

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of breathing intervention on anxiety and physiological parameters of hemodialysis patients

Protocol summary

Summary

The aim of this study was to determine the effect of breathing intervention on the anxiety and physiological parameters of hemodialysis patients. This study was a single-blind clinical trial. This study was performed on chronic renal failure patients undergoing hemodialysis, referring to hemodialysis department of Hajar hospital in Shahrekord, in 1396. Sampling was available. 100 hemodialysis patients had inclusion criteria. These patients were divided into two groups of 50. Sampling was done randomly. Sampling was done on pairs days. Control group sampling was done on individual days. The experimental group performed breathing intervention (deep breathing) for eight sessions in a month and under the guidance of a nurse. The control group received usual care. The research instrument was a three-part questionnaire (demographic information, Spielberger's State-Trait Anxiety and physiological parameters (systolic and diastolic blood pressure, heart rate and respiratory rate) by interventional questionnaire, ten minutes before and ten minutes later. The intervention was completed by interviewing. Inclusion criteria: a chronic kidney disease under hemodialysis two or three sessions a week. The age of the participants was 18 years and older. The participants should have the following conditions: Absence of hearing impairment Under hemodialysis for more than three months The absence of psychiatric disorders approved by the psychiatrist Lack of underlying illness of the respiratory system that makes it difficult for the patient to perform breathing exercises. The desire to participate in the study. Exclusion criteria: Hospital admission to hospital for any reason. Lack of regular referral for dialysis during the course of the study. Patient death.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100736611N1**

Registration date: **2017-11-15, 1396/08/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-15, 1396/08/24

Registrant information

Name

Fatemeh Seife

Name of organization / entity

Faculty of Nursing, University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2017-06-07, 1396/03/17

Expected recruitment end date

2017-07-08, 1396/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of breathing intervention on anxiety and physiological parameters of hemodialysis patients

Public title

The effect of breathing intervention on anxiety and physiological parameters

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Chronic kidney disease and hemodialysis, two or three sessions, per week; age 18 and above; non-acute hearing impairment; hemodialysis for more than three months; lack of mental disorders confirmed by a psychiatrist; It lacks the underlying condition of the respiratory system that makes it difficult for the patient to perform breathing exercises and tends to participate in the study. (Exclusion criteria: if the patient is hospitalized for any reason; absence of regular referral for dialysis during the study period; patient's death).

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Research Deputy of Shahrekord University of Medical Sciences

Street address

Research Deputy, University of Medical Sciences, Kashani Street , Shahrekord

City

Shahrekord

Postal code**Approval date**

2017-06-06, 1396/03/16

Ethics committee reference number

(IR.SKUMS.REC1396.56)

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

Chronic kidney disease - hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

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

Situational anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger's State-Trait Anxiety Questionnaire

2**Description**

Physiological parameters

Timepoint

Before and after intervention

Method of measurement

Blood pressure in mm of mercury Medical barometer and Stethoscope and radial pulse rate measurement and breathing rate for one minute

Secondary outcomes

empty

Intervention groups**1****Description**

This is a single-blind clinical trial that was done In the experimental group, these exercises were performed in 3 stages. The nurse's guidance was performed in three ways and in three stages as follows: 1) Respiratory training was provided to nurses individually (face to face) for 10 minutes. 2) The instructions for the respiratory program (adequate abdominal respiration, respiratory rate, body condition, and abdominal contraction and expansion along the tail and exhalation) were broadcast through the audio device for 10 minutes. Then, in the music background, the patients with the speaker's guidance Or the nurse (2, 3, 4 and breath 2, 3, 4, and breath) breathed deeply and slowly. 3) In the next step, the patients performed respiratory exercises under direct guidance of the nurse for 30 minutes (2). At the first session, all three stages were supervised by the nurse. In the next sessions of the last stage, it was done by the nurse's indirect care for breathing exercises. Of course, at each training session, the nurse should make sure that the patient learned the exercises and

performed properly. Also, the patient did not sleep during the training.

Category

Treatment - Other

2

Description

The control group received usual care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital Affiliated to Shah-re-kord University of Medical Sciences

Full name of responsible person

Fatemeh Seifi Critical Care Nursing MSc Student

Street address

Mahdi Complex Unit 6, Alley 27, Bozorgmehr Street, Mirabad, Shah-re-kord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord Medical Sciences University

Full name of responsible person

Dr. Ali Hassanpour

Street address

Research Deputy, University of Medical Sciences, Kasehaneh Street, Shah-re-kord

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord Medical Sciences University

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

School of Nursing, Shahrekord University of Medical Sciences

Full name of responsible person

fatemeh seife

Position

Critical Care Nursing (MSc) Student

Other areas of specialty/work

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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