Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

The effect of 3 months of functional training above and below the lactate threshold in retired military veterans with type 3 diabetes

Protocol summary

Study aim
Comparison of the effect of 3 months of functional exercises with higher and lower intensity than the lactate threshold on the metabolic status, cognitive function and physical function of retired military veterans with type 3 diabetes.

Design
Clinical trial with control group, with other case groups, single-blind, randomized by Randomization.com website

Settings and conduct
This study was designed at Baqiyatullah University of Medical Sciences and with collaboration of Shahrekord University and Shahrekord Diabetes Association. The location of the study is Shahrekord Diabetes Association. 90 elderly diabetic patients were divided into high-intensity functional training, low-intensity functional training, and control groups, after cognitive impairment evaluation, and received the targeted intervention for 3 months. Blinding will be done for all 3 groups of subjects, trainers and data analysts.

Participants/Inclusion and exclusion criteria
Age over 60 years, diagnosis of type 2 diabetes, diagnosis of cognitive impairment, no participate in regular exercise programs or drug interventions, no smoking and alcohol consumption, no cancer and surgery.

Intervention groups
Functional training group with intensity higher than the lactate threshold (120-125% of lactate threshold) The functional training group is lower than the lactate threshold (70-75% of the lactate threshold). Both training groups will perform functional exercises for a 3-month period (5 sessions per week). The control group will not do sports during the intervention period.

Main outcome variables
improvement of anthropometric indices; Physical performance (aerobic endurance, upper and lower body strength, balance, speed, reaction speed and walking ability) and cognitive performance (attention, processing speed, learning, memory)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230502058055N1**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date
2023-06-11, 1402/03/21

Registrant information

Name
Majid Mardaniyan Ghahfarrokhi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of 3 months of functional training above and below the lactate threshold in retired military veterans with type 3 diabetes

Public title
Investigating the effect of different intensity of functional training on type 3 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥ 60 years Diagnosis of type 2 diabetes Suffering from cognitive impairment based on MMSE score less than 20

Exclusion criteria:
Diabetic foot ulcer Participating in regular sports programs or special drug and sports interventions Smoking and drinking alcohol Cancer and performing surgery

Age
From **60 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects were randomly assigned by a research assistant outside the study and in blocks of 4 and using sealed envelopes in one of the functional training group with an intensity higher than the lactate threshold, functional training with Intensity below the lactate threshold and control group. Randomization will be performed using Randomization.com (http://www.randomization.com). The subjects are completely unaware of the grouping and the exercises and counseling sessions will be held on completely separate days.

Blinding (investigator's opinion)
Single blinded

Blinding description
All subjects will be completely blinded to the grouping. For this purpose, exercises and counseling sessions related to each group will be held on completely separate days. Clinical caregivers (trainers) who are separate from the research investigators will be blinded to the grouping. The analysis of the research data will be done by a biostatistician who is not aware of the details of the intervention protocol. Also, in presenting the data to the statistician, it will be avoided to include the names of the subjects and the names of the groups, and the names and groups will be presented in coded form.

Placebo
Not used

Assignment
Other

Other design features
All subjects are randomly divided into 3 groups: high-intensity functional training, low-intensity functional training, and control. In this research design, 2 exercise groups receive independent interventions, while the control group does not receive any intervention and does its daily activities.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Baqiyatullah University of Medical Sciences

Street address
Vanak Square, Mollasadra St., South Sheikh Bahai St

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2023-02-05, 1401/11/16

Ethics committee reference number
IR.BMSU.BAQ.REC.1401.109

Health conditions studied

1

Description of health condition studied
Type 3 Diabetes

ICD-10 code
E12.4

ICD-10 code description
Malnutrition-related diabetes mellitus with neurological complications

Primary outcomes

1

Description
Processing speed. Processing speed score in the SDMT questionnaire.

Timepoint
The evaluation will be done in the pre-test (before the start of the intervention) and the post-test (after the end of the intervention).

Method of measurement
In order to evaluate the processing speed in the present

research, the SDMT test is used to check the processing speed. The SDMT test consists of placing the number associated with a set of symbols in the 90 cells of a table, and the subject has 90 seconds to do this. The final score obtained from this test is considered as the processing speed score.

2

Description

Memory. Memory score in BVMT test.

Timepoint

The evaluation will be done in the pre-test (before the start of the intervention) and the post-test (after the end of the intervention).

Method of measurement

The BVMT test is related to visual memory, for this purpose, the subject must remember six geometric shapes on a white paper in a 10-second time and draw the shapes 3 times with 25-minute intervals. Putting each shape in its place and with the correct shape has 1 point respectively and the total of the test in each stage is 12 points. The average score of the 3 stages is considered as the memory score.

3

Description

learning Learning score in CVLT test.

Timepoint

The evaluation will be done in the pre-test (before the start of the intervention) and the post-test (after the end of the intervention).

Method of measurement

The CVLT test is related to learning 16 words that are read by the test taker, and the test taker must try to write the words he has memorized five times with five minute intervals. Words generally consist of 4 groups of 4 words. The number of correct words recalled in five recall repetitions is considered as the subject's learning score.

4

Description

Attention. attention score in the Stroop test.

Timepoint

The evaluation will be done in the pre-test (before the start of the intervention) and the post-test (after the end of the intervention).

Method of measurement

The Stroop test requires subjects to view a list of words printed in a different color than the meaning of the word. Participants are required to name the font or ink color of the word as best they can, not the word itself. For example, when presented with the word "green" written in red ink, the person must choose red. It is much easier to name a word whose spelling and ink color are the same, as opposed to when the ink color and the word itself are different. This degree of difficulty is what we call the Stroop effect. Stroop test score will be considered as attention score.

Secondary outcomes

1

Description

Anthropometric, metabolic and physical performance indicators are the secondary variables of the present study. Anthropometric variables such as height, weight, body mass index and fat percentage. Metabolic variables including fasting blood sugar, insulin, glycated hemoglobin, lipid profile and blood lactate. Physical performance variables include. Aerobic endurance, upper and lower body strength, balance, speed, reaction speed and walking ability.

Timepoint

pre-test (before the intervention) and post-test (after the intervention)

Method of measurement

Height using a wall-mounted scale, weight using a digital scale, body mass index using the body mass index formula, fat percentage using a body composition analysis device will be measured as anthropometric indicators. Blood samples will be taken before and after 3 months of intervention to measure serum glucose, serum insulin, insulin resistance index, glycosylated hemoglobin, lipid profile and blood lactate. In order to measure the ability to walk from a 6-minute walk test, upper body and lower body strength from handgrip tests and standing up and sitting 5 times, balance using static and dynamic balance tests, speed using a 10 meter test. Walking, reaction speed will be measured using long-time intensity and walking tests and six-step walking test.

Intervention groups

1

Description

Intervention group: First: high-intensity functional exercises. Subjects of the functional group with an intensity higher than the lactate threshold (75-85% of the reserve heart rate, equivalent to 80-85% of the maximum oxygen consumption, equivalent to 120-125% of the lactate threshold) first under a A 1-week training course (five sessions per week) will be arranged to familiarize them with the details of the exercises, the gym environment and the equipment. After learning the necessary training for a period of 3 months (5 sessions per week), they will continue functional exercises under the supervision of trainers. Each session of high-intensity performance training will consist of 20-25 minutes of activity, which will include 1- endurance exercises, 2- upper and lower body strength, 3- balance exercises and maintaining posture, 5- hip control exercises and mid-body stability. . The ratio of rest time to activity in this group will be 1:1. 5 minutes of warming up before each session and 5 minutes of cooling down at the end of each session will be considered. The heart rate will be monitored by a polar heart rate monitor to control the training intensity during the training program. Also, lactate levels will be evaluated after the end of each

session to determine the intensity level of sports activity.

Category

Rehabilitation

2

Description

Intervention group: Second: functional exercises with low intensity. Subjects of the functional group with an intensity lower than the lactate threshold (35-45% of the reserve heart rate, equivalent to 50-60% of the maximum oxygen consumption, equivalent to 70-75% of the lactate threshold) first underwent a 1-week training course (five sessions per week) will be placed to get to know the details of functional exercises, gym environment and equipment. After learning the necessary training for a period of 3 months (5 sessions per week), they will continue the functional exercises under the supervision of the trainers. Low-intensity functional exercises will be similar to the high-intensity training group, with the difference that the number of repetitions of each movement will be less, but the rest time will be longer. The ratio of rest time to activity in this group is 3:1. Therefore, the approximate time of each session will be between 35-40 minutes. 5 minutes of warming up before each session and 5 minutes of cooling down at the end of each session will be considered. The heart rate will be monitored by a polar heart rate monitor to control the training intensity during the training program. Also, lactate levels will be evaluated after the end of each session to determine the intensity level of sports activity.

Category

Rehabilitation

3

Description

Control group: no intervention. The control group will not exercise during the intervention period and will do their usual daily activities. In the weekly meetings, the researchers will evaluate the status of the weekly activities of the control group in the form of questions and answers.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

انجمن دیابت شهرکرد

Full name of responsible person

لیلا خواجه علی- میلاد طاهریان

Street address

شهرکرد-خیابان مولوی، خیابان ۱۲ محرم-کوچه‌ی ساختمان پزشکی نور-واحد 19

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Hossein Shirvani

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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

Bagheiat-allah 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

Shahrekord University

Full name of responsible person

Majid Mardaniyan Ghahfarrokhi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Clinical exercise physiology

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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
No - There is not a plan to make this available

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

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Considering that the main goal of the current research is clinical rehabilitation for the elderly who have cognitive, metabolic and movement disorders. Therefore, sharing the results, data and protocol of the current research can be used for different groups. The results and information obtained from this rehabilitation protocol can initially be used for the health system to deal with the prevalence of old age in the near future in the country. Also, organizations and institutions related to the elderly, including welfare, nursing homes and other areas related to the elderly can use the results and protocol of this research. Therefore, the researchers of this research are responsible for providing the non-identifiable research data, research protocol, statistical information and clinical report to the aforementioned organizations and institutions.

When the data will become available and for how long
Access to the data starts immediately after the end of the intervention

To whom data/document is available
All scientific and academic researchers, organizations or institutions active in the field of rehabilitation

Under which criteria data/document could be used
Any use under the title of plagiarism without mentioning the names of the researchers and sponsoring organization is not allowed.

From where data/document is obtainable
Applicants can apply through the following email to receive documents. majid.mardaniyan@gmail.com

What processes are involved for a request to access data/document
After registering the request, the researchers of this research will obtain the approval of the university and the research vice-chancellor and send the documents.

Comments