Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Education Based on Leininger's Nursing Model on Nurses' Cultural Competence: A Randomized Controlled Trial.

Protocol summary

Study aim
To determine the effect of training based on Leininger’s nursing model on nurses' cultural competence.

Design
A randomized controlled trial with a control group and a parallel-group design.

Settings and conduct
This study will be conducted at teaching hospitals in Yasuj. The intervention group will receive training based on Leininger's model, while the control group will continue to receive routine care; the study will be conducted without blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Employment at teaching hospitals in Yasuj, age 23–60, minimum of a bachelor's degree, at least one year of clinical experience, informed consent, and active employment. Exclusion criteria: Unwillingness to continue participation, withdrawal from the study, or failure to complete the research procedures.

Intervention groups
Intervention Group: Nurses in this group will receive education based on Leininger’s Nursing Model to improve their cultural competence. Their cultural competence will be assessed before and after the intervention. Control Group: Nurses in this group will not receive education based on Leininger’s Nursing Model and will continue their usual activities. Their cultural competence will be assessed at the same time points as the intervention group.

Main outcome variables
Nurses’ cultural competence, measured before the intervention, immediately after the intervention, and two months after the intervention.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20261013071423N1**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **prospective**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date
2026-10-14, 1405/07/22

Registrant information
Name
Hassan Jahanbin
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 74 3323 0327
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hassanjahanbin0@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-10-16, 1405/07/24
Expected recruitment end date
2026-10-31, 1405/08/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Education Based on Leininger's Nursing Model on Nurses' Cultural Competence: A Randomized Controlled Trial.

Public title

Effect of Education Based on Leininger’s Nursing Model on Nurses’ Ability to Provide Culturally Appropriate Care

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Nurses working in teaching hospitals affiliated with Yasuj University of Medical Sciences. Nurses aged between 23 and 60 years Holding at least a bachelor's degree Having at least one year of clinical work experience. Willingness to participate in the study and provision of informed consent Being employed under a permanent, temporary (contractual), or active compulsory service (طرحی) employment arrangement at the time of the study.

Exclusion criteria:

History of substance and alcohol abuse Experience participating in training courses similar to cultural competence.

Age

From **23 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used to assign the study hospitals to the research groups. Among the eligible teaching hospitals affiliated with Yasuj University of Medical Sciences, two hospitals will be assigned to the intervention group and one hospital to the control group. Subsequently, the required number of eligible nurses working in the clinical wards of the selected hospitals will be recruited using stratified sampling with proportional allocation. Clinical wards will be considered sampling strata, and the sample size for each ward will be determined proportionally to the number of eligible nurses working in that ward. Finally, eligible nurses will be randomly selected from the list of nurses in each ward.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

Street address

Enghelab Boulevard, Enghelab 20, Shahid Fattah Abbasi Street

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

75913693556

Approval date

2026-10-13, 1405/07/21

Ethics committee reference number

IR.YUMS.REC.1405.145

Health conditions studied

1

Description of health condition studied

Nurses' Cultural Competence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The total score of nurses’ cultural competence measured using the 51-item Moulder Cultural Competence Questionnaire, with a score range of 51 to 255. A higher score indicates greater cultural competence.

Timepoint

Before the intervention, immediately after the intervention, and two months after the intervention.

Method of measurement

The Persian version of the Moulder Cultural Competence Questionnaire consists of 51 items across four subscales: cultural care knowledge, attitudes toward cultural care, cultural competence, and cultural care readiness. The questionnaire uses a five-point Likert scale, with a total score ranging from 51 to 255. The Persian version was psychometrically evaluated by Bastami et al. in 2016, with a reported Cronbach’s alpha coefficient of 0.86.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nurses in this group will receive education based on Leininger’s Nursing Model to improve

their cultural competence. Cultural competence will be assessed using the Moulder Cultural Competence Questionnaire before the intervention, immediately after the intervention, and two months later.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti hospital, Shahid jalil hospital, Imam sajad hospital

Full name of responsible person
Hassan Jahanbin

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Enghelab Boulevard, Enghelab 20, Shahid Fattah Abbasi Street

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hassanjahanbin0@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Hassan Jahanbin

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yasouj University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Hassan Jahanbin

Position
Master's student in management nursing, Student Research Committee, Yasuj University Of Medical Scie

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Master's student in management nursing, Student Research Committee, Yasuj University Of Medical Science, Yasuj, Iran

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Person responsible for scientific inquiries

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Full name of responsible person
Hassan Jahanbin

Position
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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the need to maintain participant confidentiality and the limited scope of this academic study, there is currently no plan to share individual participant data. The study results will be reported in aggregate form without disclosing participants' identities.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study Protocol and Final Study Report: These documents will include the study objectives, methodology, implementation of the educational intervention based on Leininger's Nursing Model, the instrument used to assess nurses' cultural competence, and the overall study results. No identifiable or confidential participant information will be disclosed.

When the data will become available and for how long

The study protocol will be made available after finalization, subject to publication feasibility. The final study report will be made available after study completion and publication of the results, subject to applicable conditions.

To whom data/document is available

Researchers, academic faculty members, and university students may request access to the published study documents. Access is subject to compliance with research ethics principles and the confidentiality of participant information.

Under which criteria data/document could be used

The documents may be used for scientific, educational, and research purposes. Users must comply with research ethics principles, provide appropriate citations, and maintain confidentiality. Commercial use and any attempt to identify study participants are not permitted.

From where data/document is obtainable

Requests for access to the study documents may be directed to the principal investigator at Yasuj University of Medical Sciences. Contact details and the method of access will be provided once the official dissemination route has been determined.

What processes are involved for a request to access data/document

Requests should be submitted in writing and should include a description of the intended purpose of using the documents. The principal investigator will review each request to ensure compliance with research ethics principles. If approved, the available documents will be provided through an agreed method. The response time will depend on the nature of the request and the availability of the documents.

Comments