Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of 8 weeks Multi-Component program (VIVIFRAIL) on gait, balance and quality of life in the elderly with slight limitation

Protocol summary

Study aim
Evaluation of 8 weeks Multi-Component program (VIVIFRAIL) on gait, balance and quality of life in the elderly with slight limitation

Design
A randomized, controlled clinical trial with two experimental and two control groups on 34 subjects. The Random.org website was used for randomization.

Settings and conduct
This study is applied in terms of its objective and prospective in terms of its timeframe. It will be conducted using a quasi-experimental design with a pre-test-post-test format and two groups: experimental and control. Participants will be randomly assigned to one of the two groups. The experimental group will undergo multicomponent training based on the Vivitrail protocol for a duration of 8 weeks, while the control group will receive no intervention. The variables of gait, balance, and quality of life will be assessed before and after the intervention. Practices and exams will be held at the Kerman Faculty of Physical Education and Sport Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having a minor limitation in the screening test Elderly people aged 60 to 75 years Female gender Informed consent from the elderly to participate in the study No history of stroke or inner ear disorders (39). No answer to any of the questions on the Physical Activity Readiness Questionnaire (PARQ) was yes (39). Ability to walk independently (39). Exclusion criteria: Number of absences of more than 3 sessions during the protocol implementation stages Non-attendance at the pre-test and post-test Sedatives or any type of medication affecting the subjects' balance or cognitive status

Intervention groups
The experimental group will perform multi-component exercises based on the vivifrail protocol for 8 weeks, and the control group will not receive any intervention during this period.

Main outcome variables
Balance Spatial and temporal parameters of gait Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250410065276N1**
Registration date: **2025-05-25, 1404/03/04**
Registration timing: **prospective**

Last update: **2025-05-25, 1404/03/04**
Update count: **0**

Registration date
2025-05-25, 1404/03/04

Registrant information

Name
Maryam Talai zade

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3244 3468

Email address
talaizade.maryam@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-20, 1404/03/30

Expected recruitment end date
2025-07-21, 1404/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of 8 weeks Multi-Component program (VIVIFRAIL) on gait, balance and quality of life in the elderly with slight limitation

Public title
The effect of 8 weeks Multi-Component program (VIVIFRAIL) on gait, balance and quality of life in the elderly with slight limitation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a slight limitation in the screening test Seniors 60 to 75 years old Female gender Obtaining informed consent from the elderly to participate in the study No stroke or inner ear disorders The answer to any of the questions on the Physical Activity Readiness Questionnaire (PARQ) is not yes. Ability to walk independently
Exclusion criteria:
Number of absences of more than 3 sessions during the protocol implementation process Absence from pre-test and post-test Sedatives or any type of medication that affects the subjects' balance or cognitive status
Age
From **60 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
To select subjects in the first stage, explanations about the purpose of the research and its implementation will be provided orally to assess the participation of volunteers for cooperation. After receiving written consent, the individual and physical fitness of the participants will be assessed by completing questionnaires and interviews. Based on the results, those who did not meet the necessary conditions (such as a history of surgery or serious injury) were excluded from the study process. Finally, 34 people who are eligible for the study will be purposefully selected and, after a pre-test, will be randomly divided into two training and control groups (each group includes 17 people) through the RANDOM.ORG website.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
University of Medical Sciences campus, beginning of Haft Bagh Alavi axis, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.KMU.REC.1403.538

Health conditions studied

1

Description of health condition studied
elderly with slight limitation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Spatial and temporal parameters of walking
Timepoint
At the beginning of the study and 3 days after completing the exercise protocol
Method of measurement
These parameters are evaluated by placing markers on the subjects' lower limbs and analyzing the video taken of walking with a Canon camera in the Kinovea software.

2

Description
Balance
Timepoint
At the beginning of the study and 3 days after completing the exercise protocol
Method of measurement
Mini-BESTest

Secondary outcomes

1

Description
Balance and Coordination
Timepoint
At the beginning of the study and 3 days after completing the exercise protocol
Method of measurement
Six Spot Step Test

2

Description
Quality of life
Timepoint
At the beginning of the study and 3 days after completing the exercise protocol
Method of measurement
Quality of Life Questionnaire (SF-36)

Intervention groups

1

Description
Intervention group: Multi-component exercise program (resistance, flexibility, balance and gait) called VIVIFRAIL for 8 weeks, at least 3 sessions per week for 45-60 minutes.
Category
Other

2

Description
Control group: This group will not do any exercise at the same time as the training group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Domus Pensionatorum Mehr
Full name of responsible person
Mohammad Soleimani
Street address
Madar Park, Parastar Blvd, Kerman
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1414771118
Phone
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info@cspf.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Shahid Bahonar University of Kerman
Full name of responsible person
Dr. Alireza Saeidi
Street address
Shahid Bahonar University of Kerman, Pajouhesh Square, Imam Khomeini Highway, Kerman
City
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Province
Kerman
Postal code
7616913439
Phone
+98 34 3325 7141
Email
saidi@uk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Shahid Bahonar University of Kerman
Proportion provided by this source
1
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
Maryam Talai zade
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Master's student in sports injuries and corrective exercises
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No. 2, Alley 25, Arnos Street
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Person responsible for scientific inquiries

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Position
student

Latest degree
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Other areas of specialty/work
Master's student in sports injuries and corrective exercises

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information 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
In this section, the shared data will pertain to the primary outcomes of the study and general participant characteristics. The data will be anonymized, removing any personally identifiable information, and will be available in aggregate form for future research or scientific collaboration. Information including primary outcome measures, such as gait, balance, and Quality of life, will be made publicly accessible.

When the data will become available and for how long
The data will be publicly available six months after the publication of the study results. This period allows sufficient time for data analysis and necessary reviews.

To whom data/document is available
The data and documentation of this study will be available to researchers affiliated with academic and scientific institutions. Additionally, researchers working in industry or other related fields may also request access to the documentation, provided that their intended use is for scientific research and the advancement of knowledge in the field of elderly exercise.

Under which criteria data/document could be used
In this study, in addition to the aforementioned conditions for those authorized to request non-identifiable individual data or other study documents, the following conditions apply: Authorized Analysis Types: Data is only permitted for scientific and research analyses. Commercial use or non-scientific purposes are prohibited. The analysis should be conducted in a way that no identifiable information can be derived from the data. Permitted Use of Documents: Documents are only permitted for scientific review, analysis related to the research outcomes, and advancing research related to aging and fall prevention. Usage Limitations: Data and documents must not be transferred to any third party and should only be used for the specific research project for which access was requested. Request Submission Conditions: Applicants must submit an official request form along with a project description and the intended use of the data. Requests must be sent via email or the designated online system. All requests will be reviewed by the ethics committee and the data management officer. Access Period: Access to data is only permitted

during a specified period after the study results have been published and final data approval by the principal investigator. Privacy Protection: All data should be protected in accordance with data privacy laws (such as GDPR or similar regulations in different countries).

From where data/document is obtainable

talaizade.maryam@gmail.com

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

The process for requesting and accessing the documents or data files is as follows: Submitting a Request: The applicant must send their request via email to the specified addresses (talaizade.maryam@gmail.com). The request should include personal information, the reason for accessing the data, and the type of data requested. Review of Request After receiving the request, the responsible party will review it and may request additional information from the applicant. This step typically takes 5 to 7 business days. Evaluation of Conditions Requests will be evaluated based on the conditions mentioned in previous sections (type of use, allowed analyses, etc). This step may take an additional 7 business days. Sending Data or Documents: if the request is approved, de- identified individual data or documents will be sent in an appropriate format to the applicant. This step typically takes between 7 to 10 business days. Total Duration: The entire process of requesting and receiving the documents typically takes between 2 to 3 weeks For further inquiries or status updates on the request, applicants can contact via the provided email addresses.

Comments