) and assess its effectiveness in enhancing the cultural competence of nurses and improving patient satisfaction in a tertiary care hospital setting.
- To evaluate the impact of a structured Culturally Competent Care Module (CCCM) on nurses' cultural competence and patient satisfaction compared to standard nursing care, using a randomized controlled trial design.

Study Setting and Participants

The study will be conducted in the medical-surgical wards of Acharya Vinoba Bhave Rural Hospital, a tertiary care teaching hospital located in Wardha District, Maharashtra. The hospital's diverse patient population and clinical setting provide an appropriate environment for evaluating culturally competent nursing care.

Registered nurses working in the medical-surgical wards will be randomly assigned to either the intervention group, receiving training through the Culturally Competent Care Module (CCCM), or the control group, providing standard nursing care.

Additionally, adult inpatients who receive care for three or more consecutive days from these nurses will be included for the assessment of patient satisfaction. This dual level participation enables evaluation of both nurse-level outcomes (cultural competence) and patient-level outcomes (satisfaction with care).

Study Design

This study will follow a three-phase, parallel-group randomized controlled trial design, conducted at a tertiary care hospital in Wardha, Maharashtra.

Phase 1 will involve the development of a Culturally Competent Care Module (CCCM) through in-depth interviews with nurses, educators, and culturally diverse patients. Data will be analyzed thematically to identify core domains of culturally competent nursing care.

Phase 2 will focus on the refinement and validation of the CCCM and a custom-developed Patient Satisfaction Assessment Tool using the Delphi method, ensuring content validity and contextual relevance through expert review.

Phase 3 will implement the intervention among registered nurses in either medical-surgical wards, who will be randomly assigned to an intervention group (receiving CCCM training) or a control group (standard care). The CCCM training will consist of five one-hour sessions over five days, with refresher sessions on days 15,35 and 45.

Outcomes will include nurses' cultural competence, measured pre- and post-intervention using the validated **Cultural Competence Assessment Tool–India (CCT-I),** and patient satisfaction, assessed using the newly validated tool among inpatients receiving care for ≥3 days. Comparative statistical analysis will assess between-group differences to evaluate the effectiveness of the intervention

Participants' Characteristics

Inclusion Criteria

I. Registered nurses working in the medical-surgical wards for at least one year.
II. Nurses and patients who are willing to provide informed consent.
III. Adult patients (≥18 years) admitted in medical-surgical wards for more than three consecutive days.

IV. Patients who are able to read and write in the language of the data collection tools.

Exclusion Criteria

I. Nurses who have previous formal training in culturally competent or culturally sensitive care.

II. Patients with cognitive, psychiatric, or neurological impairments that may affect their ability to provide valid responses.

III. Patients in critical care, isolation, or palliative care units, where consistent interaction with the assigned nurse may not be feasible

Sample Size: will be calculated based on the Pilot Study.

Methodology: A mixed (Qualitative and quantitative**)**

Methods of Data collection

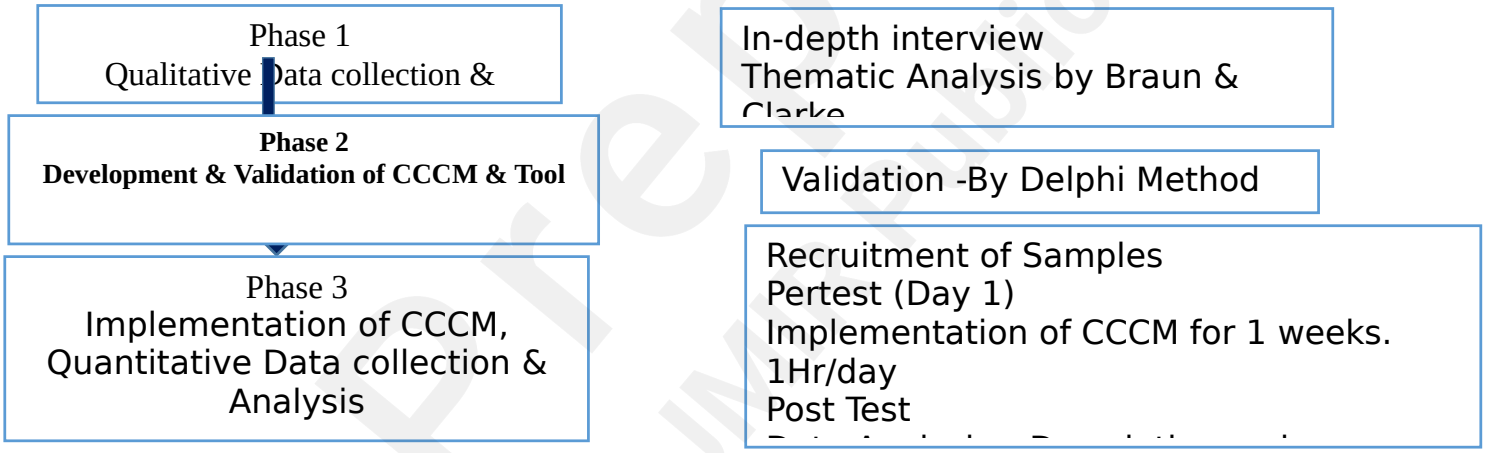

Fig: 1 Methods of Data Collection

Intervention -Phase 111: random allocation and Implementation of Culturally competent Care Module and standard nursing care

Nurses in the intervention group (Group A) will undergo CCCM training over five sessions (1 hour per day) delivered using a blended teaching approach. Session topics will include: (1) Cultural competence in healthcare, (2) Communication and language barriers, (3) Respect for religious,

cultural, and end-of-life practices, (4) Global readiness and regional adaptability, and (5) Culturally competent leadership and organizational policies in nursing. Refresher sessions will be conducted on days 15, 35, and 45 post-training. Group B (control) will continue with standard nursing care. Cultural competence will be assessed pre- and post-intervention using CCT-I, patient satisfaction and will be measured using a validated tool among inpatients receiving care from both groups.

Data management & Monitoring

Data will be securely stored and regularly monitored by the principal Investigator Participant confidentiality will be maintained. Statistical analysis will be performed using SPSS or other appropriate software.

Dissemination Plan

The findings of this study will be disseminated through peer-reviewed journal publications and presentations at national and international conferences related to nursing and healthcare. Summarized results will also be shared with relevant nursing councils and regulatory bodies to support the integration of cultural competence training into nursing education and continuing professional development programs.

Discussion

Cultural competence is essential for delivering equitable and patient-centered care, particularly in multicultural healthcare settings like India. As frontline providers, nurses must possess the knowledge and skills to address patients' cultural needs, fostering trust, communication, and satisfaction.

This study evaluates the impact of a structured Culturally Competent Care Module (CCCM) on nurses' cultural competence and patient satisfaction, compared to standard nursing care. By systematically implementing CCCM training supported by nurse leaders and educators—this intervention aims to integrate culturally congruent practices into routine care delivery.

Despite India's diverse sociocultural landscape and growing role in global medical tourism, there is a lack of validated training frameworks tailored to local contexts. Existing international evidence supports the effectiveness of blended cultural competence training in improving care outcomes (Červený, 2022) and nurse-patient communication (Joshi et al., 2024). However, comparative trials within Indian healthcare systems remain sparse.

This study contributes to closing that gap by offering evidence on the efficacy and feasibility of CCCM integration into nursing practice, with potential implications for nursing education, hospital policy, and culturally responsive healthcare delivery in India.

DECLARATION

Ethical Approval and Consent to participate

Approved by- Datta Meghe Institute of Higher Education & Research – Institutional Ethics Committee- **Ref No: DMIHER (DU)/IEC/2024/ 52** as per the meeting held on 20/12/2024

Written informed consent will be obtained from all participants before enrolment in the study. The study will adhere to the principles of The Declaration of Helsinki, ensuring participants rights, privacy, and confidentiality throughout the research process.

Consent for Publication: Not Applicable

Availability of Data and Materials: Data sharing is not applicable to this article as no datasets were generated or analysed during the current Study.

Competing Interests:-"The authors declares that they have no competing interests".

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publication. The study is decided to be carried on by the principal Investigator. There is no other specific funding sources.

Author's contributions: Ligy C. Ittup contributed substantially to the study's conceptualization, methodology development, intervention design, and manuscript drafting. Dr. Ranjana Sharma assisted in formulating the study title, conducting the literature review, and critically reviewing and editing the manuscript. Both authors reviewed and approved the final version of the manuscript.

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