

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of the effect of tai chi exercise and walking on HbA1C levels health related quality of life in patient with type 2 diabetes

#### Protocol summary

##### Study aim

Determining and comparing the effect of tai chi exercise and walking on HbA1C levels health related quality of life in patient with type 2 diabetes

##### Design

Clinical trial with control group, with parallel, randomized groups, 96 patients

##### Settings and conduct

Approval of the research plan in the university ethics committee. At the beginning of the study, completion of the checklist of demographic characteristics, Diabetes Quality of Life-Brief Clinical Inventory and analysis of HbA1C level with HPLC model DS5. Intervention in both tai chi and walking groups, 60 minutes and for 12 weeks. 12 weeks after the start of the study, re-completion of the Diabetes Quality of Life-Brief Clinical Inventory and analysis of HbA1C level with HPLC model DS5. The training place is a gym.

##### Participants/Inclusion and exclusion criteria

Admission requirements: 1- Willingness to participate in the study 2- Age 20-60 years. Conditions of non-entry: 1- Diabetic foot ulcer 2- Lack of regular participation in exercises

##### Intervention groups

Intervention group 1: tai chi exercise: This exercise is performed for 12 weeks (1 to 2 hours after eating). Subjects will participate in two 60-minute Tai Chi training sessions per week for 12 weeks. Each session will include 10 minutes of warm-up, 40 minutes of tai chi and 10 minutes of cooling down. Intervention group 2: walking: This exercise is performed for 12 weeks (1 to 2 hours after eating). Each session will include 10 minutes of warm-up and 10 minutes of cool-down. Control group: Non-intervention: This training group will not be given.

##### Main outcome variables

Hemoglobin A1C and Health related quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220713055466N1**

Registration date: **2022-07-18, 1401/04/27**

Registration timing: **prospective**

Last update: **2022-07-18, 1401/04/27**

Update count: **0**

##### Registration date

2022-07-18, 1401/04/27

##### Registrant information

##### Name

Maryam Layeghi Motlagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 4721

##### Email address

maryam.layeghi93@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of tai chi exercise and walking on HbA1C levels health related quality of life in patient with type 2 diabetes

#### Public title

Comparison of the effect of tai chi exercise and walking on HbA1C levels health related quality of life in patient with type 2 diabetes

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having type 2 diabetes with the approval of a specialist doctor Treated with oral diabetes medications Willingness to participate in the study Awareness of your illness being alert Not suffering from mental retardation and not suffering from mental illness Age 20-60 years Obtaining an average and unfavorable quality of life score related to health based on a questionnaire

##### Exclusion criteria:

Hospitalization during the study Creating emergency conditions such as non-ketonic hyperosmolar or hypoglycemia Patients with decreased visual activity due to diabetic retinopathy and decreased body movement due to diabetic foot disease Unwillingness to continue cooperation Migration Exercise intolerance Diabetic foot ulcer Suffering from musculoskeletal or cardiovascular diseases Lack of regular participation in exercises Diabetic patients with hemoglobinopathy or anemia Diabetic patients with uremia Diabetic patients with microvascular complications such as retinopathy, nephropathy and neuropathy

#### Age

From **20 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **96**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation by block method will be in order for the researcher to make sure that exactly the same number of patients will enter the intervention and control groups in a consecutive, but equal, time interval. The groups will be formed as B, A and C. Before assigning people to one of the groups, a list of these letters (B, A, and C), in other words, blocks of sizes 3, 9, and 12, will be created by the reliable website <https://www.sealedenvelope.com>. Each of the referring and qualified people will be assigned to one of the groups.

#### 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 Yasuj University of Medical Sciences

###### Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

###### City

Yasuj

###### Province

Kohgilouyeh-va-Boyerahmad

###### Postal code

7591741417

##### Approval date

2022-05-18, 1401/02/28

##### Ethics committee reference number

IR.YUMS.REC.1401.022

#### Health conditions studied

##### 1

##### Description of health condition studied

Patient with type 2 diabetes

##### ICD-10 code

E11

##### ICD-10 code description

Type 2 diabetes mellitus

#### Primary outcomes

##### 1

##### Description

Hemoglobin A1C

##### Timepoint

Hemoglobin A1C level of patients at the beginning of the study (before the intervention) and 12 weeks after the study.

##### Method of measurement

Analysis with HPLC model DS5

##### 2

##### Description

Health related quality of life

##### Timepoint

The level of Health related quality of life of patients at the beginning of the study (before the intervention) and 12 weeks after the study.

## Method of measurement

Diabetes Quality of Life-Brief Clinical Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: tai chi exercise: This exercise is performed for 12 weeks (1 to 2 hours after eating). Subjects will participate in two 60-minute Tai Chi training sessions per week for 12 weeks. Each session will include 10 minutes of warm-up, 40 minutes of tai chi and 10 minutes of cooling down. warm up includes; Exercise major joints and muscle groups at a low intensity level to prepare the skeletal muscles, heart and lungs for a gradual increase in exercise intensity following the recommendation of the American Diabetes Association. During each session, in addition to gentle, coordinated and smooth movements of different body parts, relaxation and deep breathing will be emphasized during the exercise. A tai chi workout will be followed by a cool-down workout that is structured like a warm-up to gradually lower the heart rate to pre-exercise levels. Because tai chi involves significant footwork, participants are advised to take precautions to prevent blisters and keep feet dry to minimize foot injury, as recommended by the American Diabetes Association. Recommends. Participants will also be reminded to drink enough water before, during and after exercise, as dehydration can negatively affect blood glucose levels and heart function. To prevent dehydration due to the heat caused by the activity, the gym will have air conditioning. Also, precautions such as eating a snack before exercise will be taken to prevent hypoglycemia caused by exercise. Participants will be advised to notice and report symptoms such as hunger, nervousness, tremors, or sweating. Glucose tablets, juice, soft drinks will be provided to increase blood glucose if needed. In addition, brochures and educational CDs will be given.

#### Category

Lifestyle

### 2

#### Description

Intervention group 2: walking: This exercise is performed for 12 weeks (1 to 2 hours after eating). Each session will include 10 minutes of warm-up and 10 minutes of cool-down. warm up includes; Exercise major joints and muscle groups at a low intensity level to prepare the skeletal muscles, heart and lungs for a gradual increase in exercise intensity following the recommendation of the American Diabetes Association. Participants will be reminded to drink enough water before, during and after exercise, as dehydration can negatively affect blood glucose levels and heart function. To prevent dehydration due to the heat caused by the activity, the gym will have air conditioning. Also, precautions such as

eating a snack before exercise will be taken to prevent hypoglycemia caused by exercise. Participants will be advised to notice and report symptoms such as hunger, nervousness, tremors, or sweating. Glucose tablets, juice, soft drinks will be provided to increase blood glucose if needed. In addition, the relevant brochure will be given.

#### Category

Lifestyle

### 3

#### Description

Control group: Non-intervention: This training group will not be given.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Maryam Layeghi Motlagh

##### Street address

Shahid Beheshti Hospital, Shahid Montazeri Ave., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591719154

##### Phone

+98 74 3322 4721

##### Fax

+98 74 3322 1811

##### Email

beheshthospital@yasooj.ir

### 2

#### Recruitment center

##### Name of recruitment center

Martyr Dr. Jalil Hospital

##### Full name of responsible person

Maryam Layeghi Motlagh

##### Street address

Martyr Dr. Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591387493

##### Phone

+98 74 3333 7001

**Email**

maryam.layeghi93@gmail.com

**3****Recruitment center****Name of recruitment center**

Imam Sajjad Hospital

**Full name of responsible person**

Maryam Layeghi Motlagh

**Street address**Imam Sajjad Hospital, Next to Hotel Azadi, Yasuj,  
Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591719154

**Phone**

+98 74 3322 0166

**Email**

maryam.layeghi93@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Seyed Amin Hossaini Motlagh

**Street address**Yasuj University of Medical Sciences, Shahid Motahari  
Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic  
Republic of Iran**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6078

**Fax**

+98 74 3334 6079

**Email**

nursing@yums.ac.ir

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

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Maryam Layeghi Motlagh

**Position**

Msc student in Medical-Surgical nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**No. 51, Shahid 1 Alley., 30 meters from Maad Ave.,  
Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic  
of Iran**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591719154

**Phone**

+98 74 3322 4721

**Email**

maryam.layeghi93@gmail.com

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

Yasouj University of Medical Sciences

**Full name of responsible person**

Maryam Layeghi Motlagh

**Position**

Msc student in Medical-Surgical nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**No. 51, Shahid 1 Alley., 30 meters from Maad Ave.,  
Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic  
of Iran**City**

ياسوج

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591719154

**Phone**

+98 74 3322 4721

**Email**

maryam.layeghi93@gmail.com

## Person responsible for updating data

maryam.layeghi93@gmail.com

### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Maryam Layeghi Motlagh

**Position**

Msc student in Medical-Surgical nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 51, Shahid 1 Alley., 30 meters from Maad Ave.,  
Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic  
of Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591719154

**Phone**

+98 74 3322 4721

**Email**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available