Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of empowerment program on moral distress and caregiving behaviors among intensive care unit nurses in end-of-life patients care

Protocol summary

Study aim
Determine the effect of an empowerment program on moral distress and caregiving behaviors among intensive care unit nurses in end-of-life patient care

Design
In this two-group randomized controlled trial study, first, 104 nurses will be selected through convenience sampling, and subsequently, they will be divided into control and intervention groups using the quadruple block randomization method.

Settings and conduct
This study will be a two-group randomized controlled trial involving 104 nursing practitioners in Hamadan. Within the intervention group, the researcher will conduct seven weekly sessions of the empowerment program, each lasting between 45 to 60 minutes. These sessions will cover topics such as recognising caring behaviors and moral distress, the ramifications of non-adherence, strategies to counteract unethical conduct, management of disruptive behaviors, mitigation of factors contributing to unethical practices, approaches to address moral distress, and subsequent evaluation. Assessments of moral distress and the caring behaviors of nurses will be conducted immediately after, and one month following, the final session of the empowerment program. The control group will not partake in any intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: consent to participate in the study, at least one year of work experience in intensive care units, and not having completed ethics-related courses in the past year. Exclusion criteria: unwillingness to continue participating in the study and absence of more than one session in the course classes.

Intervention groups
The researcher will hold Empowerment program sessions for the intervention group during 7 weekly sessions for 45 to 60 minutes. Control group: nurses in the control group will not receive any intervention.

Main outcome variables
Nurses's moral distress and caring behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211227053551N5**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **prospective**

Last update: **2024-06-08, 1403/03/19**
Update count: **0**

Registration date
2024-06-08, 1403/03/19

Registrant information

Name
Vahid Yousofvand

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 3252 6339

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-05, 1403/04/15

Expected recruitment end date
2025-02-17, 1403/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of empowerment program on moral distress and caregiving behaviors among intensive care unit nurses in end-of-life patients care

Public title
Effect of empowerment program on moral distress and caregiving behaviors among nurses

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study At least one year of work experience in the intensive care unit Failure to pass courses related to ethics up to the last year
Exclusion criteria:
Unwillingness to continue participating in the study Absence of more than one session in the course classes

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be done using the permutation block method. In such a way that first, four blocks of ABBA, AABB, ABAB, BBAA, BAAB and BABA will be produced in a number that covers the study sample and will be placed in envelopes. Then, when the nurse enters the study, one of the envelopes will be randomly selected, and the first four nurses will be assigned to two groups according to the desired block. This process will continue until the total number of samples is completed.

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 Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
38698-65178

Approval date
2024-05-11, 1403/02/22

Ethics committee reference number
IR.UMSHA.REC.1403.091

Health conditions studied

1

Description of health condition studied
Moral distress

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Caring behaviors of nurses

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Moral distress

Timepoint
Immediately, and one month after the intervention

Method of measurement
Corelli moral distress questionnaire

2

Description
Nurses caring behaviors

Timepoint
Immediately, and one month after the intervention

Method of measurement
Pattistelli nurses caring behaviors questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, the sessions of the empowerment program for nurses will be

held by the researcher during 7 weekly sessions for 45 to 60 minutes. The empowerment program used in this research includes steps designed by the researcher using the moral calculation theory of Alvita K. Nathaniel in nursing. Evaluation of moral distress and caring behaviors of nurses will be done immediately and one month after the last empowerment session.

Category
N/A

2

Description
Control group: The control group will not receive any intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Haspital

Full name of responsible person
Mohammad Torabi

Street address
Shahid Beheshti Blvd., Besat hospital, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza Shokouhi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy of research and technology

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
Hamedan University of Medical Sciences

Full name of responsible person
Mohammad Torabi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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