Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Independent and Combined Effects of Progressive Resistance Training and Nano-Curcumin on Physical Performance and Muscle Health in Older Adults with Confirmed Sarcopenia: A 2×2 Factorial Randomized Placebo-Controlled Trial

Protocol summary

Study aim
To evaluate the independent and combined effects of 16 weeks of progressive resistance training and nano-curcumin on physical performance and muscle health in older adults with sarcopenia

Design
Randomized, placebo-controlled, four-group, 2×2 factorial trial with 252 participants; variable block stratified randomization; study phase is not applicable

Settings and conduct
The study will be conducted at selected university and health centers. Supplement allocation will be blinded, and outcome assessors and data analysts will remain blinded to group allocation

Participants/Inclusion and exclusion criteria
Adults aged 65 to 85 years with confirmed sarcopenia according to EWGSOP2 and baseline SPPB scores of 4 to 10; major exclusions include unstable cardiovascular disease, severe renal or hepatic disease, active cancer or inflammation, significant cognitive impairment, and contraindications to curcumin

Intervention groups
Four groups: exercise plus nano-curcumin, exercise plus placebo, nano-curcumin, and placebo. Exercise will be performed three times weekly for 16 weeks; nano-curcumin will be administered at 40 mg twice daily

Main outcome variables
Change in total Short Physical Performance Battery score from baseline to week 16

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241205063953N7**
Registration date: **2026-09-12, 1405/06/21**
Registration timing: **prospective**

Last update: **2026-09-12, 1405/06/21**
Update count: **0**

Registration date
2026-09-12, 1405/06/21

Registrant information

Name
akram jafari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-21, 1405/06/30

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Independent and Combined Effects of Progressive Resistance Training and Nano-Curcumin on Physical Performance and Muscle Health in Older Adults with

Confirmed Sarcopenia: A 2×2 Factorial Randomized Placebo-Controlled Trial

Public title
Effect of Progressive Resistance Training and Nano-Curcumin on Physical Performance in Older Adults with Sarcopenia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 65 and 85 years Ability to provide written informed consent Confirmed sarcopenia according to the EWGSOP2 criteria Low muscle strength based on handgrip strength or five-times chair stand test Low appendicular skeletal muscle index measured by dual-energy X-ray absorptiometry Baseline SPPB score between 4 and 10 No regular resistance training during the previous three months Stable use of major medications and supplements for at least four weeks before enrollment Medical clearance for participation in moderate-to-high intensity resistance training
Exclusion criteria:
Unstable cardiovascular disease or uncontrolled hypertension Recent stroke or major surgery
Age
From **65 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **252**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated in a 1:1:1:1 ratio to the four study groups. The randomization sequence will be generated by an independent statistician using variable block randomization stratified by study center, sex, and sarcopenia severity. Allocation concealment will be ensured using a central randomization system or sequentially numbered, opaque, sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, outcome assessors, laboratory personnel, and data analysts will be blinded to nano-curcumin or placebo allocation. Nano-curcumin and placebo capsules will be identical in appearance and packaging and independently coded. Due to the nature of the resistance training intervention, blinding of participants and trainers to exercise allocation is not feasible; however, outcome assessors and data analysts will remain blinded to group allocation.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

1

Registry name
کمیته اخلاق دانشگاه ازاد اسلامی واحد شهرکرد
Secondary trial Id
IR.IAU.SHK.REC.1405.110
Registration date
2026-06-10, 1405/03/20

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Shahrekord Branch
Street address
Rahmatieh, Islamic Azad University Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817630003
Approval date
2026-06-10, 1405/03/20
Ethics committee reference number
IR.IAU.SHK.REC.1405.110

Health conditions studied

1

Description of health condition studied
Sarcopenia
ICD-10 code
M62.5
ICD-10 code description
Muscle wasting and atrophy, not elsewhere classified

Primary outcomes

1

Description
Change in total Short Physical Performance Battery score from baseline to week 16
Timepoint
Measurement at baseline before intervention initiation and at week 16 after completion of the intervention
Method of measurement
Using the Short Physical Performance Battery assessment including balance test, walking speed test,

and chair stand test, performed by a trained outcome assessor blinded to group allocation

Secondary outcomes

1

Description
Knee extension muscle strength
Timepoint
Measurement at baseline before intervention initiation and at week 16 after completion of the intervention
Method of measurement
Using an isokinetic dynamometer to assess knee extension strength by a trained assessor

2

Description
Appendicular skeletal muscle index
Timepoint
Measurement at baseline before intervention initiation and at week 16 after completion of the intervention
Method of measurement
Using dual energy X ray absorptiometry to measure appendicular lean mass divided by height squared

3

Description
Quadriceps muscle quality
Timepoint
Measurement at baseline before intervention initiation and at week 16 after completion of the intervention
Method of measurement
Using muscle ultrasound to assess muscle thickness and echo intensity of the quadriceps muscles including rectus femoris and vastus lateralis

4

Description
Sarcopenia related quality of life
Timepoint
Measurement at baseline before intervention initiation and at week 16 after completion of the intervention
Method of measurement
Using the validated Persian version of the sarcopenia specific quality of life questionnaire

5

Description
Handgrip strength
Timepoint
Measurement at baseline, week 8, and week 16
Method of measurement
Using a standard handgrip dynamometer in a seated position according to a standardized handgrip strength assessment protocol

6

Description
Knee extension muscle strength
Timepoint
At baseline before intervention initiation and at the end of week 16
Method of measurement
Measured using an isokinetic dynamometer

7

Description
Appendicular skeletal muscle mass index
Timepoint
At baseline and at the end of week 16
Method of measurement
Appendicular lean mass measured by dual-energy X-ray absorptiometry and divided by height squared

8

Description
Quadriceps muscle thickness
Timepoint
At baseline and at the end of week 16
Method of measurement
Measured by muscle ultrasound in the rectus femoris and vastus lateralis using standardized settings

9

Description
Quadriceps muscle echo intensity
Timepoint
At baseline and at the end of week 16
Method of measurement
Measured from grayscale ultrasound images of the rectus femoris and vastus lateralis using fixed ultrasound settings

10

Description
Sarcopenia-specific quality of life score
Timepoint
At baseline and at the end of week 16
Method of measurement
Measured using the validated Persian version of the Sarcopenia Quality of Life questionnaire

11

Description
Handgrip strength
Timepoint
At baseline, week 8, and the end of week 16
Method of measurement
Measured using a standard handgrip dynamometer according to a standardized assessment protocol

12

Description

Walking speed

Timepoint

At baseline, week 8, and the end of week 16

Method of measurement

Measured using the standardized four-meter walking speed test

13

Description

Five-times chair stand test time

Timepoint

At baseline, week 8, and the end of week 16

Method of measurement

Measured as the time required to complete five consecutive chair stands according to a standardized protocol

14

Description

Timed Up and Go test time

Timepoint

At baseline, week 8, and the end of week 16

Method of measurement

Measured as the time required to stand from a chair, walk three meters, return, and sit down according to a standardized protocol

15

Description

Serum irisin concentration

Timepoint

At baseline and at the end of week 16

Method of measurement

Measured in serum using a validated enzyme-linked immunosorbent assay kit in the central laboratory

16

Description

High-sensitivity C-reactive protein concentration

Timepoint

At baseline and at the end of week 16

Method of measurement

Measured in serum at the central laboratory using a validated laboratory assay

17

Description

Serum interleukin 6 concentration

Timepoint

At baseline and at the end of week 16

Method of measurement

Measured in serum using a validated immunoassay in duplicate at the central laboratory

18

Description

Serum tumor necrosis factor alpha concentration

Timepoint

At baseline and at the end of week 16

Method of measurement

Measured in serum using a validated immunoassay in duplicate at the central laboratory

19

Description

Serum insulin-like growth factor 1 concentration

Timepoint

At baseline and at the end of week 16

Method of measurement

Measured in serum using a validated laboratory assay at the central laboratory

20

Description

Serum myostatin concentration

Timepoint

At baseline and at the end of week 16

Method of measurement

Measured in serum using a validated immunoassay at the central laboratory

21

Description

Serum alanine aminotransferase concentration

Timepoint

At baseline, week 8, and the end of week 16

Method of measurement

Measured using a standard clinical blood chemistry assay

22

Description

Serum aspartate aminotransferase concentration

Timepoint

At baseline, week 8, and the end of week 16

Method of measurement

Measured using a standard clinical blood chemistry assay

23

Description

Serum alkaline phosphatase concentration

Timepoint

At baseline, week 8, and the end of week 16

Method of measurement

Measured using a standard clinical blood chemistry assay

Intervention groups

1

Description

Intervention group 1: Participants in this group will receive progressive resistance training for 16 weeks, three sessions per week. The exercise program will include resistance exercises targeting major upper and lower limb muscles with gradually increasing intensity

under supervision of a trained instructor. In addition, participants will receive nano-curcumin 40 mg twice daily.

Category

Rehabilitation

2

Description

Intervention group 2: Participants in this group will receive progressive resistance training for 16 weeks, three sessions per week. The exercise program will include resistance exercises targeting major muscle groups with gradually increasing intensity under supervision of a trained instructor. This group will receive a placebo identical to nano-curcumin.

Category

Rehabilitation

3

Description

Intervention group 3: Participants in this group will receive nano-curcumin 40 mg twice daily for 16 weeks. Participants will receive usual lifestyle advice and will not participate in the resistance training program.

Category

Lifestyle

4

Description

Control group: Participants in this group will receive placebo identical to nano-curcumin for 16 weeks. The placebo will be identical in appearance, packaging, and physical characteristics to the nano-curcumin product. Participants will not participate in the resistance training program.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University Shahrekord Branch

Full name of responsible person
Mehrdad Yadegari Dehkordi

Street address
Rahmatieh, Islamic Azad University Shahrekord Branch

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Physioligy

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Latest degree

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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

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

De-identified individual participant data, study protocol, statistical analysis plan, analysis codes, and data dictionary will be made available to qualified researchers after publication of the primary study results. Requests will be reviewed by the research team based on scientific and ethical considerations.

When the data will become available and for how long

Access to data and documents will begin 6 months after publication of the primary study results and will remain available for 5 years.

To whom data/document is available

Academic researchers, scientists from research institutions, and qualified investigators submitting a valid scientific request will be eligible for access.

Under which criteria data/document could be used

Data will be available for scientific research purposes, valid analyses, and advancing knowledge in multiple sclerosis and exercise science. Data reuse must comply with research ethics principles and must not attempt participant re-identification.

From where data/document is obtainable

Requests for data access should be submitted to the corresponding investigator through the official email address of the research center. Final contact information will be provided after publication of the primary study results.

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

Requests will be reviewed by the research team. After scientific and ethical approval, a data use agreement will be completed and access to de-identified data will be provided.

Comments