

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of 8 Weeks of Pickleball on Balance, Spatio-Temporal Parameters of Gait, and Psychosocial Factors in Older Women

#### Protocol summary

##### Study aim

The effect of 8 weeks of pickleball training on balance, spatiotemporal gait parameters, and psychosocial factors in elderly women

##### Design

This study is a randomized, single-blind clinical trial with parallel groups. Forty participants were randomly assigned to the intervention and control groups.

##### Settings and conduct

Eligible elderly women who visited the Faculty of Sports Sciences at Shahid Bahonar University of Kerman were randomly assigned to the intervention and control groups. This study was single-blind, and the assessors were unaware of the intervention type.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age  $\geq 60$  years, ability to perform moderate physical activity, no need for assistive devices for walking, ability to participate in training sessions, signed consent form. Exclusion criteria: Severe sensory-motor/visual impairments, pathological diseases, history of lower limb musculoskeletal problems, incomplete screening questionnaires, recent use of painkillers, limb deformities, recent history of falls, inability to perform the programs, participation in parallel studies, neurological/psychiatric disorders (epilepsy, Parkinson's, MS).

##### Intervention groups

Intervention group: Participants in this group took part in an eight-week pickleball program with 3 sessions of 60 minutes per week, including warm-up, main exercises, and cool-down. The goal of the program was to improve physical activity and balance in elderly women. Control group: Participants in this group did not receive any specific training program and continued with their usual daily activities. Their physical activity was monitored weekly.

##### Main outcome variables

Balance, stride length, stride velocity, cadence, double support duration and social capital.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230701058629N1**

Registration date: **2025-03-26, 1404/01/06**

Registration timing: **retrospective**

Last update: **2025-03-26, 1404/01/06**

Update count: **0**

##### Registration date

2025-03-26, 1404/01/06

##### Registrant information

##### Name

Shima Sheikh bahaie

##### Name of organization / entity

Shahid Bahonar University of Kerman

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 3066

##### Email address

sh18.shima@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-06, 1403/01/18

##### Expected recruitment end date

2024-06-07, 1403/03/18

##### Actual recruitment start date

2024-04-06, 1403/01/18

##### Actual recruitment end date

2024-06-07, 1403/03/18

##### Trial completion date

2024-06-07, 1403/03/18

**Scientific title**

The effect of 8 Weeks of Pickleball on Balance, Spatio-Temporal Parameters of Gait, and Psychosocial Factors in Older Women

**Public title**

Investigating the Impact of Pickleball on Balance, Spatial-Temporal Gait Parameters, and Psychosocial Factors in Older Women

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age  $\geq 60$  years Ability to perform moderate physical activity No need for assistive devices for walking Ability to participate in training sessions Signed consent form

**Exclusion criteria:**

Severe sensory-motor/visual impairments Pathological diseases History of lower limb musculoskeletal problems Incomplete screening questionnaires Recent use of painkillers Limb deformities, Recent history of falls Inability to perform the programs Participation in parallel studies Neurological/psychiatric disorders (epilepsy, Parkinson's, MS)

**Age**

From **60 years** old to **75 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the random allocation process for assigning participants to experimental and control groups was meticulously designed based on robust methodological principles. Initially, a balanced (1:1) random sequence was generated using **\*\*Randomiser.org\*\*** software, which employs cryptographic algorithms for random number generation. This sequence was structured in fixed blocks of 8 participants (block randomization), with each block containing 4 allocations to the experimental group and 4 to the control group in a completely random and variable arrangement (e.g., experimental-control-experimental-control-control-experimental-control-experimental). The block size remained concealed from researchers to prevent prediction of allocation sequences. Following eligibility confirmation and completion of initial registration, each participant was automatically assigned the next code in this block sequence without any human intervention. To maintain allocation concealment, the allocation system was designed so that neither research team members nor participants knew group assignments until final registration and allocation were complete. This was implemented through a secure, encrypted online platform that only revealed the random sequence after

definitive participant registration. The generated random sequence was verified and certified by an independent statistician uninvolved in study execution. All steps of random sequence generation, allocation execution, and data recording were thoroughly documented for methodological auditability. This sophisticated approach offered several key advantages: (1) it precisely maintained group balance both during and at study completion; (2) the concealed, automated allocation mechanism prevented selection bias and researcher influence; and (3) it ensured equitable chances for all participants to be assigned to either group. Such rigorous randomization design effectively prevented selection bias and confounding factors, significantly enhancing the study's internal validity. Complete randomization documentation, including generated codes, allocation timestamps, and related information, has been archived for future reference and verification.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

For blinding the study, the evaluators also had no information about the factors considered by the researcher until the end of the study. For example, regarding the assessment of participants' walking using the motion analysis system, the evaluator was unaware of the analysis of factors such as speed, step length, and double support during testing and merely conducted the test.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Sport Sciences Research Institute

**Street address**

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1587958711

**Approval date**

2023-08-22, 1402/05/31

**Ethics committee reference number**

IR.SSRC.REC.1402.120

## Health conditions studied

### 1

#### Description of health condition studied

Older adults

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Balance

#### Timepoint

Before the start of the intervention and eight weeks after the start of the intervention

#### Method of measurement

Balance is assessed using the Mini-BESTest.

### 2

#### Description

Stride length

#### Timepoint

Before the start of the intervention and eight weeks after the start of the intervention

#### Method of measurement

In the present study, stride length is assessed using a motion analysis system.

### 3

#### Description

Stride velocity

#### Timepoint

Before the start of the intervention and eight weeks after the start of the intervention

#### Method of measurement

In the present study, stride velocity is assessed using a motion analysis system.

### 4

#### Description

Cadence

#### Timepoint

Before the start of the intervention and eight weeks after the start of the intervention

#### Method of measurement

In the present study, cadence is assessed using a motion analysis system.

### 5

#### Description

Double support duration

#### Timepoint

Before the start of the intervention and eight weeks after the start of the intervention

#### Method of measurement

In the present study, double support duration is assessed

using a motion analysis system.

### 6

#### Description

Social capital

#### Timepoint

Before the start of the intervention and eight weeks after the start of the intervention

#### Method of measurement

Social capital is assessed using the Onyx and Bullen questionnaire.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Group: Participants in this group took part in a structured pickleball training program for eight weeks. The program included three sessions per week, with each session lasting 60 minutes. The training was conducted in a controlled environment using standard pickleball equipment, including paddles, balls, and a designated court. Each session consisted of three phases: 1. Warm-up (10 minutes): Stretching exercises and light activities to prepare the body. 2. Main Pickleball Training (40 minutes): Skill drills, court movement exercises, and guided gameplay to enhance balance and gait performance. 3. Cool-down (10 minutes): Stretching and relaxation exercises to reduce muscle fatigue. This program was designed to increase physical activity levels, improve balance, and enhance mobility in older women. The training was supervised and conducted by certified pickleball instructors and sports physiologists.

#### Category

Rehabilitation

### 2

#### Description

Control group: Participants in this group did not receive any specific pickleball training intervention. They continued with their usual daily activities, and no structured exercise program was assigned to them. However, to monitor and control physical activity levels, participants were assessed weekly using a physical activity questionnaire.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Bahonar University of Kerman

**Full name of responsible person**

Shima Sheikhbahaie

**Street address**

Shahid Bahonar University, Imam Khomeini Highway,  
Pajoohesh Square.

**City**

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76169-14111

**Phone**

+98 34 3132 3066

**Email**

sh18.shima@gmail.com

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

Shahid Bahonar University of Kerman

**Full name of responsible person**

Alireza Saidi

**Street address**

Shahid Bahonar University, Imam Khomeini Highway,  
Pajoohesh Square.

**City**

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Kerman

**Postal code**

7616913439

**Phone**

+98 34 3325 7168

**Fax****Email**

saidi@uk.ac.ir

**Web page address**

<https://uk.ac.ir/>

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

Yes

**Title of funding source**

Shahid Bahonar University of Kerman

**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**

Shahid Bahonar University of Kerman

**Full name of responsible person**

Shima Sheikh Bahaie

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Sport Medicine

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

Shahid Bahonar University of Kerman

**Full name of responsible person**

Shima Sheikh Bahaie

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Sport Medicine

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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**

Not applicable

**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 can be shared after individuals are de-identified.

**When the data will become available and for how long**

The data access period will begin immediately after the results are published.

**To whom data/document is available**

The data will be available to researchers, organizations, and departments related to the pickleball discipline for journals.

**Under which criteria data/document could be used**

To assist in scientific research and advance executive goals with the approach of improving the health of the elderly

**From where data/document is obtainable**

Shima Sheikh Bahaie sh18.shima@gmail.com

**What processes are involved for a request to access data/document**

Requests for data review will be responded to within one week.

**Comments**