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Effects of training with fitness equipment on physical and psychological health in adults and older adults

Submission date 15/07/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/07/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/08/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Strength training seems to offer benefits to adults and older people. An exercise programme has been developed specifically for older people to test the physical and psychological health benefits in adults and older people who train in short- and long-term programmes.

Who can participate?
Patients aged 50 and over with functional independence

What is the study about?
Participants are randomly assigned to one of three groups. An experimental group will train 2 days a week, another experimental group will train 3 days a week and a control group will not train. The participants will have an evaluation of their physical and psychological health where the changes produced by the applied exercise program will be checked in comparison with people of the same age who do not exercise.

What are the possible benefits and risks of participating?
The exercise program can improve the symptoms of the participants, and give them better physical, psychological and social health. This is not guaranteed, so this study is necessary because it is necessary to know how many weeks and training sessions are necessary to provoke these changes at these ages. The exercise training program has been shown to be safe, and the exercise is supervised by an experienced professional. Participants may feel a little more tired than usual immediately after the exercise session, or even the next day, and may stop training at any time.

Where did the study come from?
Catholic University San Antonio of Murcia (Spain)

When does the study begin and how long is it expected to last?
September 2019 to June 2021 (updated 06/08/2020, previously: July 2021)

Who is funding the study?
Ministerio de Ciencia, innovación y Universidades (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Psychophysiological effects of exercise training programs in older adults

Acronym
Exer-Age

Study objectives
1. A resistance exercise program will improve balance, functional capacity, strength, peak rate of force development (RFD), physical function and physical activity in the short and long term
2. People who follow a Mediterranean diet and exercise will have better results in body composition and blood values
3. The long-term resistance training program will improve bone mineral density
3. The resistance training program will improve physical fitness and condition and have a positive effect on depressive symptoms and psychological well-being, both in the short and long term, and will increase safety and reduce falls.
4. The exercise program is perceived as positive in the quality of life of the participants
5. Long-term exercise program practitioners have greater intrinsic motivation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2019 by Ethical Committee of Catholic University of Murcia (Campus de los Jerónimos, Guadalupe, 30107, Murcia, Spain; +34 (0)968 278 161; mjimenez@ucam.edu), ref: CE111908

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Physical inactivity, multimorbidity in people aged over 50 years

Interventions
The intervention program lasts 12 - 24 weeks (updated 06/08/2020, previously: 16 weeks). It consists of physical activity counselling and a resistance training program that has been developed according to current recommendations on physical activity in older adults (ACSM /AHA 2007). Every participant is instructed and supervised by sports science professional.

Nutritional and physical activity counselling:
The counselling is aiming to improve knowledge and understanding of the preventive and therapeutic effects of the Mediterranean diet and physical activity on chronic conditions and ageing conditions.

Activity program:
1. A combination of resistance-exercises to improve strength and balance (2/3 days per week)
2. Walking for exercise to improve aerobic capacity (2/3 days per week)
3. Flexibility exercises (2/3 days per week)
An experimental group will train two days a week, another experimental group will train three days a week and a control group will not train. Participants were randomly assigned to three different treatment arms. Participants are assigned to one of the two therapy groups based on a sequence generated by the online randomization tool at www.randomizer.org, following a parallel-group design.
Days of rest are accepted according to the patient's needs. Patients are instructed to record their daily activity (activity log).

1. Exercises:
1.1. Resistance exercises:
In order to train all major muscle groups, strengthening exercises comprise a combination of three lower body exercises, three core exercise and six upper body exercises.

Every exercise can be performed in two different variations: less intensive ('moderate intensity') or more intensive ('high intensity'). Some exercises are to be performed using an elastic resistance band (Thera-Band®) or resistance machines. Depending on the performance and the progress, participants can be instructed to increase intensity by resistance advancing to the next color of elastic band (yellow band = lower resistance; red band = higher resistance). The level of effort should be moderate (5 or 6 on a 10-point scale, where no movement is 0, and maximal effort of a muscle group is 10). Participants should perform 3 sets of 15 repetitions of every exercise. They are instructed to not hold their breath during the exercises in order to prevent exercise-induced blood pressure elevations.

1.2. Flexibility exercises:
Flexibility exercises (stretching) comprise two upper body and two lower body exercises. Participants are instructed to perform the exercises slowly, holding each position for approximately 15 seconds. They are instructed to stretch to a point of moderate tension without pain in the joints or muscles, gradually increasing the range of motion.

1.3. Balance exercises:
The program comprises two balance exercises that can be performed in two different variations ('basic' or 'intensive') depending on the participant's abilities.

2. Walking:
To improve aerobic capacity, participants are instructed to walk for exercise (around their homes) four times a week for 30 minutes. The level of effort should be moderate (5 or 6 on a 10-point scale, where sitting is 0 and all-out effort is 10). Depending on the physical activity habits and the abilities of the participant, it can be necessary to start with shorter walks of lower intensity.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, 12 and 24 weeks:
1. Muscle strength and power in arms and legs measured with load cell and lineal encoder:
1.1. Voluntary isometric strength test
1.2. Rate of force production
2. Mobility (habitual and maximal walking velocity) measured by 10-meter walk test
3. Daily physical activity measured by Global Physical activity questionnaire
4. Fall risk (mobility and balance) measured by Timed Up and Go test
5. Strength of the lower extremities measured by Chair Raise Test
6. Functional autonomy measured by GDAM battery test, SPPB battery test and grip strength
7. Mediterranean diet adherence measured by Mediterranean diet questionnaire
8. Nutritional status assessed by Mini Nutritional Assessment
9. Blood pressure measured by a digital monitor and blood biochemistry measured by Alele Afinion analyzer

Secondary outcome measures
Measured at baseline, 12 and 24 weeks:
1. Balance:
1.1. Static and dynamic balance measured on a force plate
1.2. Functional balance measured by Berg balance scale
2. Body composition measured by bioelectric impedance and by anthropometry ISAK method
3. Bone density measured by dual densitometry
4. Quality of life measured by SF36 questionnaire
5. Motivation and adherence measured by BREQ-3, BPNS questionnaire, Intrinsic Motivation Inventory scale, satisfaction with life scale
6. Depression measured by Geriatric Depression Scale (GDS-15) and depression scale (CESD-R)

Overall study start date
01/09/2019

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. People aged 50 years or older, women and men
2. Physically independent persons
3. People who don't have resistance training experience.
4. People who do not have any muscle-skeletal injuries

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
300 persons (50 per group). There will be three groups from 50 to 64 years old and three groups over 65 years old.

Key exclusion criteria
1. Serious mental disorders and/or diagnoses/conditions that prevent testing or training
2. The criteria of American College of Sports Medicine (e.g. severe cardiovascular disease)
3. Severe progressive (e.g. cancer) or neurological disease (e.g. advanced Alzheimer's disease)
4. Lower limb amputation
5. Inability to walk outside without assistance of another person
6. Alcohol abuse

Date of first enrolment
01/12/2019

Date of final enrolment
30/05/2020

Locations

Countries of recruitment
Spain

Study participating centre
Catholic University of Murcia
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Sponsor information

Organisation
Ministerio de Ciencia, Innovación y Universidades

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Sponsor type

Government

Website
https://www.ciencia.gob.es/portal/site/MICINN/contacto

Funder(s)

Funder type
Government

Funder Name
Proyecto Retos colaboración 2018 del Ministerio de Ciencia, innovación y Universidades con número de expediente: RTC-2017-6145-1 (Spain)

Results and Publications

Publication and dissemination plan
1. The study protocol will be published but is not yet available.
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		10/09/2020	18/08/2023	Yes	No