

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Benson relaxation technique on pain, physical activity, quality of sleep, quality of life, and clinical and biomedical parameter in hemodialysis patients

Protocol summary

Summary

Hemodialysis patient suffer many problem such as pain, impairment in physical activity, quality of sleep and quality of life. Moreover, some of the changes were happened in their clinical and biomedical parameter. The aim of this study was to determine the effect of Benson relation technique on pain, physical activity, quality of life, quality of sleep and clinical and biomedical parameter in hemodialysis patients. In a randomized controlled trial was carried out in the hemodialysis centers of Shiraz University of Medical sciences. Clinically stable hemodialysis patients (n = 86) were included and followed in two groups: the Benson relaxation technique group (n = 43) and the control group (n = 43). Benson relaxation technique was done in experimental groups for 10-20 min, twice a day for 8 weeks. Physical activity, pain, quality of life, quality of sleep and clinical and biomedical parameter were assessed in both groups at baseline and 8 weeks after intervention. Data were analyzed with two independent and dependent samples t-test, chi-square.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061613690N1**
Registration date: **2013-07-11, 1392/04/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-11, 1392/04/20

Registrant information

Name

Masoume Rambod

Name of organization / entity

Shiraz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical sciences

Expected recruitment start date

2011-02-01, 1389/11/12

Expected recruitment end date

2012-01-09, 1390/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Benson relaxation technique on pain, physical activity, quality of sleep, quality of life, and clinical and biomedical parameter in hemodialysis patients

Public title

Effect of Benson relaxation technique on pain, physical activity, quality of sleep, quality of life, and clinical and biomedical parameter in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria of the study were being 18 years old or above, being on HD twice a week or more for at

least the previous 3 months, and being alerted and oriented. On the other hand, the patients having unstable hypertension and angina, arrhythmia, congestive heart failure, acute cerebrovascular accident, hepatic failure, physical limitation for learning and performing the relaxation technique, and prior training or current use of relaxation therapy were excluded from the study. The patients with emotional upheaval during the previous month were excluded, as well. The reason for these exclusions was that these complications might affect the concentration which is important in the relaxation technique and these patients might have difficulty in performing this procedure.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 86

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

shiraz university of medical sciences

Street address

71345-1978, 7th floor, shiraz university of medical sciences, beside the Red-Crescent building, Zand Street, Shiraz,

City

Shiraz

Postal code**Approval date**

2009-09-23, 1388/07/01

Ethics committee reference number

(88-4666)

Health conditions studied**1****Description of health condition studied**

Renal failure, Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

quality of life

Timepoint

first day of study and 8th week

Method of measurement

Ereance and Powers quality of life index, Dialysis version

Secondary outcomes**1****Description**

pain

Timepoint

first day and 8th week of study

Method of measurement

VAS

2**Description**

physical activity

Timepoint

first day and 8th week

Method of measurement

Daily Living Activity (ALD) & IADL

3**Description**

sleep

Timepoint

first day and 8th week

Method of measurement

quality of sleep Index

4**Description**

Adherence and Biomedical Markers

Timepoint

first day and 8th week

Method of measurement

Biomedical Markers

Intervention groups

1

Description

Relaxation training was performed in separate rooms while the patient was in the bed in supine position. The instruction of BRT lasted for twenty minutes and the subjects needed to: 1) Sit in a comfortable condition, 2) Close their eyes, 3) Completely make all their muscles less tense beginning from the soles of the feet forward up and relax all parts of the body, 4) Breathe through their nose, listen carefully to the sound of their breathing, and when the breath was out, silently say the word 'one' to themselves, for example, breath in . . . out, 'one'; in . . . out, 'one' . . . , and 5) Continue for twenty minutes. The patients were instructed to check the time while opening their eyes; however, alarm did not have to be used.

Category

Behavior

2

Description

Control The control group received the routine care without any BRT intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazee and Shahid Faghihi Hospital of Shiraz
University of Medical Sciences

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Skandari

Street address

71345-1978, 7th floor, Shiraz university of medical sciences, beside the Red-Crescent building, Zand Ave, Shiraz.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masoume Rambod

Position

MS, and Candidate of PhD

Other areas of specialty/work

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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