Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Hatta yoga on hope and fatigue of hemodialysis patients referred to dialysis center

Protocol summary

Study aim
Determining the effect of hatha yoga on hope and fatigue of dialysis patients referring to Bou Ali Dialysis Center in Qazvin city

Design
Clinical trial with control group, simple randomization, sample size 62 people

Settings and conduct
The present study will be conducted as a clinical trial with a pre-test/post-test design with a control group. All the hemodialysis patients of Bu Ali sina Hospital Qazvin form the statistical population of the research. Sampling will be done in a simple random way.The names of the patients will be sent to the respected nephrology doctor to confirm their readiness to participate in yoga classes.

Participants/Inclusion and exclusion criteria
Inclusion criteria At least six months have passed since their first hemodialysis appointment Not participating in yoga classes since 6 months ago Absence of medical prohibition of sports Exclusion criteria Any change in the general state of the patient's body during exercise so that he is not able to exercise.

Intervention groups
The course of the program is conducted by a specialist yoga trainer who has training experience in a specialized yoga club. The intervention program includes physical movements (50 minutes), meditation (15 minutes) and breathing and relaxation exercises (10 minutes). the participants in this group, 10 weeks of yoga, two sessions a week, where the beginning of the yoga intervention is 15 minutes per session and at the end of the study, it increases to 30 minutes per session.

Main outcome variables
Observing the significant effectiveness of yoga in improving the hopelessness of dialysis patients Observing the significant effect of yoga on the fatigue of dialysis patients In case of significant effectiveness, this method can be used as a complementary treatment for dialysis patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230926059516N1**
Registration date: **2024-02-16, 1402/11/27**
Registration timing: **retrospective**

Last update: **2024-02-16, 1402/11/27**
Update count: **0**

Registration date
2024-02-16, 1402/11/27

Registrant information

Name
fatemeh Aghakhanbeigi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2212 5454

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Hatta yoga on hope and fatigue of hemodialysis patients referred to dialysis center

Public title
The effect of Hatta yoga on hope and fatigue of hemodialysis patients referred to dialysis center
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
At least six months have passed since their first hemodialysis appointment Not participating in yoga classes since 6 months ago To have the ability to train and perform Hatha Yoga exercises Be able to do exercises Absence of diagnosed cognitive and movement disorders Absence of medical prohibition of sports
Exclusion criteria:
Any change in the general state of the patient's body during exercise (occurrence of acute problems) so that he is not able to exercise. Withdrawal or unwillingness to do continuous exercises during the study.
Age
From **18 years** old to **55 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization according to entry and exit criteria Selection of the intervention and control group using a lottery, "yoga" and "non-yoga" were written on the paper and poured into a bag with the number of samples, then according to the list, the people of the group identify themselves.
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 Qazvin University of Medical Sciences
Street address
Qazvin univerdity medical of sience , Bahonar Blvd ,Qazvin
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Approval date
2023-05-08, 1402/02/18
Ethics committee reference number
IR.QUMS.REC.1402.028

Health conditions studied

1

Description of health condition studied
Hemodialysis patients
ICD-10 code
Z49.0
ICD-10 code description
Preparatory care for dialysis

Primary outcomes

1

Description
Hope rate in dialysis patients
Timepoint
Since starting hemodialysis
Method of measurement
Schneider hope questionnaire

2

Description
Fatigue in hemodialysis patients
Timepoint
Since starting hemodialysis
Method of measurement
Multidimensional Fatigue Inventory questionnaire

Secondary outcomes

1

Description
Hope rate after Hatha Yoga intervention
Timepoint
After 10 weeks
Method of measurement
Schneider hope questionnaire

2

Description
Fatigue rate after Hatha Yoga intervention
Timepoint
After 10 weeks
Method of measurement

Multidimensional Fatigue Inventory questionnaire

Intervention groups

1

Description

Intervention group: The intended intervention in this research includes the implementation of a type of Hatha Yoga program. The course of the program is conducted by a specialist yoga instructor who has training experience in a specialized yoga club. The intervention program includes physical movements (50 minutes), meditation (15 minutes) and breathing and relaxation exercises (10 minutes), which have been selected based on several studies that have used this type of yoga. Also, the participants in this group, 10 weeks of yoga, two sessions per week, the beginning of the yoga intervention is 15 minutes per session and at the end of the study, it increases to 30 minutes per session. Patients with vascular access in 1 arm only perform unilateral arm movements in the free arm and legs. Patients with vascular access in the chest move both arms and legs. The yoga intervention will consist of slow coordinated body movements with breathing within the patient's comfortable range of motion

Category

Lifestyle

2

Description

Control group: In the control group, the usual care of dialysis patients that all patients receive will be provided.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Boo Ali Dialysis Center
Full name of responsible person
Fatemeh Aghakhanbeigi
Street address
qazvin university medical of science School of Nursing and Midwifery, Blv Bahonar , Qazvin
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Aghakhanbeigi
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Aghakhanbeigi
Position
nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers and people who are also engaged in the industry

Under which criteria data/document could be used
Researchers working in academic and scientific institutions People who are also engaged in industry In order to provide better services and care to dialysis patients

From where data/document is obtainable
f.aghakhanbeigi@gmail.com

What processes are involved for a request to access data/document
Send your request to email State your resume and job status Also state your purpose for using the data

Comments