

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Effects of Hatha Yoga exercises on the quality of life in Hemodialysis patients

#### Protocol summary

##### Summary

Objectives: Determination of the effect of Hatha Yoga on the quality of life in hemodialysis patients. Design: This study is a clinical trial that performed for an experimental and control groups. Setting and conduct: researcher does the sampling based on objective among all the patients who are admitted to the Hemodialysis Department of 5 Azar hospital in Gorgan with the Population size of 174 people, (89 men and 85 women). The sample size is 16 people, so 32 patients are assigned and placed in experimental and controls groups of 16 people, randomly. For adjustment of gender variable in sampling based on objective, 16 female patients from women group and 16 male patients from men group of research community selected, Then based on a random numbers table, from each group of 16 male and female, 8 female and 8 male patient placed in experimental group and 8 female and 8 male patient in control group, randomly. Thus 2 experimental and control groups are selected and experimental group similar to the control group includes 8 male and 8 female who have all the Inclusion criteria and the only difference is Hatha Yoga intervention that is done for the experimental group. Data collection tool is a questionnaire consists of two parts include demographic information and quality of life questionnaire SF36. First, the quality of life of patients in both groups checked. During the 12 weeks, each week two times, Patients in the experimental group will participate in the training sessions of Hatha yoga which will be held in the Sports Hall of Hospital by master trainer who has a history of training. After 12 weeks, the patients' life quality in groups will re-examine and compare. Participants including major eligibility criteria: 3 months have passed since the first turn of hemodialysis of patients. Be interested in participating in the study, filling out the questionnaire and attending the Hatha Yoga exercise classes. Not being membership of yoga classes. Participants excluding major eligibility criteria: Absence

of more than 4 sessions of 24 session training class, Withdrawal or reluctance to exercise during the study. Interventions: in 12 weeks, 2 times each week (A total of 24 sessions), Patients in the experimental group will participate in the training sessions of Hatha yoga which will be held in the Sports Hall of Hospital by master trainer who has a history of training. Training sessions of male and female patients will be separate and held with a separate instructor. The main outcome variable: Quality of life of Hemodialysis patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015113024047N3**

Registration date: **2016-10-08, 1395/07/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-08, 1395/07/17

##### Registrant information

##### Name

Hedayat Jafari

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3311 7268

##### Email address

hjafari@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Mazandaran University of Medical Sciences

**Expected recruitment start date**

2016-06-21, 1395/04/01

**Expected recruitment end date**

2016-09-22, 1395/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of Hatha Yoga exercises on the quality of life in Hemodialysis patients

**Public title**

Effects of Hatha Yoga exercises on the quality of life in Hemodialysis patients

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Inclusion criteria: 3 months have passed since the first turn of Hemodialysis of patients : Be interested in participating in the study, filling in the questionnaire and attending the Hatha Yoga exercise classes : Not being membership of yoga classes : Be educable (patients with consciousness 15/15, with abstract thinking, without interrupting the focus is known about mental Retard, Alzheimer's disease, stroke that lead to memory impairment and movement and be able to exercise independently on the slopes motion. so they can learn and perform yoga movements) : Have confirmation of doctor for doing exercise : Not doing physical activity at least three times a week : not using of complementary therapies simultaneously with the intervention : Not being membership in yoga classes. Participants excluding major eligibility criteria: Absence of more than 4 sessions of 24 session training class: Withdrawal or reluctance to exercise during the study.

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked***No information***Sample size**

Target sample size: 32

**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**

Ethics Committee of Mazandaran University of Medical Science

**Street address**

Moalem Street, Moalem Square, Sari

**City**

Sari

**Postal code**

4815696869

**Approval date**

2016-07-03, 1395/04/13

**Ethics committee reference number**

IR.MAZUMS.REC.95

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

end stage kidney disease

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

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

Quality of life

**Timepoint**

Before and 3 months after the intervention

**Method of measurement**

SF36 quality of life questionnaire

**Secondary outcomes**

empty

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

In the intervention group at 3 months (12 weeks, 2 times per week) of the patients in the hospital for 60 minutes sessions of Hatha yoga exercises that will be held in the presence of coach, participated SF36 quality of life questionnaire before and after intervention by the Group the intervention is completed.

**Category**

Lifestyle

## 2

### Description

In the control group there is no intervention and they will just fill in the SF36 quality of life questionnaire before and after the intervention of experiment group.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

5 Azar Hospital of Gorgan city

**Full name of responsible person**

Elahe Mahmudi

**Street address**

Hemodialysis department, 5 Azar Hospital, Azar Street, Vali Asr Square, Gorgan. Iran.

**City**

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research Mazandaran University of Medical Sciences.

**Full name of responsible person**

Dr. Ahmahali Enayati

**Street address**

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran.

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Elahe Mahmudi

**Position**

MSc in critical care nursing

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Hedayat Jafari

**Position**

Assistant Professor, scientific committee

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## Person responsible for updating data

### Contact

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**Web page address****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*