Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 74 3322 4721

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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

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Province

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Postal code

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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

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

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Sponsors / Funding sources

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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
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
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Person responsible for scientific inquiries

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Other areas of specialty/work
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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