Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the Effectiveness of Dignity Therapy Versus Usual Supportive Psychological Care in Reducing Demoralization and Improving Quality of Life in Patients with Limb Amputation: A Randomized Clinical Trial

Protocol summary

Study aim

Comparing the Effectiveness of Dignity Therapy Versus Usual Supportive Psychological Care in Reducing Demoralization and Improving Quality of Life in Patients with Limb Amputation: A Randomized Clinical Trial

Design

A randomized, parallel-group clinical trial with intervention and control groups, no blinding, and a total of 60 patients.

Settings and conduct

This randomized clinical trial will be conducted among patients with limb amputation at a hospital affiliated with Hamadan University of Medical Sciences. Given the nature of the interventions and participants' awareness of the intervention they receive, the study will be conducted using an open-label design. After collecting demographic information, two questionnaires will be used: the Missoula-VITAS Quality of Life Index and the Demoralization Scale (DS-II), using their Persian versions. Participants in both groups will complete these questionnaires before the intervention begins and after it is completed to assess and compare changes in the study variables between the two groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: being at least 18 years of age, having undergone limb amputation during the study period, being able to read and speak Persian, and providing written informed consent. The exclusion criteria were: cognitive disorders such as dementia or delirium; being too ill to meet the study requirements; having a severe neurological disorder (the severity of the illness and neurological disorder will be assessed based on the physician's judgment); and unwillingness to continue participating in the study.

Intervention groups

Patients in Group A (the intervention group) will receive dignity therapy, while patients in Group B (the control group) will receive usual supportive psychological care.

Main outcome variables

Demoralization (Existential Despair) – Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261017071464N1**
Registration date: **2026-10-25, 1405/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-25, 1405/08/03**
Update count: **0**

Registration date

2026-10-25, 1405/08/03

Registrant information

Name
Zahra Zeinolabedini
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effectiveness of Dignity Therapy Versus Usual Supportive Psychological Care in Reducing Demoralization and Improving Quality of Life in Patients with Limb Amputation: A Randomized Clinical Trial

Public title
Comparing the Effectiveness of Dignity Therapy Versus Usual Supportive Psychological Care in Reducing Demoralization and Improving Quality of Life in Patients with Limb Amputation: A Randomized Clinical Trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who underwent amputation during the study period Ability to read and speak Persian Obtaining Written Informed Consent
Exclusion criteria:
Individuals with cognitive disorders, such as dementia and delirium. Patients who were too ill to meet the study requirements Severe neurological disorder (the severity of the illness and neurological disorder will be assessed based on the physician’s judgment).
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The study participants will be randomly assigned to two groups, A and B, using block randomization with a block size of 4. Randomization will be performed using an envelope containing four slips of paper, two labeled A and two labeled B. For each patient, one slip will be drawn to determine group allocation. The selected slip will not be returned to the envelope until all four slips have been drawn. After the allocation of the first four patients, all four slips will be returned to the envelope, and the same procedure will be repeated for each subsequent block of four patients until the required sample size is reached. Patients in Group A will receive dignity therapy, while patients in Group B will receive supportive psychological care.
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
Research Ethics Committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pajouhesh Square, Hamadan, Iran
City
hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۷۸۴
Approval date
2026-10-19, 1405/07/27
Ethics committee reference number
IR.UMSHA.REC.1405.581

Health conditions studied

1

Description of health condition studied
Patients with limb amputation
ICD-10 code
Y83.5
ICD-10 code description
Amputation of limb(s)

Primary outcomes

1

Description
Demoralization (Existential Distress)
Timepoint
Before the intervention and after the completion of the intervention
Method of measurement
Use of questionnaire scores

2

Description
Quality of Life
Timepoint
Before the intervention and after the completion of the intervention
Method of measurement
Use of questionnaire scores

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group (Dignity Therapy): Dignity therapy is a brief psychotherapeutic intervention designed to enhance a sense of worth, meaning, and purpose in life and to reduce psychosocial and existential distress. The intervention will consist of three sessions. In the first session, a trained therapist will explain the goals of the therapy and the interview process to the patient and introduce the dignity therapy questions. In the second session, approximately 24–48 hours later, a semi-structured interview lasting approximately 60 minutes will be conducted, focusing on the patient's life history, meaningful memories, accomplishments, values, hopes, and messages they wish to leave for their loved ones. The interview will be audio-recorded, transcribed, and compiled into a written document known as a generativity document. In the final session, the document will be presented to the patient for review and approval. After incorporating any requested revisions, the finalized document will be provided to the patient, who may share it with family members and loved ones if desired. At the end of the intervention, the study questionnaires will be administered again.

Category

Other

2

Description

Control Group: Patients assigned to Group B, who will receive usual supportive psychological care, will have access to the full range of supportive services available to all study participants, including specialist physicians and nurses (i.e., professionals trained in providing supportive psychological care), social workers, and psychologists or psychiatrists. This will ensure that the necessary resources are available to address the physical, existential, and psychosocial needs of patients and their families. Healthcare professionals providing these services will address patients' current concerns and problems but will not focus on enhancing their sense of legacy. In other words, a structured intervention comparable to dignity therapy will not be provided to patients randomly assigned to this group. Patients will be asked to complete the study questionnaires immediately after allocation to Group B and again after receiving usual supportive psychological care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital, Hamadan, affiliated with Hamadan University of Medical Sciences

Full name of responsible person

Sina Ghasemi

Street address

Besat Specialized and Subspecialized Hospital, Shahid Beheshti Boulevard, Hamadan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Soltanian

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Hamadan University of Medical Sciences, Shahid Fahmideh Boulevard, Pajouhesh Square, Hamadan, Iran

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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

Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Sina Ghasemi

Position
Faculty Member – Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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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