

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of planned physical and mental exercises during hemodialysis on adequacy of dialysis and fatigue in hemodialysis patients

Protocol summary

Summary

The current study was conducted with the aim of specifying the effect of intradialytic physical and mental exercises on the quality of dialysis and fatigue in hemodialytic patients. In a controlled trial, 66 hemodialytic patients were selected via Purposive sampling, then, divided into two groups of control and experimental. The criteria for inclusion in the study involved patients' undergoing hemodialysis 3 times a week who at least three months had passed since the start of hemodialysis, and not participating in the regular exercise program in the past 6 months; and The exclusion criteria involved reluctance to continue participating in the exercises, kidney transplant, or the patient's death. The experimental group was subjected to planned intradialytic training twice a week for 2 months by a senior expert in physical education. Their fatigue was measured via a fatigue severity scale questionnaire, and dialysis adequacy was measured using Kt/v formula before, one month after, and two months after intervention in both groups and then compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061112509N2**

Registration date: **2013-09-10, 1392/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-10, 1392/06/19

Registrant information

Name

Batool Nehrir

Name of organization / entity

Baqyatallah Medical Science University

Country

Iran (Islamic Republic of)

Phone

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rnehrr1739@yahoo.com

Recruitment status

Recruitment complete

Funding source

Nephrology and Urology Research Center have paid for funding this research.

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of planned physical and mental exercises during hemodialysis on adequacy of dialysis and fatigue in hemodialysis patients

Public title

The effect of physical and mental exercises during dialysis on adequacy of dialysis and fatigue in dialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria:Patients' undergoing hemodialysis 3 times a week who at least three months had passed since the start of hemodialysis; Not participating in the

regular exercise program in the past 6 months; Being capable of learning during the exercises; Having no medical prohibition for the exercise; Having no record of ischemic heart disease according to the case history; Having no record of 3rd degree congestive heart failure; No record of unstable angina. exclusion criteria: High blood pressure over 180.110 mmHg, low blood pressure equal to 90 mmHg; Reluctance to continue participating in the exercises; Kidney transplant; Death

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Faculty of Nursing

Street address

Faculty of Nursing, Building of Velayat, Street of bedside to the Artesh Square, The Northern End of the Emam Ali Highway, Tehran, Iran.

City

Tehran

Postal code

1956837172

Approval date

2012-12-26, 1391/10/06

Ethics committee reference number

32

Health conditions studied

1

Description of health condition studied

CKD(ESRD)

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Fatigue

Timepoint

before, one month after intervention, two months after intervention

Method of measurement

Fatigue Severity Scale

2

Description

adequacy of dialysis

Timepoint

before, one month after intervention, two months after intervention

Method of measurement

Kt/v formula

Secondary outcomes

1

Description

Sleep

Timepoint

before, one month after intervention, two months after intervention

Method of measurement

Pittsburgh questionnaire

2

Description

stress

Timepoint

before, one month after intervention , two months after intervention

Method of measurement

DASS questionnaire

3

Description

anxiety

Timepoint

before, one month after intervention , two months after intervention

Method of measurement

DASS questionnaire

4

Description

depression

Timepoint

before, one month after intervention , two months after intervention

Method of measurement

DASS questionnaire

Intervention groups

1

Description

The amount of urea and the weight were measured prior to hemodialysis through arteriovenous sampling. At the end of hemodialysis and before disconnecting the patient from the machine, an arterial blood sample was once more prepared from the dialyzer. In the end, patients' weight was monitored again and samples were transferred to the Laboratory. The dialysis adequacy for both groups was measured before, 1 month after, and 2 months after the intervention and then compared, also fatigue in patients was measured via a fatigue severity scale questionnaire before, one month after, and two months after intervention and then compared. Each patient was initially questioned about their kinetic limitations and comorbid diseases so as to propose an exercise program corresponding to their individual capabilities. The exercises were given by a senior expert in physical education during the dialysis half an hour after the patients were connected to the machine. At the beginning of each session, the trainer began taking about the system of the universe, the infinite power of God Almighty and positive thinking about the self. Then, the patients were encouraged to do stretching and flexibility movements. For the limb inflicted with fistula, the patient was told to close their eyes and imagine moving it. During the exercise intervals the patients were required to take a deep breath or do diaphragm breathing with inhalation and exhalation. Ultimately, they were taught to do relaxation exercises under the trainer's guidance, while a soft music without lyrics was being played. In the next sessions the exercises were extended with respect to the subjects' capabilities in terms of severity and repetition. They were continued twice a week for almost two months with a maximum time of 20 minutes.

Category

Prevention

2

Description

The control group did not receive any intervention. The amount of urea and the weight were measured prior to hemodialysis through arteriovenous sampling. At the end of hemodialysis and before disconnecting the patient from the machine, an arterial blood sample was once more prepared from the dialyzer. In the end, patients' weight was monitored again and samples were transferred to the Laboratory. The dialysis adequacy for both groups was measured before, 1 month after, and 2 months after the study and then compared, also fatigue

in patients was measured via a fatigue severity scale questionnaire before, one month after, and two months after study and then compared.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatollah Hospital

Full name of responsible person

Batool Nehrir(Instructor,PHD student of Nursing Education)

Street address

Baqiatollah Hospital, Molasadra Street, Vanak Square, Tehran.

City

Tehran

2

Recruitment center

Name of recruitment center

Labbafinejad Hospital

Full name of responsible person

Batool Nehrir(Instructor,PHD student of Nursing Education)

Street address

Labbafinejad Hospital, Boostan Ninth Street, Pasdaran Street, Tehran.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nephrology and Urology Research Center

Full name of responsible person

Behzad Eynollahi PHD

Street address

Nephrology and Urology Research Center, Ground Floor, Baghiyatallah Hospital, Molasadra Street, Vanak Square, Tehran.

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Nephrology and Urology Research Center

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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City**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