

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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

Name

Malihe Imeni

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2951

Email address

malihe.imeni@nm.mui.ac.ir

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

Other areas of specialty/work

Street address

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

City

Isfahan

Postal code

Phone

+31 37922951

Fax

Email

malihe.imeni@nm.mui.ac.ir

Web page address

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

Person responsible for scientific 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

Street address

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

City

Isfahan

Postal code

Phone

+31 37922951

Fax

Email

malihe.imeni@nm.mui.ac.ir

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