

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of benson relaxation on fatigue, depression and Daily Activities in hemodialysis patients

Protocol summary

Study aim

evaluate the effect of Benson relaxation on fatigue, depression and daily activities in hemodialysis patients.

Design

This study was a clinical trial with control group with parallel design. The sample size of 65 patients was randomly divided into two equal groups.

Settings and conduct

Vasei Hospital in Sabzevar

Participants/Inclusion and exclusion criteria

Aged between 18 to 65 years; History of hemodialysis more than 6 months; Patients with dialysis charts in the hemodialysis centers and regular referring to the centers; Absent of disability or chronic disease.

Intervention groups

After approving of the study by sciences vice chancellor of Sabzevar University of medical sciences and completing of written consent form by all participants in the study, Patients will be divided randomly into two equal groups: 33 patients in experimental and 32 in control group. The experimental group will receive supportive intervention and get education of Benson relaxation with video tape and every patient will get one CD and pamphlet for use in home. Patients in experimental group will do Benson relaxation for 15 minute, twice a day during one month. No intervention will be made in control group. Brief Fatigue Inventory (BFI) questionnaire, Beck depression and Nottingham Questionnaire questionnaire will complete by all patients before and 2 week and 4 week after intervention. In cases that the patients can't able to read or write, the researcher will complete the questionnaire based on exact patient's statements.

Main outcome variables

Fatigue, depression and daily activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011115393N2**

Registration date: **2014-01-19, 1392/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-19, 1398/02/29**

Update count: **1**

Registration date

2014-01-19, 1392/10/29

Registrant information

Name

Narjes Heshmati Far

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 57 1444 6070

Email address

nheshmatifar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of benson relaxation on fatigue, depression and

Daily Activities in hemodialysis patients

Public title

Effect of benson relaxation on fatigue, depression and Daily Activities

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18 to 65 years History of hemodialysis more than 6 months ; Patients with dialysis charts in the hemodialysis centers and regular referring to the centers Absent of disability or chronic disease

Exclusion criteria:

Reluctance to continue participating in the exercises Presence of disability or chronic disease, Except diabetes or hypertension Kidney transplant Death

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation with random numbers

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

Sabzevar University of Medical Scinces

Street address

School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2013-12-06, 1392/09/15

Ethics committee reference number

92.7.medsab.Rec

Health conditions studied

1

Description of health condition studied

End stage renal failure

ICD-10 code

N18.9

ICD-10 code description

Chronic kidney disease, unspecified

Primary outcomes

1

Description

Fatigue in hemodialysis patients

Timepoint

before, 2week and 4 week after intervention

Method of measurement

Brief Fatigue Inventory (BFI), Beck Depression and Nottingham

Secondary outcomes

empty

Intervention groups

1

Description

After approving of the study by sciences vice chancellor of Sabzevar University of medical sciences and completing of written consent form by all participants in the study, Patients will be divided randomly into two equal groups: 33 patients in experimental and 32 in control group. The experimental group will receive supportive intervention and get education of Benson relaxation with video tape and every patient will get one CD and pamphlet for use in home. Patients in experimental group will do Benson relaxation for 15 minute, twice a day during one month. Brief Fatigue Inventory (BFI), Depression and daily activities questionnaire will complete by experimental group before, 2 week and 4 week after intervention. the researcher will complete the questionnaire based on exact patient's statements. After approving of the study by sciences vice chancellor of Sabzevar University of medical sciences and completing of written consent form by all participants in the study, patients will be divided randomly into two equal groups: 33 patients in experimental and 32 in control group. No intervention in control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Vasei hospital

Full name of responsible person

Mehran Hosseini

Street address

Shohadaye Hasteii Boulevard, Sabzevar Vasei hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Moosa Reza Tadayonfar

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Sabzevar - Nuclear Martyrs Boulevard - Above the Mazar-e Martyrs of Anonymous-Prestige of Sabzevar University of Medical Sciences - Deputy of Research and Technology

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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

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Narjes Heshmatifar

Position

Student of MSc Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Mohsen Koushan

Position

MSc./Member of Faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Latest degree
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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