Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of gamification interventions on improving sedentary behaviors, self-care, and cognitive decline in the elderly: A Randomized Control trial study

Protocol summary

Study aim

determine the effectiveness of a gamification intervention compared with usual care on reducing sedentary behaviors, improving self-care, and reducing cognitive decline in older adults aged 60 years and older.

Design

Parallel randomized controlled trial, single-blind, with two experimental and control groups, on 190 older adults aged 60 years and older (95 in each group). Randomization is performed using block randomization with blocks of 4 and 6 and an allocation ratio of 1:1. Trial phase is not applicable (non-pharmacological intervention).

Settings and conduct

A parallel, single-blind RCT in Yasuj, Iran, randomized 190 older adults (60+ years) from health centers, after informed consent, using block randomization into two groups of 95. The experimental group received an 8-week gamification intervention (3 sessions/week, 60–90 minutes each, groups of 10–15) including physical activity, cognitive training, and self-care discussion. The control group received usual care (health education and a pamphlet). Pre- and post-test assessments were performed by a blinded assessor.

Participants/Inclusion and exclusion criteria

Older adults aged 60 years and older residing in Yasuj city, able to communicate verbally and perform activities of daily living, without severe cognitive impairment (MoCA score of 18 or higher), willing to participate and signing the informed consent form, will be included in the study. No specific exclusion criteria before randomization have been defined.

Intervention groups

Experimental group: Gamification intervention, 8 weeks, 3 sessions per week, each session 60 to 90 minutes, including physical activity, cognitive training, and self-care discussion. Control group: Usual care including general health education and a healthy lifestyle pamphlet, without gamification.

Main outcome variables

Sedentary behaviors; self-care; cognitive decline (cognitive function).

General information

Reason for update

Acronym

GAMOS: Gamification for Mobility, Older adults, and Self-care

IRCT registration information

IRCT registration number: **IRCT20240718062460N4**
Registration date: **2026-10-20, 1405/07/28**
Registration timing: **prospective**

Last update: **2026-10-20, 1405/07/28**
Update count: **0**

Registration date

2026-10-20, 1405/07/28

Registrant information

Name

ayoub hashemi

Name of organization / entity

University of yasouj

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of gamification interventions on improving sedentary behaviors, self-care, and cognitive decline in the elderly: A Randomized Control trial study

Public title

The Effect of Cognitive and Physical Games on Mobility, Self-care, and Memory in Older Adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 years or older. Residence in Yasouj city. Ability to communicate verbally and perform activities of daily living. No severe cognitive impairment (MoCA score ≥ 18). Willingness to participate in the study and signing the informed consent form.

Exclusion criteria:

Voluntary withdrawal at any stage of the study. Development of an acute illness or exacerbation of chronic diseases during the intervention period. Missing more than 3 consecutive sessions or 5 non-consecutive sessions of the intervention. Lack of cooperation in completing the questionnaires or performing the between-session assignments.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block randomization was performed with variable block sizes of 4 and 6 and an allocation ratio of 1:1. No quasi-randomization methods were used. Unit of randomization: Individual. Stratification: Stratified randomization was not used for allocation. Randomization tool: Computer-generated random number software. Random sequence generation: The random sequence was generated by an independent statistician, separate from the research process, using computer-generated random number software, in random blocks of variable sizes of 4 and 6 with an allocation ratio of 1:1. The sequence was kept confidential until allocation. Allocation concealment: Allocation concealment was performed using opaque, numbered, and sealed envelopes. The contents of the envelopes were prepared by an individual independent of the research process, and the envelopes were numbered sequentially. The envelopes were impermeable to light, and the next numbered envelope was opened only after recording the participant’s name and details and obtaining informed consent.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single-blind. Only the outcome assessors and the data analyst are unaware of group allocation (data are analyzed using codes A/B). Participants, researchers, and intervention providers are not blinded due to the non-pharmacological and interactive nature of the study. There is no data monitoring committee.

Placebo

Not used

Assignment

Parallel

Other design features

The aim of this study is to evaluate the effectiveness of a non-pharmacological intervention (gamification) on improving sedentary behaviors, self-care, and cognitive function in older adults. This study does not aim to treat a specific disease, prevent disease occurrence, diagnose disease, or screen. Rather, its purpose is to improve physical and mental health, function, and quality of life in older adults and reduce complications associated with aging. Therefore, the option "Supportive Care (and Rehabilitation)" is the most appropriate classification for the primary purpose of this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahroud University of Technology

Street address

Research Ethics Committee, Shahroud University of Technology, Hafte Tir Boulevard, Shahroud, Iran

City

semnan

Province

Semnan

Postal code

3619995161

Approval date

2026-05-06, 1405/02/16

Ethics committee reference number

IR.SHAHROODUT.REC.1405.007

Health conditions studied

1

Description of health condition studied
Sedentary behaviors
ICD-10 code
Z72.3
ICD-10 code description
Lack of physical exercise

2

Description of health condition studied
Self-care
ICD-10 code
Z74.1
ICD-10 code description
Need for assistance with personal care

3

Description of health condition studied
Cognitive Decline
ICD-10 code
R41.81
ICD-10 code description
Age-related cognitive decline

Primary outcomes

1

Description
Primary Outcome Variable 1 - Sedentary Behaviors: Score of sedentary behaviors in older adults measured using the Physical Activity Scale for the Elderly (PASE) and daily step counts recorded by a digital pedometer.
Timepoint
Measurement is performed at two time points: before the start of the intervention (pre-test) and immediately after the end of the 8-week intervention (post-test).
Method of measurement
Physical Activity Scale for the Elderly and a digital pedometer to record daily step counts.

2

Description
Description of Primary Outcome Variable 2 – Self-care: The self-care ability score of older adults, measured using the Persian version of the Self-Care Ability Scale for the Elderly (SASE).
Timepoint
Measurement is performed at two time points: before the start of the intervention (pre-test) and immediately after the end of the 8-week intervention (post-test).
Method of measurement
Self-Care Ability Scale for the Elderly, Persian version.

3

Description
Description of Primary Outcome Variable 3 – Cognitive Decline: The cognitive performance score of older adults, measured using the Persian version of the Montreal Cognitive Assessment (MoCA-P).
Timepoint
Measurement is performed at two time points: before the start of the intervention (pre-test) and immediately after the end of the 8-week intervention (post-test).
Method of measurement
Montreal Cognitive Assessment, Persian version.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: The gamification intervention consists of 8 weeks, 3 sessions per week, with each session lasting 60 to 90 minutes. The sessions are held in groups of 10 to 15 older adults at local health centers in Yasouj. The structure of each session includes the following components: Warm-up and review of weekly assignments: 10 minutes Gamified physical activity: 20 to 30 minutes, including balance, strength, and aerobic exercises with game elements such as team challenges, individual competition, and receiving badges Gamified cognitive training: 20 to 30 minutes, including group mental games such as memory, attention, and problem-solving with challenge cards and scoring Group discussion and self-care: 10 minutes, including exchanging experiences about medication management, nutrition, sleep, and mental health using educational cards Summary and setting individual challenges for the next week: 5 minutes The scoring system is designed based on the Octalysis framework. Each participant receives 140 base points at the beginning of the week. Completing the daily assignment earns 10 points, completing the group assignment earns 10 points, attending the session earns 5 points, active participation earns 5 to 10 points, and winning the group challenge earns 10 bonus points. If the daily assignment is not completed, 20 points are deducted. Progress levels include Beginner from 0 to 200 points, Silver from 201 to 500 points, Gold from 501 to 800 points, and Platinum from 801 points and above. Badges include the First Step badge for completing the first week of the intervention, the Teamwork badge for the highest cooperation with the team, and the Persistence badge for attending all sessions. Between-session assignments include daily walking for at least 30 minutes using a pedometer, performing a simple mental game such as crossword puzzles or Sudoku, and recording medication intake, sleep quality, nutrition, and self-care status in self-care cards.
Category
Rehabilitation

2

Description
Control group: The control group receives only routine care. This care consists of a general health education session and the provision of a pamphlet on a healthy lifestyle. Additionally, they are provided with a pedometer to track their daily step count; however, no gamification interventions are implemented for them.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasouj Comprehensive Health Centers
Full name of responsible person
Dr. Ayoub Hashemi
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Postal code
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
yasouj university
Full name of responsible person
Dr. Seyed Mohamad Zamani
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Yasouj University, Daneshjoo Street, Yasouj, Kohgiluyeh and Boyer-Ahmad Province, Iran
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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
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
Full name of responsible person
Dr. Ayoub Hashemi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person
Dr.Ayoub Hashemi
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Person responsible for updating data

Contact

Name of organization / entity

Yasouj University

Full name of responsible person

Dr. Ayoub Hashemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Geriatrics

Street address

Yasouj University, Daneshjoo Street, Yasouj, Kohgiluyeh and Boyer-Ahmad Province, Iran

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Kohgilouyeh-va-Boyrahmad

Postal code

7591874934

Phone

+98 74 3100 3000

Email

a.hashemi@yu.ac.ir

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

Yes - There is a plan to make this available

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

Title and Further Details about the Data/Document - English: Document Title: De-identified individual participant data and supporting trial documents. Details: After the study completion and publication of the main results, de-identified individual participant data (without name, national ID, address, and contact information) can be shared. These data include demographic information, scores of the Physical Activity Scale for the Elderly, the Self-Care Ability Scale for the Elderly, the Montreal Cognitive Assessment, and pedometer data. Access is provided only after a written request from eligible researchers, approval by the ethics committee, and signing a confidentiality agreement. Raw data that can identify individuals and identity information will not be shared under any circumstances.

When the data will become available and for how long

Data access will begin 6 months after the publication of the main study results and will remain available for 5 years.

To whom data/document is available

Access to de-identified data is possible only for researchers working in academic and scientific institutions, after submitting a written request, approval by the ethics committee, and signing a confidentiality agreement. Individuals working in industry or other non-scientific organizations are not permitted to receive the data.

Under which criteria data/document could be used

The de-identified data and study documents may be used only for non-commercial research purposes, including secondary analyses, meta-analyses, verification of findings, and advancing scientific knowledge in the field of older adult health. Commercial, industrial, or for-profit use of the data is prohibited. Conditions of use include: Submitting a written request stating the specific research purpose. Obtaining approval from the requesting institution's ethics committee. Signing a data use agreement that includes a commitment not to attempt re-identification of individuals, not to transfer the data to third parties, and to cite the original study in publications. Publishing results from secondary analyses only with citation of the original study as the data source. Not using the data for clinical, diagnostic, or commercial purposes. Full compliance with confidentiality and research ethics principles.

From where data/document is obtainable

Applicants may request access to the de-identified data or study documents in the following order: Submit a written request via email to the principal investigator: Dr. Ayoub Hashemi Email: a.hashemi@yu.ac.ir Send an official letter by post to: Yasuj University, Daneshjoo Street, Yasuj, Iran Postal Code: 7591874934 Attention: Dr. Ayoub Hashemi Call Yasuj University for further guidance: Phone: 0098 74 33221000 Visit the university website for additional contact information: www.yu.ac.ir Applicants must state in their request the research purpose, their affiliated institution, and their commitment to confidentiality principles and the conditions of use.

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

The process for requesting access to de-identified data or study documents is as follows: Submit a written request: The applicant sends a request via email to the principal investigator (Dr. Ayoub Hashemi, a.hashemi@yu.ac.ir). The request must include the applicant's name and affiliated institution, specific research purpose, type of data or documents needed, approval from the applicant's institutional ethics committee, and a commitment to confidentiality and conditions of use. Acknowledgement of receipt: The research team acknowledges receipt of the request

within a maximum of 5 working days. Initial review: The principal investigator and research team review the request for alignment with study objectives, non-commercial use conditions, and completeness of documents. This stage takes 1 to 2 weeks. Referral to the ethics committee: If initially approved, the request is referred to the Ethics Committee of Yasuj University for final approval. This stage takes 2 to 4 weeks. Notification of outcome: The outcome (approval, rejection, or need for revision) is communicated to the applicant. Signing the data use agreement: If approved, the applicant and their institution must sign a data use agreement that includes a commitment not to attempt re-identification, not to transfer data to third parties, and to cite the original study in publications. Data preparation: The de-identified data and requested documents are prepared by the research team. This stage takes 1 to 2 weeks. Secure data delivery: Data are delivered via an encrypted link or the secure server of Yasuj University. This stage takes about 1 week. Total timeframe: If the request is complete, the entire process usually takes 6 to 10 weeks. Incomplete requests or those requiring revision take longer. Also, access to data before the end of the embargo period (6 months after publication of the main results) is not possible.

Comments

This study is a randomized, parallel, single-blind clinical trial with a non-pharmacological intervention. The intervention under investigation is gamification for older adults, and the control group receives only usual care. This project was approved by the Research Ethics Committee of Shahroud University of Technology with ethics code IR.SHAHROODUT.REC.1405.007, and its execution site is Yasuj University. Financial support for the project is provided by the Iran National Science Foundation. No placebo, pharmaceutical agent, or invasive intervention is used in this study. Trial registration will be performed before the start of sampling. Also, there is no conflict of interest for the principal investigator and project collaborators.