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Study Identification

Unique Protocol ID:	UCMurcia-BiohealthyPark
Brief Title:	Effectiveness of Bio-Healthy Park on Adult
Official Title:	Physical and Psychological Effectiveness of Bio-Healthy Park on Adult
Secondary IDs:	

Study Status

Record Verification:	July 2021
Overall Status:	Not yet recruiting
Study Start:	July 15, 2021 [Anticipated]
Primary Completion:	August 1, 2021 [Anticipated]
Study Completion:	September 30, 2021 [Anticipated]

Sponsor/Collaborators

Sponsor:	Universidad Católica San Antonio de Murcia
Responsible Party:	Principal Investigator Investigator: Noelia González-Gálvez [ngonzalez-galvez] Official Title: Principal investigator Affiliation: Universidad Católica San Antonio de Murcia
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: CE111908 Board Name: Maquinaria Bio-saludable: Diseño y fabricación de nueva maquinaria de fitness outdoor ergonómica, eficiente, saludable y con aplicación para dispositivos móviles (App) de valoracióin y control del entrenamiento Board Affiliation: UCAM Phone: Email: ngonzalez@ucam.edu Address:

Av. de los Jerónimos, 135, 30107 Guadalupe, Murcia

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Bio-healthy parks are an alternative for practicing physical activity outdoors and free of charge. However, there is no research that analyzes the effect of a planned training program in these parks. There are two types of parks under development, with and without externally added resistance. Therefore, general objective of this project are to evaluate the effect of 8 weeks of targeted training in bio-healthy parks on body composition, bone mineral density, blood pressure, strength, functional capacity, sarcopenia, sagittal disposition of the spine, quality of life, life satisfaction and Mediterranean diet adherence in adults and older adults. The present project will be developed through a randomized controlled trial, with 1 experimental and 1 control group, with pre-test and post-test, with intra-group and inter-group analysis for each of the dependent variables of the study. It will be measure body composition, bone mineral density, blood pressure, upper limb strength, lower limb strength, functional capacity, sarcopenia, sagittal disposition of the spine, Health-related quality of life, satisfaction with life and Mediterranean diet adherence. Experimental group will receive the exercise program on bio-healthy park machine with a frequency of 2 sessions per week of 55 minutes for 8 weeks. The control group will not perform any intervention program following their usual activity.

Detailed Description: The aging process is associated with physiological, psychological and functional deterioration. It has been demonstrated that the practice of physical activity can prevent, slow or reduce this deterioration. Bio-healthy parks are an alternative for practicing physical activity outdoors and free of charge. However, there is no research that analyzes the effect of a planned training program in these parks. There are two types of parks under development, with and without externally added resistance.

Therefore, the objectives of this project are to evaluate the effect of 8 weeks of targeted training in bio-healthy parks, with a frequency of 2 sessions per week on body composition, bone mineral density, blood pressure, strength, functional capacity, sarcopenia, sagittal disposition of the spine, quality of life, life satisfaction and mediterranean diet satisfaction in adults and older adults.

The present project will be developed through a randomized controlled trial, with 1 experimental and 1 control group, with pre-test and post-test, with intra-group and inter-group analysis for each of the dependent variables of the study.

The inclusion criteria are: (a) not having participated in a structured exercise program for at least 1 year, (b) being older than 50 years of age, and (c) being physically independent. The exclusion criteria are: (a) having musculoskeletal injuries or limitations that could affect the health and physical performance of the person; (b) being under medical prescription for taking medications that could influence physical performance; (c) not regularly attending the proposed sessions.

Body composition and bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA).

Blood pressure by means of an automatic device (Colin BP 880, Inc., Tampa, FL). Strength by manual dynamometry (TKK 5401; Co., Ltd., Tokyo, Japan) and maximal isometric strength of knee extension and biceps flexion.

Functional capacity will be assessed by means of the Chari stand test, gait speed, time up and go test and Short physical performance battery

(SPPB), Sarcopenia will be assessed taking into account the reference values established for muscle quality (hand grip strength and chair stand test), muscle quantity (DEXA fat-free mass) and functional competence (gait speed, time up and go test, SPPB and 400 meter walk) established by the European Consensus (EWGSOP2).

The Spinal Mouse device (Switzerland) will be used to assess the sagittal disposition of the spine (thoracic curve, lumbar curve and pelvic tilt) in standing and relaxed sitting. This technique is non-invasive.

Health-related quality of life and satisfaction with life will be assessed by means of the SF36 and The Satisfaction with Life Scale (SWL) questionnaires.

Mediterranean diet adherence will be assess with a Mediterranean diet adherence questionaire.

Experimental group 1 will receive the exercise program on bio-healthy machinery with a frequency of 2 sessions per week of 55 minutes for 8 weeks. The machines used will be rider, low gemini, high gemini, walk, bottoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be controlled by subjective perception of effort and heart rate (Polar 420). There will be a warm-up 8-10 minutes, a main part 40-45 minutes and a return to calm 5-10 minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be progressed every 2 weeks. The control group will not perform any intervention program following their usual activity.

Conditions

Conditions: Adult Disease

Keywords: Adults
Older
Physical activity
Exercise
Bio-healthy park
Training

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 120 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Bio-Healthy Park	Behavioral: Bio-healthy Park

Arms	Assigned Interventions
This group is the experimental group. The intervention program consisted in the realization of the program on bio-healthy machinery.	Experimental group will receive the exercise program on bio-healthy machinery with a frequency of 2 sessions per week of 55 minutes for 8 weeks. Experimental group 1 will perform the intervention program using machinery designed for self-loading use. The machines used will be rider, low gemini, high gemini, walk, bottoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be controlled by subjective perception of effort and heart rate (Polar 420). There will be a warm-up 8-10 minutes, a main part 40-45 minutes and a return to calm 5-10 minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be progressed every 2 weeks.
No Intervention: Control Adults and older assigned to the control group will not received any structured exercise programme. They will maintain their usual physical activities.	

Outcome Measures

Primary Outcome Measure:

1. Muscle quality sarcopenia
   Sarcopenia will be assessed taking into account the reference values established for muscle quality. The muscle quality will be measure by hand grip strength test. This test will be performance with manual dynamometry (TKK 5401; Scientific Instruments Co., Ltd., Tokyo, Japan). Maximal isometric upper limb strength will be performance by maximal isometric strength. Upper strength will be register by kilogrammes. Higher value show high strength.

   [Time Frame: Changes from baseline to 8 weeks]

Secondary Outcome Measure:

2. Change Body composition
   Body composition will be assessed by dual energy X-ray absorptiometry (DEXA). This is noninvasive technique. The result will be register in absolutes and percentages results.

   [Time Frame: Changes from baseline to 8 weeks]
3. Change Blood pressure
   Blood pressure and heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). This is noninvasive technique. The result will be register in millimeters of mercury (bood pressure) and number of pulse per minutes (heart rate).

   [Time Frame: Changes from baseline to 8 weeks]
4. Change Chair stand test
   Chair stand test measure the functional capacity. This is a easy physical test. This test measures the functionality of getting up and sitting down from a chair five times. The participant have to performance the test as faster as possible. The total time is recorded in seconds. A better time indicates better functional ability.

   [Time Frame: Changes from baseline to 8 weeks]
5. Change Upper strength
   Maximal isometric upper limb strength will be performance by maximal isometric strength of knee extension and biceps flexion with load cell. Maximal isometric lower limb will be registered in newton. Higher value show high strength.

   [Time Frame: Changes from baseline to 8 weeks]
6. Change Sagittal spinal curvature

Sagittal spinal curvature will be assess with the Spinal Mouse device (Switzerland). It will be measured: angle of the dorsal and lumbar curve and pelvic tilt when standing and in asthenic sitting. This is noninvasive technique. The result is register in grades.

[Time Frame: Changes from baseline to 8 weeks]

7. Health-related quality
   Health-related quality of life will be assessed by means of the Short Form 36 questionaire. This questionaire have 11 questions and show result for 9 area: physical role, pain, general health, vitality, social function, emotional role, mental health, and evolution of the health care system. Each area is reported from 0 to 100 point. Higher score represent better health-related quality.

   [Time Frame: Changes from baseline to 8 weeks]

8. Satisfaction with Life Scale (SWL)
   Satisfaction with Life Scale (SWL) questionnaires include 5 affirmation about the satisfaction with the life and the participant have to answers from strongly agree to strongly disagree. The final score is reported from 5 to 35 point. Higher value show better satisfaction with life.

   [Time Frame: Changes from baseline to 8 weeks]

9. Adherence to the Mediterranean diet
   It will be used the Adherence to the Mediterranean diet. This questionaire have 14 questions (yes and no answer) about their adherence to the mediterranean diet. The sum of the answers are collect. Higher score show higher adherence to mediterranean diet.

   [Time Frame: Changes from baseline to 8 weeks]

10. Functional competence 400 meter walk
    Functional competence 400 meter walk is a test included in the European Consensus (EWGSOP2) to measure sarcopenia. Participant have to walk as fast as possible 400 meter. The total time is register.

    [Time Frame: Changes from baseline to 8 weeks]

11. Change bone mineral density
    Bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA). This is noninvasive technique. The result will be register in absolutes and percentages results.

    [Time Frame: Changes from baseline to 8 weeks]

12. Change heart rate
    Heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). This is noninvasive technique. The result will be register in number of pulse per minutes (heart rate).

    [Time Frame: Changes from baseline to 8 weeks]

13. Gait speed change
    Gait speed will be measure by 4. 6 and 10 meter test. This is easy physical test in with the participant have to walk 4. 6 and 10 metres as faster as possible. The result will be register in seconds. Less time indicates better functional ability.

    [Time Frame: Changes from baseline to 8 weeks]

14. Time up and go test change
    Time up and go test measure the functional capacity of getting up, walking and sitting down form a chair. Participant have to performance this test as faster as possible. This is a easy physical test. Total seconds are records. Less seconds indicates better functional ability.

    [Time Frame: Changes from baseline to 8 weeks]

15. Short physical performance battery (SPPB)
    Short physical performance battery (SPBB) include three test (balance, chair stand test and gait speed) and report a final score. Chair stand test and gait speed were describe in other outcome. Balance test is a easy physical test. The participant must maintain three balancing positions for 10 seconds to overcome it. Each test offers a different score. Higher score show better functional capacity.

    [Time Frame: Changes from baseline to 8 weeks]

16. Change in lower limb strenght

Maximal isometric lower limb will be performance by maximal isometric strength of knee extension with load cell. Maximal isometric lower limb will be registered in newton. Higher value show high strength.

[Time Frame: Changes from baseline to 8 weeks]

Eligibility

Minimum Age:	50 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria: • not having participated in a structured exercise program for at least 1 year; • being older than 50 years of age • being physically independent. Exclusion Criteria: • having musculoskeletal injuries or limitations that could affect the person's health and physical performance • being under medical prescription for taking medications that could influence physical performance • not regularly attending the proposed sessions.

Contacts/Locations

Central Contact Person:	Pablo Jorge Marcos-Pardo, PhD Telephone: 696243274 Email: pjmarcos@ual.es
Central Contact Backup:	Noelia Gonzalez-Galvez, PhD Telephone: 627146613 Email: ngonzalez@ucam.edu
Study Officials:	Pablo Jorge Marcos-Pardo, PhD Study Principal Investigator Universidad de Almería Noelia Gonzalez-Galvez, PhD Study Principal Investigator UCAM
Locations:	**Spain** Pablo Jorge Marcos-Pardo Murcia, Spain Contact: Pablo Jorge Marcos-Pardo, PhD 696243274 pjmarcos@ual.es Contact: Noelia Gonzalez-Galvez, PhD 627146613 ngonzalez@ucam.edu

IPDSharing

Plan to Share IPD:	No

References

Citations:

NOTE : Either PubMed ID or Citation Text should be specified.

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