

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 ≥ 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)

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+98 34 3132 3066

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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 ≥ 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

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

City

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

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Full name of responsible person

Alireza Saidi

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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**

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Other areas of specialty/work

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

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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