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# Effects of a combined exercise programme on physical fitness, heart-rate regulation and continued physical activity in older adults

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| **Submission date**<br>14/08/2026 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>19/08/2026 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>18/08/2026 | **Condition category**<br>Other | [_] Individual participant data<br>[X] Record updated in last year |

## Plain English summary of protocol

Background and study aims

Ageing is accompanied by changes in muscular strength, endurance, balance, body composition, metabolism and the regulation of heart rate. These changes can affect independence and the ability to carry out everyday activities. Exercise programmes that combine several types of training may help older adults maintain or improve these capacities.

This study examines how a supervised programme combining resistance, aerobic endurance, flexibility, balance and coordination affects physical fitness, functional performance, body composition, metabolic health, heart-rate regulation and continued participation in physical activity. It also examines how these outcomes evolve during a subsequent six-month period when some participants continue supervised training and others stop attending the supervised programme.

Who can participate?

Men and women aged 60 years or older who are functionally autonomous and able to participate safely in physical exercise

What does the study involve?

Sixty older adults participate in the first phase. Participants are recruited from two institutions in Monterrey, Nuevo León. The centre from which they are recruited determines their first-phase group. This first comparison is therefore not randomised.

Participants recruited from Servicios Médicos of the Universidad Autónoma de Nuevo León complete a supervised multicomponent exercise programme three times per week. Participants recruited from DIF Casa Club del Adulto Mayor Los Altos receive no structured exercise programme and continue their usual recreational and social activities, such as board games, crafts and educational talks.

The exercise programme includes resistance, aerobic endurance, flexibility, balance and coordination activities. It is delivered for 24 effective weeks, three times per week, with each session lasting approximately 60 minutes. The difficulty and training load are adjusted according to participants' abilities and responses.

Assessments are performed before the programme, after three effective months and after six

effective months. They include body measurements, body composition and bone health, muscular strength, flexibility, aerobic endurance, mobility, balance, walking and chair-rise performance, blood pressure, glucose, cholesterol, triglycerides, heart-rate variability and stage of physical activity behaviour.
Supervised activities are interrupted for about one month because of an institutional closure. The first six effective months of training therefore take about seven calendar months.
After the first phase, 22 participants from the exercise group enter the second phase and are randomly allocated by a manual paper draw. Eleven continue supervised training and eleven stop attending the supervised programme. Participants who stop the programme are not required to avoid all physical activity, and independently performed activity is not systematically recorded. Both groups are assessed again at months 7, 9 and 12.

What are the possible benefits and risks of participating?
Possible benefits include maintenance or improvement of physical fitness, functional performance, cardiovascular and metabolic health, and confidence in participating in physical activity. Benefits cannot be guaranteed.
Possible risks include temporary fatigue, muscle soreness, sprains, soft-tissue or skeletal injury, dizziness or fainting. Cardiovascular complications may also occur during exercise, although they are uncommon. Participants are screened before participation, monitored during assessments and supervised sessions, and instructed to report symptoms immediately.

Where is the study run from?
The study is conducted through the Faculty of Sports Organization of the Universidad Autónoma de Nuevo León, the Centro de Salud y Bienestar of Servicios Médicos UANL, and DIF Casa Club del Adulto Mayor Los Altos in Nuevo León, Mexico.

When is the study starting and how long is it expected to run for?
August 2018 to September 2019

Who is funding the study?
The study is partly funded by the Programa de Apoyo a la Investigación Científica y Tecnológica of the Universidad Autónoma de Nuevo León, grant SA842-19. The investigators and participating institutions also provide material, facilities and logistical support.

Who is the main contact?
José Raúl Hoyos-Flores, jose.hoyosfl@uanl.edu.mx

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Silvia Carolina Medrano Mena

### ORCID ID
https://orcid.org/0000-0003-0840-2410

### Contact details
Faculty of Sports Organization, Universidad Autónoma de Nuevo León, Niños Héroes, Ciudad Universitaria

San Nicolás de los Garza, Nuevo León
Mexico
66455
+52 (0)81 1340 4450
silvia.medranomn@uanl.edu.mx

### Type(s)
Public, Scientific

### Contact name
Dr José Raúl Hoyos Flores

### ORCID ID
https://orcid.org/0000-0003-1486-4814

### Contact details
Faculty of Sports Organization, Universidad Autónoma de Nuevo León, Niños Héroes, Ciudad Universitaria
San Nicolás de los Garza, Nuevo León
Mexico
66455
+52 (0)81 1340 4451
jose.hoyosfl@uanl.edu.mx

# Additional identifiers

# Study information

### Scientific Title
Effects of supervised multicomponent training versus no structured exercise intervention on physical fitness, cardiac autonomic modulation and physical activity adherence in functionally autonomous older adults: a two-phase controlled study with a quasi-experimental first phase and a randomised maintenance-versus-cessation follow-up

### Study objectives
The overall objective was to examine the effects of a supervised multicomponent training programme on physical fitness, internal training load, cardiac autonomic modulation and physical activity adherence in functionally autonomous older adults, and to examine the subsequent evolution of these outcomes during supervised maintenance or programme cessation.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 18/02/2020, Institutional Ethics Committee, Technological Institute of Sonora (5 de Febrero No. 818 Sur, Ciudad Obregón, Sonora, 85000, Mexico; +52 (0)644 410 0900 ext 2139; flares@itson.edu.mx), ref: Dictamen No. 64

### Primary study design

Interventional

## Allocation
Non-randomized controlled trial

## Masking
Open (masking not used)

## Control
Uncontrolled

## Assignment
Parallel

## Purpose
Health services research, Health promotion and maintenance of physical and functional capacity in older adults through multicomponent exercise

## Study type(s)

## Health condition(s) or problem(s) studied
Healthy ageing, including physical fitness, functional performance, cardiometabolic health, cardiac autonomic modulation and physical activity adherence in older adults

## Interventions
The study comprises two consecutive phases. Recruitment begins on 4 June 2018 through advertisements, leaflets, notices and direct invitations addressed to older adults attending two institutions in Monterrey, Nuevo León, Mexico. Before recruitment, meetings are held with the authorities of each participating centre and the required institutional permissions are obtained.

Eligible volunteers within each institution are assigned anonymous identification codes and selected through a simple random-selection procedure until 30 participants have been enrolled at each centre. This random procedure is used only to select participants within each institution and does not determine allocation to the intervention condition.

Participants recruited from the Centro de Salud y Bienestar of Servicios Médicos, Universidad Autónoma de Nuevo León, constitute the experimental group. Participants recruited from DIF Casa Club del Adulto Mayor Los Altos constitute the concurrent control group. Therefore, the first phase uses a quasi-experimental, non-randomised, parallel-group design with a non-equivalent control group.

All participants receive a verbal and written explanation of the study procedures, potential benefits and risks and provide written informed consent before baseline testing. Baseline assessments are conducted between 13 and 24 August 2018 over two consecutive weeks, with one group assessed each week. Measurements are performed at the participating centres and at the Faculty of Sports Organization of the Universidad Autónoma de Nuevo León.

The experimental group begins supervised multicomponent training on 27 August 2018. The initial programme comprises 24 effective weeks, with three 60-minute sessions per week. Each session consists of a 10-minute warm-up, a 40-minute main section and a 10-minute cool-down. The programme combines resistance, aerobic-endurance, flexibility, balance and coordination

exercises. Training begins with an adaptation period and progresses through planned changes in exercise difficulty, intensity, volume and density according to participants' responses and tolerance.

Resistance training is performed approximately twice per week for about 20 minutes, targeting the major upper- and lower-body muscle groups. Training comprises approximately 1–3 sets of 8–12 repetitions, with progression from light intensities of approximately 40–50% to moderate intensities of approximately 60–80% of one-repetition maximum. Exercises include bodyweight activities, free movements and elastic resistance.

Aerobic-endurance training is performed three times per week for approximately 20 minutes per session, progressing from light or moderate to more vigorous perceived intensity. Activities include dance, marching, light jogging and movement drills, with intensity monitored through perceived exertion.

Balance and coordination are trained approximately twice per week for about 10 minutes using static and dynamic tasks, changes of direction, obstacle courses, body-weight transfer and coordinated movements with hoops, balls, ropes, cones and mats. Flexibility is trained approximately three times per week for 10–15 minutes using static and dynamic exercises performed without pain and progressed according to the participants' abilities.

The control group receives no structured exercise intervention. Participants continue their usual recreational and social activities at the institution, including board games, crafts and educational talks. These activities are not prescribed, structured or monitored as physical exercise and are not intended to reproduce any component of the multicomponent training programme.

Participants in the experimental and control groups are assessed at baseline (T1), after 3 effective months (T2) and after 6 effective months of intervention (T3).

Supervised activities are temporarily interrupted for approximately one month, from mid-December 2018 to mid-January 2019, because of an institutionally determined closure. This interruption is not planned as part of the intervention. Some participants informally report continuing physical activity during this period, but no activity is prescribed, restricted or systematically quantified. Delivery of six effective months of supervised training therefore extends over approximately seven calendar months.

Following T3, 22 participants from the experimental group enter the second phase. They are randomly allocated in a 1:1 ratio through a simple manual paper-draw procedure to a maintenance group (n = 11) or a programme cessation group (n = 11). No formal allocation-concealment mechanism is used.

The maintenance group continues supervised multicomponent training without interruption for a further six effective months. Training frequency remains at three sessions per week and session duration remains at 60 minutes. Intensity and volume are periodically adjusted within the prescribed ranges to maintain an appropriate relative training stimulus. These adjustments are intended to support the adaptations achieved during the initial intervention.

The programme cessation group discontinues the supervised programme delivered by the research team. Participants are not instructed to avoid habitual or self-directed physical activity. Consequently, subsequent activity varies among participants, and its type, frequency, duration

and intensity are not systematically recorded. Programme cessation therefore represents withdrawal from the supervised research programme rather than compulsory withdrawal from all physical activity.

Both second-phase groups are assessed 1 month after re-randomisation (T4), at month 9 (T5) and at month 12 (T6). The original control group is not assessed during the second phase. Baseline assessment is conducted over 2 weeks, whereas subsequent assessments are generally completed within 3-day windows. During the second phase, both groups are evaluated during the same assessment windows.

The study comprises 12 effective months of intervention and follow-up and approximately 13 calendar months because of the institutionally imposed interruption. Outcome-specific analyses may include fewer participants when technically valid measurements are unavailable. Such exclusions do not modify the original enrolment or group-allocation figures of the parent study.

## Intervention Type
Behavioural

## Primary outcome(s)
1. Physical fitness: Lower- and upper-body muscular strength measured using the number of complete repetitions performed in the 30-second chair-stand and 30-second arm-curl tests, respectively. Lower- and upper-body flexibility are measured as the distance achieved in the chair sit-and-reach and back-scratch tests, respectively. Aerobic endurance is measured as the number of complete steps performed in the 2-minute step test, and agility and dynamic mobility are measured as the completion time in the 8-foot up-and-go test. All measures form part of the Senior Fitness Test and are obtained at baseline (T1), month 3 (T2), month 6 (T3), month 7 (T4), month 9 (T5), and month 12 (T6). The original control group is assessed only at T1, T2, and T3.

2. Functional performance: Lower-extremity functional performance measured using the Short Physical Performance Battery (SPPB), comprising standing balance, usual gait speed, and repeated chair-rise tasks. It is assessed at baseline (T1), month 3 (T2), month 6 (T3), month 7 (T4), month 9 (T5), and month 12 (T6). The original control group is assessed only at T1, T2, and T3.

3. Anthropometry, body composition, and bone health: Body mass and standing height measured using a seca 700 mechanical scale and seca 220 height rod, respectively, and body mass index is calculated as kg/m2. These measurements are obtained at baseline (T1), month 3 (T2), month 6 (T3), month 7 (T4), month 9 (T5), and month 12 (T6). Fat mass, lean mass, bone mineral content, and bone mineral density are measured using dual-energy X-ray absorptiometry with a Lunar Prodigy scanner (GE Healthcare) at baseline (T1), month 6 (T3) and month 12 (T6). The original control group is not assessed after T3.

4. Cardiometabolic health: Systolic and diastolic blood pressure measured using manual auscultation using an aneroid sphygmomanometer and stethoscope. Fasting capillary glucose, total cholesterol, and triglycerides are measured using the Accutrend Plus system. These measures are obtained at baseline (T1), month 3 (T2), month 6 (T3), month 7 (T4), month 9 (T5), and month 12 (T6). The original control group is assessed only at T1, T2, and T3.

5. Heart rate variability as an indicator of cardiac autonomic modulation measured using 10-minute seated beat-to-beat heart-rate recordings obtained in the morning using the Polar Team2 system after 10–12 minutes of seated rest in a quiet, temperature-controlled

environment at baseline (T1), 3 effective months (T2) and 6 effective months (T3) in the control and experimental groups; months 7 (T4), 9 (T5) and 12 (T6) in the maintenance and programme cessation groups. The original control group is not assessed during the second phase.

6. Physical activity adherence and stage of behavioural change measured using the short Stages of Change for Exercise Questionnaire (CEC-E) and based on the Transtheoretical Model at baseline (T1), 3 effective months (T2), 6 effective months (T3), month 7 (T4), month 9 (T5) and month 12 (T6)

### Key secondary outcome(s)

### Completion date
27/09/2019

# Eligibility

### Key inclusion criteria
1. Men and women aged 60 years or older
2. Functionally autonomous older adults able to perform the physical assessments and exercise activities required by the study
3. Apparently healthy or presenting one or more stable, clinically controlled chronic conditions without associated complications that contraindicated exercise
4.Available and willing to attend the study assessments and, when applicable, the supervised multicomponent training programme
5. Able to understand and follow the instructions required for study participation

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
60 Years

### Upper age limit
120 Years

### Sex
All

### Total final enrolment
60

### Key exclusion criteria
1. Medical, musculoskeletal or functional contraindications that prevented safe participation in physical exercise or the study assessments
2. Presence of a pacemaker or another implanted cardiac device
3. Uncontrolled clinical conditions, including uncontrolled blood pressure of 160/100 mmHg or higher

4. Current chest pain, exertional angina, dizziness, fainting, unusual discomfort or other symptoms requiring medical evaluation before exercise participation

### Date of first enrolment
13/08/2018

### Date of final enrolment
24/08/2018

## Locations

### Countries of recruitment
Mexico

### Study participating centre
**Faculty of Sports Organization**
Universidad Autónoma de Nuevo León, Niños Héroes, Ciudad Universitaria
San Nicolás de los Garza, Nuevo León
Mexico
66455

### Study participating centre
**Centro de Salud y Bienestar, Servicios Médicos, Universidad Autónoma de Nuevo León**
Avenida Dr. José Eleuterio González, Mitras Norte
Monterrey, Nuevo León
Mexico
64460

### Study participating centre
**DIF Casa Club del Adulto Mayor Los Altos**
Jalostitlán, Colonia Los Altos
Monterrey, Nuevo León
Mexico
64370

## Sponsor information

### Organisation
Universidad Autónoma de Nuevo León

### ROR

https://ror.org/01fh86n78

# Funder(s)

**Funder type**

**Funder Name**
Universidad Autónoma de Nuevo León

**Alternative Name(s)**
Autonomous University of Nuevo León, UANL

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
Mexico

**Funder Name**
Investigator initiated and partly investigator funded

**Funder Name**
DIF Casa Club del Adulto Mayor Los Altos — facilities and logistical support

# Results and Publications

**Individual participant data (IPD) sharing plan**
De-identified participant-level data supporting the findings of this study may be made available from the corresponding authors upon reasonable written request after publication of the main study results. Requests will be evaluated according to their scientific purpose, participant privacy, ethical and institutional requirements, and compatibility with the original informed consent. Data will be shared only for approved research purposes and, where required, after completion of a data-use agreement. Direct personal identifiers will not be shared. No unrestricted public repository is planned. Requests should be directed to the corresponding authors through jose.hoyosfl@uanl.edu.mx.

**IPD sharing plan summary**
Available on request