Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of spiritual care on body image in patients with type 2 diabetes-related amputation

Protocol summary

Summary

The effect of spiritual care on body image in patients with type 2 diabetes-related amputation attending to the Isfahan Al Zahra hospital clinics and rehabilitation centers in 2014 Objectives: This study was conducted to investigate the effect of spiritual care on body image in patients with type 2 diabetes-related amputation. Design: In this study an experimental pretest-posttest design with two experimental groups was used. A number of 60 participants aged between 40 and 72 who had diabetes-related amputation took part in the study. The participants were randomly assigned to meditation and control group Setting and conduct: For experimental group, three sessions of meditation and for control group, three sessions about prevention of diabetic foot ulcer were held. The participants in experimental group were asked to perform meditation exercises for a month. The data was collected via Amputee Body Image Scale (ABIS), before and 4 weeks after the intervention. Participants: In this study participants were people who were older than 18 years who have amputations due to diabetes type 2; Patients with type 2 diabetes caused the amputation of toes, ankle, below the knee; At least 3 months have passed since the amputation Main outcome measures: In this study Body Image, Quality of Life and Spiritual Health were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090219015N1**
Registration date: **2015-08-22, 1394/05/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-22, 1394/05/31

Registrant information

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Malihe Imeni
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-10-20, 1393/07/28

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care on body image in patients with type 2 diabetes-related amputation

Public title

The effect of spiritual care on body image

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Patients older than 18 years who have amputations due to diabetes type 2; Patients with type 2 diabetes caused the amputation of toes, ankle, below the

knee; At least 3 months have passed since the amputation; Lack of use of complementary medicine practices in the past three months; patients who are interested in participating in the study; Patients who have allowed by their specialist to participate in the study; patients who are fluent in Farsi; patients who have literacy; Patients with no mental retardation, blindness and deafness; Patients who don’t have active mental disorders based on their specialist diagnosis; Patients who have audio and video features to use of educational CD exclusion criteria:Patients remain on study at least 75% of the time specified interventions are done, otherwise they will be excluded; If patients do not have the desire to continue to participate in the study; In case of any problems so that the subjects were not able to participate in the study.

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

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 Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar jarib street, Azadi Square, Isfahan, Iran

City
Isfahan

Postal code

Approval date
2014-10-15, 1393/07/23

Ethics committee reference number
393479

Health conditions studied

1

Description of health condition studied
Diabetes Mellitus

ICD-10 code
E10,E11,E1

ICD-10 code description
With neurological complications

Primary outcomes

1

Description
Body image

Timepoint
before intervention- Immediately after intervention

Method of measurement
standard questionnaire of amputee body image scale

2

Description
Quality of Life In Diabetic Patients

Timepoint
before intervention- Immediately after intervention

Method of measurement
Standard Questionnaire of Diabetic Quality of Life

3

Description
Spiritual Health

Timepoint
before intervention- Immediately after intervention

Method of measurement
Standard Questionnaire of Spiritual Health

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: spiritual care consist of meditation training, and repeat meditation for 4 weeks and every day 15 minutes

Category
Other

2

Description
control group:Holding 3 training sessions in relation to health care and general tips on diabetic foot

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital of Isfahan

Full name of responsible person
Malihe Imeni

Street address
Isfahan University of Medical Sciences, Hezar jarib street, Azadi Square, Isfahan, Iran

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Fakhri Sabohi

Street address
Isfahan University of Medical Sciences, Hezar jarib street, Azadi Square, Isfahan, Iran

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Isfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences, nursing & midwifery faculty

Full name of responsible person
Malihe Imeni

Position
Student of postgraduate nursing

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty