

Effects of football versus aerobic exercise training on muscle architecture and patella tendon properties in healthy seniors: A study protocol of a two-armed randomized controlled trial.

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Study protocol

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Abstract

Background: Sports and exercise training can attenuate age-related declines in physical function. Aging is associated with a progressive deterioration of overall muscle structure and function, such as muscle diameter, strength, mass, and power. Loss of lower limb strength can lead to both an increased risk of falls and – as a consequence - an immobile lifestyle. Several forms of exercise (strength, agility, endurance, balance and flexibility) are recommended. In this regard, football has been repeatedly shown to be an integrative approach to promote measures of strength, endurance and agility. However, no previous randomized controlled trial comparatively investigated the effects of football training versus traditional aerobic exercise training on muscle architecture and patella tendon properties in healthy community dwellers. The study protocol is designed to investigate whether football differentially affects muscle thickness, muscle length, fascicle length, pennation angle, patellar tendon length, and thickness compared to a workload matched traditional aerobic exercise training regimen.

Methods: The study sample consists of 60 untrained but healthy men (50-60 years old), who will be randomly assigned (Strata: age, activate) to two groups: Football Group (n = 30), Aerobic Group (n = 30). The intervention will take place within 12 consecutive weeks, two times a week for 60 min each session. The football group will perform recreation football training as a large sided game, whereas the aerobic group undergoes a running exercise. Both groups have the same external workload ranging between moderate to high exercise intensity. The outcome measure will be collected before and after the intervention period.

Discussion: Findings of this study will provide insight into the effects of 24 sessions of both football and aerobic training program on the selected groups of seniors, including detecting their effects on the thigh muscle architecture and patellar tendon.

Trial registration: DRKS - German Clinical Trials Register, DRKS00020536. Registered 30 January 2020, https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00020536.

Administrative Information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Introduction

Background and rationale {6a}

Besides impaired endurance and balance performance, declines in muscle strength increase the risk of falls and immobility in elderly people. The overall decrease in muscle mass mainly contributes to the decline of muscle strength that is related to the process of aging [5]. The significant reduction of type II fast-twitch fibers is considered highly responsible for the decline in muscle cross-sectional area [25]. Muscle mass declines by 20 to 50% in humans between the ages of 40 and 80 years, which is accompanied by a decrease in muscle strength [6,22]. The annual strength decline from 50 years of age onwards amounts to 1.4% to 2.5% per year with an increasingly progressive loss of muscle fibers in the limbs [33,34]. Almost half of the muscle fibers are reported to be lost by the age of 80 years [22]. All these age-related changes lead to a variety of non-communicable diseases and health issues on individual and societal levels. In comparison, the sarcopenia as a condition characterized by progressive

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and generalized loss of skeletal muscle mass and function [43], dynapenia, for example, is referring to age-related declines of muscle strength, not necessarily as a result of neurological or muscular diseases [15]. Both sarcopenia and dynapenia cause limited force production capacity and contraction velocity.

In this regard, muscle architecture is considered an important contributor to the muscle's overall function. Crucial parameters of muscle architecture include muscle mass, muscle fiber length, pennation angle, and sarcomere length [50]. Furthermore, muscle size and force production are strongly influenced by fascicle arrangement (i.e., muscle architecture) within the muscle [3]. Many studies have shown that specific training programs have the potential to enhance cardiorespiratory fitness, metabolism, muscle strength, balance and psychological health of the elderly people [16]. In this regard, muscle architecture response to diverse loading regimens [13]. One of these training methods is recreational football training. Recreational football effectively stimulates musculoskeletal, metabolic and cardiovascular adaptations of importance for health and thereby reduces the risk of developing lifestyle diseases [28]. It has positive effects in various age categories and populations on muscular fitness, health profile and physical capacity [29]. Football can be regarded as a comprehensive recreational activity that effectively

improves metabolic fitness by improving blood lipid profile, fat oxidation, capillary density, muscle mass and glucose tolerance [33]. Also, football training can elevate the rate of force development and can lead to higher total lean body mass as well as better postural stability [44]. Moreover, elderly subjects exposed to lifelong football training have higher rapid muscle force characteristics, providing an enhanced ability to counteract unexpected perturbations in postural balance [44]. As a result, some special physical characteristics such as sports training can help to improve muscle architecture and prevent some of the physical illnesses and disabilities experienced by seniors.

Objectives {7}

The main objective of this randomized controlled trial purpose of the study is to investigate and compare the effects of football vs. traditional aerobic exercise training on muscle architecture, such as muscle thickness, muscle length, fascicle length, pennation angle, patellar tendon length, patellar tendon thickness, thigh muscle power, work, and torque. We hypothesize that workload-matched football training in comparison to aerobic exercise provides a stronger training stimulus on muscle architecture compared to traditional endurance training.

Trial design {8}

60 untrained men between 50 and 60 years old will be randomly assigned to experimental training groups, either a training group (n = 30) following Football Training program (FG) or a group (n = 30) following traditional Aerobic Training (AG). This sample includes a drop out of 15% and provides a moderately detectable change between the group with an alpha level of $p < 0.05$ and a study power of 85% (see power analyses). All participants need to be healthy, without presenting any cardiological, orthopedic and neurological impairment that can affect testing and training (see inclusion and exclusion criteria for details). The training will be carried out two times per week on nonconsecutive days over a period of 12 weeks. Measurements of the pre-test will take place 2 weeks before the start of the intervention, and the retest will be carried out directly after 24 training sessions

Methods: Participants, Interventions And Outcomes

The sample size was calculated by using "Gpower" software 3.1.9.2. α level of 0.05 and power of 0.85, according to (Beck 2013) recommendation [10]. 60 untrained but healthy men adults equally divided into two groups- mean \pm SD age 55 ± 5 . This sample includes a drop out of 15% and provides a moderately detectable change between a group with an alpha level of $p < 0.05$. Some of them had experienced some of the age-related neuromuscular problems or diseases, at least within the last year. Firstly, they will be asked to complete health and neuromuscular problems or a disease history questionnaire and to provide written approval from their health care provider. The data can arise from two samples of participants where each participant is measured twice before and after an intervention. The measurements used in the protocol will be taken before and after the intervention period (12 weeks). The post-intervention test will be scheduled in the following week after finishing the 12-week intervention period. Assessments will be performed at the Tishreen university hospital and the intervention period will take a place from 15/04/2020 until 15/7/2020 in the sports city Latakia/Syria.

Eligibility criteria {10}

Inclusion Criteria: 1) Healthy adult male volunteers between the ages of 50 and 60 years old. 2) Subjects must be in good health as determined by screening medical history, physical examination. 3) They must not suffer from any neuromuscular cardiovascular or psychiatric disorder. The International Physical Activity Questionnaire (IPAQ) will

be used to measure health-related physical activity in populations. IPAQ has reasonable measurement properties for monitoring population levels of physical activity among 18-65 years old adults in diverse settings [19]. The questions are about the time you spent being physically active in the last 7 days. They include questions about activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for [46].

Exclusion Criteria: 1) Subjects who have a significant history of alcoholism or drug/chemical abuse within the last 2 years. 2) Subjects with positive results on tests for drugs of abuse, or alcohol at screening and check-in. 3) History of unstable psychiatric disorder requiring medications or hospitalization within the previous 12 months. 4) History of a concurrent illness that required hospitalization within 14 days prior to Day-1 of the study. 5) Any condition that in the clinical judgment of the Investigator would make the subject unsuitable for participation. 6) Subjects who have had a clinically significant illness within 4 weeks prior to Day-1. 7) History or current evidence of clinically significant hepatic, renal, cardiovascular (i.e., deep venous thrombosis, pulmonary embolism), psychological, pulmonary, metabolic, endocrine, neurologic (i.e., transient ischemic attack or stroke within the past 6 months) infectious, gastrointestinal (i.e., any condition which may affect drug absorption) hematologic, oncologic disease, retinopathy, or other medical disorders. 8) History of unexplained syncope. 9) Subjects who, in the opinion of the Investigator, should not participate in the study.

Who will take informed consent? {26a}

All participants will be informed of all research protocols and details of the training program, including the applied load intensity. The responsible researcher will discuss the trial with participants in light of the information provided in the information sheets. We will obtain written consent from patients willing to participate in the trial.

participant data and biological specimens {26b}

Not applicable

Additional consent provisions for collection and use of

Interventions

Explanation for the choice of comparators {6b}

In spite of the increasing numbers of training programs research for seniors, many age-related diseases consider as serious factors that could threaten their health and life. Our research aims to discover the effects of two different training programs method in order to delay the appearance of retraction of muscle properties. There will be two different groups with no compare with the control group.

Intervention description {11a}

The training program will be carried out in two groups at the sports city training playground (Latakia, Syria), two times a week (60 min per session) on non-consecutive days for more than 12 weeks (24 sessions). Both groups will have the same session load. According to (Monoem et al.2017) [35], football players under 18 years old practice, small or large sided games with the average heart rate is 155-to-167 bpm (HRMAX is between 70–90%). To ensure similar training loads (i.e. volume × intensity) between groups despite differences in intensity, Session-rating of perceived exertion (RPE) will be used for the Football and Aerobic Groups. Participants should answer a simple

question: “How was your workout?” using the RPE scale table (1) [23] They should be familiarized with Foster's scale according to standard procedures, developed from (Borg, 1962). [14], before beginning to collect reliable measures. Rating 6, 8, 9 is not expressed. This single number provided retrospectively by the subjects refers to the mean intensity of the entire exercise session. Table (2) presents the CR-10 [23]. A single arbitrary unit representing the magnitude of global TL for each session is then calculated by the multiplication of training intensity and the length of training (min). $TL(A.U.) = RPE \times \text{session duration (min)}$. Where: TL is Training Load; A.U. is Arbitrary Units; RPE is the Rating of RPE. All sessions will include 5 minutes of warm-up at the beginning of the training session and 5 minutes cool-down at the end of it, for both groups. The warm-up will focus on pulse-raising, mobility, and preparatory stretching for the conditioning component with joint mobility (starting at the top of the body and working the way down, from the neck, shoulders, upper back, hips, and ankles) and continuous leg movement to facilitate the venous return and coordination exercises (toe-tapping arm circles, heel walks, high knee walk, backward high knee skip). Cool-down will include transition from conditioning component to the stretching phase, which comprises static and dynamic stretching exercises for all major muscle groups. Sessions will be deemed completed when at least 90% of the prescribed exercises have been successfully performed.

Table (1) Cr.10 scale (Foster et al.2001)

Descriptor	Very Easy	Easy	Moderate	Somewhat Hard	Hard	Very Hard	Maximal			
Rating	1	2	3	4	5	6	7	8	9	10

During the entire training study, subjects in AG will perform FIFA 11+ and Functional training (7-10) exercises using the major muscle groups. Running exercises at a slow speed combined with active stretching and controlled partner contacts (8 minutes). Six sets of exercises focusing on core and leg strength, balance and plyometric/ agility, each with three levels of increasing difficulty (10 minutes). Running exercises at moderate/high speed combined with planting/cutting movements (2 minutes). The exercises will be: Running exercises (Straight ahead, hip out, hip in, circling partner, shoulder contact, quick forwards and backwards) strength, balance and agility (Sideways Bench with leg, vertical hump, jumping box and lateral jumps, across the pitch, running plant and cut bounding, running with toe raise, squats one leg squad, squats walking lunges, hold the ball, single leg test your partner, single-leg Throwing the ball with partner, Hamstring). Every single exercise has 3-5 sets with 7-10 repetition, with 40 seconds rest break. At the same time, subjects in FG will perform the same training characteristics. In the main part of the training, we will practice on small game running (20-30-40 m) x 5-10 with 3-5 sets and 1-2 minutes rest between sets for (AG), and we will focus on more competitive activities like a large sided game or a football much in the (FG). The level of effort for muscle-strengthening activities should be between moderate and high. On a 10-point scale, where no movement is 0, and maximal effort of a muscle group is 10, the moderate-intensity effort is a 5 or 6 and high-intensity effort is a 7 or 8 (The ACSM guideline recommendation have been considered) (table 2). Both groups will have the same session load (moderate and high intensity) According to (Carlos et.al 2018) [16] football players practice small-sided games (including with 7 vs 7) with the average of heart rate is 155-to-167 bpm, so the intensity of small or large sided game is moderate and high (the percentage of HRMAX is between 70–85%) Table (2).

Table (2) Exemplary training programs for the aerobic and football group

Training Time	FG	AG	Sets	Rep	Rest	Intensity
5 Min	Warm up	Warm up	-	-	-	Low
20 Min	Fitness training (FIFA11+-functional training)	Fitness training (FIFA11+-functional training)	3-5	7-10	40 sec	Moderate
30 Min	Football Match (Competition activities)	Aerobic training (Running)	3-5	5-10	1-2 min	Moderate-High
5 Min	cool down	cool down	-	-	-	Low

Criteria for discontinuing or modifying allocated interventions {11b}

Any participant is excluded as soon as he gets a serious physically injury or if he is unable to follow up on the training sessions for any other reasons.

Strategies to improve adherence to interventions {11c}

The adherence reminder sessions will take place 15 minutes before every training session. This session will include:

- The importance of following a training program for general health.
- Instructions about how to practice carefully and how to avoid physical collision between participants, especially in competitions or games.
- The importance of adherence in order to develop the performance of the body, and the negative effects of absence from any training session.
- Instructions about the purpose of the study and the training plan.
- Instructions the importance of informing the coach about any injury or physical pain.
- Participants will have an opportunity to ask questions throughout the training program at any time.

Before the starting of every single month of the training program, there will be a special recreational trip in order to increase the motivation and commitment of participants.

Relevant concomitant care permitted or prohibited during the trial {11d}

- Participants are allowed to take an additional break in the first training sessions.
- Participants are allowed to drink specific amounts of water during training.

- Participants should not eat a meal at least two hours before the exercise.
- Participants should not use any additional assistive equipment during exercise.

Provisions for post-trial care {30}

The responsible researcher will have an obligation to provide all necessary care to anyone who might get injured during and after the training program period.

Outcomes {12}

The effects of football and aerobic training programs on muscle architecture (Cross-Sectional Area, Fascicle Length, Muscle Thickness, Pennation Angle), the range of motion, passive resistive torque, isokinetic muscular power, work, tendon length and thickness in seniors are considered as the primary outcomes. All other performance-related or health-related parameters serve as secondary outcomes.

Participant timeline {13}

Participants will be assessed according to their medical reports from 01/03/2020. After meeting all the eligibility recruitment, we will make appointments for the pre-tests in the next 14 days. The training program will take place from 15/04/2020 to 15/07/2020 and the post-tests will determine depending on a special schedule starting from 18/07/2020 (Figure 1).

The schedule of enrolment, interventions, and assessments:

Table (3) The schedule of enrolment, interventions, and assessments

Post-allocation															
Study Period (weeks)															
	Enrolment	Baseline	Post-Allocation												Follow-up
TIMEPOINT**	2 weeks	0	1	2	3	4	5	6	7	8	9	10	11	12	
ENROLMENT:															
Eligibility screen	X														
Informed consent	X														
Allocation		X													
INTERVENTIONS															
<i>Football Group</i>			X	X	X	X	X	X	X	X	X	X	X	X	
<i>Aerobic Group</i>			X	X	X	X	X	X	X	X	X	X	X	X	
ASSESSMENTS:															
<i>Vo2 max, explosive leg power</i>		X												X	
<i>Range of motion, Muscular power and work,</i>		X												X	
<i>muscle architecture</i> <i>(Coss-Sectional Area, Fascicle Length, Muscle Thickness, Pennation Angle) and tendon length</i>		X												X	

Sample size {14}

The sample size was calculated by using “Gpower” software 3.1.9.2. α level of 0.05 and power of 0.85, according to (Beck 2013) recommendation [10]. 60 untrained but healthy men adults equally divided into two groups- mean \pm SD age 55 ± 5 . This sample includes a drop out of 15% and provides a moderately detectable change between a group with an alpha level of $p < 0.05$. Some of them had experienced some of the age-related neuromuscular problems or diseases, at least within the last year. Firstly, they will be asked to complete health and neuromuscular problems or a disease history questionnaire and to provide written approval from their health care provider. The data can arise from two samples of participants where each participant is measured twice before and after an intervention. The measurements used in the protocol will be taken before and after the intervention period (12 weeks). The post-intervention test will be scheduled in the following week after finishing the 12-week intervention period.

Recruitment {15}

Volunteers will be recruited through posters published in the official newspapers in the Latakia city, as well as via social media. Recruiting will finish once the number of volunteers required is complete. There will be no paid incentives to participate in this study but the researcher will be responsible for all transportation costs and things necessary for sports (shoes, uniforms, water bottles).

Assignment of interventions: allocation

Sequence generation {16a}

The random allocation sequence will be created in permuted blocks of four and six using random allocation software version 1.0.0 [51].

Concealment mechanism {16b}

Allocation concealment will be achieved using sequentially numbered, opaque sealed envelopes [52]. Participants will be assigned to two intervention groups; a football group and running group in a 1:1 ratio, depending on the order they enrol in the study.

Implementation {16c}

This additional processing and outcome evaluation will be performed by an independent specialist.

Assignment of interventions: Blinding

Who will be blinded {17a}

The Researcher in charge of recruiting, outcome evaluation, and analysis will be blinded, and personnel in charge of evaluating and conducting interventions will be trained following the protocols designed for those objectives.

Procedure for unblinding if needed {17b}

In some cases, neither participants nor staff can be blinded to allocation. An employee outside the research team will feed data into the computer in separate datasheets so that the researchers can analyse data without having access to information about the allocation.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Ultrasonography:

This technique uses sound waves at fixed frequencies to create real-time images of the limb musculature in vivo (Esaote, Technos MPX, ultrasound). Conventional B-mode ultrasound can provide both quantitative and qualitative information on skeletal muscle tendons and ligaments [47]. Muscle ultrasound is a reliable method for the measurement of human fascicle lengths, pennation angle [32] and muscle thickness in B-mode images [42]. Also, ultrasound is a reliable and valid tool for the assessment of muscle size in older adults, ICC scores ranging from 0.92 to 0.999 [17]. Participants will report to the Human Performance Laboratory for ultrasound measurements after 72 hours without any vigorous physical activity. They will be instructed to lay supine for 15 minutes to allow fluid shifts to occur before images collection. A 10-MHZ linear probe scanning head (LA523 13-4) will be used to optimize spatial resolution and coat with water-soluble transmission gel and positioned on the skin surface to provide acoustic contact without depressing the dermal layer to collect the image. The length of the muscle fascicles and the pennation angle, which is the angle of insertion of the fascicles into the muscle's aponeurosis, represent the main structural parameters that can be detected via the conventional B-mode ultrasound modality [37]. Measures of cross-sectional area (CSA) and fascicle length (FL) will be obtained using a sweep of the muscle in the extended field of view mode with the gain set to 50 dB and image depth to 5 cm.5.

All measures will be in the rectus femoris, vastus lateralis, vastus medialis and patella tendon of the dominant leg. Subsequent measures will be taken using the same limb positioning and anatomical site and will perform by the same examiner. After scanning, all images will be analyzed with image analysis software (ImageJ, version 1.45s), which quantifies muscle quality in the form of echo intensity (EI). A known distance of 1 cm as shown in the image will be used to calibrate the software program [18]. For measures of rectus femoris and medialis, the participant will be placed supine on an examination table, according to the American Institute of Ultrasound in Medicine, with the legs extended but relaxed and with a rolled towel beneath the popliteal fossa allowing for a 10 bend in the knee as will measure by a goniometer [9]. For measures of the vastus lateral and medialis participants will be placed on their non-dominant leg side with the legs together and relax to allow a 10 bend in the knee as measured by a goniometer. The measurement of rectus femoris CSA will be taken in the sagittal plane parallel to the long axis of the femur, and scanning occurs in the axial plane perpendicular to the tissue interface at 50% of the thigh length. The fifty percent of thigh-length is determined as halfway from the anteroinferior iliac spine to the proximal border of the patella. Vastus lateralis and vastus medialis CSA measures at 50% of the distance from the most prominent point of the greater trochanter to the insertion. For all muscles, consecutive CSA images will be analyzed using the polygon tracking tool in the Image J software to obtain as much lean muscle as possible without any surrounding bone or fascia.

Fascicle Length: Fascicle length will be measured using the extended field-of-view mode. A longitudinal sweep begins near the distal insertion along the muscle and continues towards the proximal head of the muscle. Fascicle length is determined by identifying a clear fascicle that extends continuously from the superficial aponeurosis to the deep aponeurosis.

Muscle Thickness (MT): Measures of MT will be at the same as described for CSA but with the probe oriented longitudinally to the muscle tissue interface for the three muscles. Within each muscle, MT measures perpendicularly from the superficial aponeurosis to the deep aponeurosis.

Pennation Angle: The pennation angle of the rectus femoris, vastus lateralis, vastus medialis will be measured using B-mode ultrasound at the same site as MT and CSA [1]. The transducer will be longitudinal to the muscle tissue interface, and 1 image will be analyzed offline. Muscle fiber will be determined as the intersection of the fascicles with the deep aponeurosis.

Patellar tendon length and Cross-section area: Patellar tendon length will be measured via ultrasound scans ((Esaote, Technos MPX, ultrasound) at knee joint angle of 90° (0° corresponding to full extension), as the distance between tendon insertions on the patella apex and the tibial tuberosity. Tendon cross-sectional area will be measured from transversal ultrasound scans (linear array transducer 5cm, LA523,10 MHz transducer). The reliability of this technique has been shown previously [41]. Patellar tendon CSA is obtained as the average of two measurements performed at the proximal (CSAp) and distal (CSAd) insertions and at tendon mid-length (CSAm). The mean CSA of these three scans' positions will be used for further analysis. Patellar tendon length will be measured as the distance between the proximal insertion of the patellar tendon and the tibial insertion. The use of ultrasound to perform quantitative measurements of musculoskeletal tissues has shown reliability (Tendon CSA: ICC of 0.91–0.98 and 0.96–0.98 for tendon length) [24].

Isokinetic dynamometer test: An isokinetic dynamometer (Genu3 Easytech, Florence, Italy) will be used to estimate knee range of motion, passive resistive torque, power and work for thigh muscles in an angular speed of 90° per second. Test-retest reliability will take a place two weeks before the intervention (the same test twice over a period of time to a group of individuals). The scores from Time 1 and Time 2 can then be correlated in order to evaluate the test for stability over time. The Pearson product-moment correlation coefficient will be used to measure the strength of the linear relationship between the variables.

Range of motion measurement (ROM): To determine the range of motion (ROM), an isokinetic dynamometer (Genu3 Easytech, Florence, Italy) will be used. Participants will be seated with a hip joint angle of 110° and their knee will fully extend on the dynamometer. Moreover, participants will be secured with a strap on the upper body to exclude any evasive movement. The foot will be fixed with a strap to the footplate of the dynamometer. Moreover, the upper leg will be fixed with a strap to avoid any movement of the knee. Participants will first move to the neutral knee joint position in the dynamometer (90°). They will then regulate the motor of the dynamometer to get into dorsiflexion (stretching) position until the point of discomfort is reached.

Passive Resistive Torque (PRT): Subjects will be positioned with their hips at approximately 80° (to minimize hamstring stiffness) and their knees at a maximal extension. Stabilization straps are placed over the knee, foot, and ankle. The knee moves passively through six continuous cycles between 10° plantar flexion to 10° dorsiflexion at 90°/s, with neutral (0°) being the line of the tibia perpendicular to the footplate. The subjects will be instructed to do the maximum plantar and dorsiflexion. Visual analysis of the curves will demonstrate consistent torque profiles, which indicate passive resistive torque.

Isokinetic muscular power and work Test: The power of knee extensor and flexor muscles will be measured in a sitting position using isokinetic dynamometers (Genu3 Easytech, Florence, Italy). After warm-up exercises, patients perform 4 maximal concentric strokes at an angular speed of 90° per second (knee extension flexion; ROM, 90°-0°).

Isokinetic tests will be performed when patients have no pain or swelling with ROM more than 120° of flexion with full extension. To ensure maximal effort, 3 to 4 training sessions are allowed before performing the test.

Vertical jump test: Vertical jumps are often used as a measurement of lower-body power [40], and thus as an indirect measure of performance. The subject should, therefore, be instructed to jump as high as possible and land on the same spot. If the subject deviates too far from this point (a landing area/ spot can be marked out), then the result should be disregarded and the jump repeated. Once the test configuration has been set up and the subject and assessor are ready, then the test will begin: the participants should walk into the take-off/ landing area and, when instructed to by the assessor, jump as high as they can and land on the same spot. At the peak of their jump height, they should hit the vanes of the Vertec device to displace as many of them as possible. This should be repeated so that the athlete completes 3 jumps in total. This way, an average or best of the three jumps can be calculated. Jump height is determined by the difference between the participants standing reach height and the highest vane displaced. The results of the test are reported in terms of jump height (cm). To ensure a valid and reliable result, it is good practice to take an average of the three jumps performed by the athlete. The following formula can be used to calculate the average jump height: $\text{Average jump height} = (\text{jump 1} + \text{jump 2} + \text{jump 3}) / 3$. Alternatively, the best score (i.e. highest jump) out of the three jumps can also be used. Vertical jump testing has been shown to be a valid and reliable measure of lower-body explosive power [40].

Yo-Yo Intermittent Recovery Test: The YYIR tests are a simple method for examining an athlete's capacity to perform a repetitive high-intensity aerobic exercise [11]. Once the configuration of the tests has been set up, test-principal investigator/officials are positioned at both shuttle lines (cone B and C) and participants are ready, then the test will begin. Participants begin the test from cone B. When instructed by the audio player, they must run towards cone C (this must be reached before the following beep signal) and immediately return to cone B before the next signal. Once cone B is reached, participants then have a 10-second recovery period in which they must jog from cone B towards cone A, and then back to cone B before the commencement of the next shuttle. In this test, the participants are only allowed two consecutive fail attempts before they are withdrawn from the test. That being, if the individual fails to reach cone C and back to cone B in the allocated time, one fail is issued. If this happens a second consecutive time, then they are eliminated. Once withdrawn from the test, the individual's score must be recorded. The YYIR1 typically last for 5-15 minutes [11]. The test is comprised of 91 shuttles and can last up to approximately 29-minutes; however, it is very unlikely somebody will complete it. Scores can be presented in three ways: 1) total distance (meters); 2) level achieved; or 3) VO2 max. Total distance is more simple to understand and calculate, whereas level achieved is more complex as the test begins at level 5 and then skips to level 9 at the beginning. Yo-Yo test has been repeatedly proven as a reliable (ICC = 0.86 to 0.95) [45], also YYIR1 has been proven as a valid and reliable tool with high-reproducibility for measuring high-intensity aerobic capacity from various sports and competition-levels [27,20]. Also, The YYIR1 has been shown to be a moderately reliable predictor of VO2 max [33,45].

Plans to promote participant retention and complete follow-up {18b}

After confirming the commitment of the participants and obtaining papers proving their consent to participate, the responsible researcher will send reminders to attend their sessions through text messages, WhatsApp messages, and phone calls. All the participants can contact the intervention coordinator and the responsible researcher 24 hours a day by calling their cell phones.

Data management {19}

Data will be stored in the department of radiographs (Tishreen university hospital) in a password-protected computer file, to which only researchers will have access. Throughout the duration of the research study, the file password will be changed once a month. The responsible researcher will have a backup copy of all the information.

Confidentiality {27}

Files with participant's information will be coded with individual identification codes.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

The laboratory evaluation will be stored in a protected file on secure computer in the Radiology Department in University Hospital. Files with participant's information will be coded with individual identification codes, as explained above.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Analysis of covariance (ANCOVA) for analyzing between group effects from pre to post measurements will be computed separately for each of the outcome measures. Thereby, baseline values will be included as covariates [49]. In case of significant main effects or interaction effects, follow up post hoc tests will be computed. A significance level of $p < 0.05$ is set as default and pairwise comparison via effect sizes estimation will also be performed.

Interim analyses {21b}

Not applicable.

Methods for additional analyses (e.g. subgroup analyses) {20b}

The statistical analysis is performed by an independent statistician, blinded for the groups allocation by the end of the retest procedure. The statistician will report the results to the responsible researcher. The responsible will discuss the results with the supervisor.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Regression imputation: [53]

Imputation is the process of replacing the missing data with estimated values. Instead of deleting any case that has any missing value, this approach preserves all cases by replacing the missing data with a probable value estimated by other available information. After all, missing values have been replaced by this approach, the data set is analyzed using the standard techniques for a complete data.

In regression imputation, the existing variables are used to make a prediction, and then the predicted value is substituted as if an actually obtained value. This approach has a number of advantages because the imputation retains a great deal of data over the list wise or pairwise deletion and avoids significantly altering the standard deviation or the shape of the distribution. However, as in a mean substitution, while a regression imputation

substitutes a value that is predicted from other variables, no novel information is added, while the sample size has been increased and the standard error is reduced.

Plans to give access to the full protocol, participant level-data and statistical code {31 c}

Data sharing statement no later than 3 years after the collection of the 1-year post-randomisation interviews,

We will deliver a completely identified data set to an appropriate data archive for sharing purposes.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

Not applicable.

Composition of the data monitoring committee, its role and reporting structure {21 a}

There is no need for a formal data monitoring committee because of the short duration of the training program and the known minimal risks.

Adverse event reporting and harms {22}

The adverse event will be defined as any serious injury occurred in a subject without regard to the possibility of a causal relationship. Adverse events will be collected after the subject has provided consent and enrolled in the study.

If a subject experiences an adverse event after the informed consent document is signed (entry) but the subject has not started to receive study intervention, the event will be reported as not related to study drug. If training is discontinued as a result of an adverse event, study personnel will document the circumstances and data leading to discontinuation of the exercise.

Investigators will determine the relatedness of an event to study protocol based on the physical health situation for the subject before beginning the training program and the temporal relationship to the study training.

Frequency and plans for auditing trial conduct {23}

Not applicable.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any modification of the research procedures including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects, will lead to a change in the study protocol

It will be under the supervision of the responsible professor and approved by the Ethics Committee of Tishreen University prior to implementation.

Dissemination plans {31 a}

The results of our research will be disseminated on the scientific Journal with a minimum of "2" impact factor.

This research is a part of a Ph.D. thesis. The results will be presented several times to a resident committee.

Additional dissemination will occur through presentations at conferences, such as teacher education and science education conferences, regionally and nationally, and through articles published in peer-reviewed journals.

Discussion

Previous research has demonstrated that practicing small-sided recreational soccer games is an effective health-promoting activity for both untrained men and women. In untrained premenopausal women, thirty-seven subjects were randomized to two training groups -Football and running- training 1h with equal average heart rates for 16 weeks (twice a week). The results show that there are effects on both left ventricular systolic and diastolic function and The training-induced cardiac adaptations appeared to be more consistent after football training compared with running [7]. In the same way, fifty healthy women were matched and randomized to a football (n=25) or a running (RG, n=25) group and compared with a control group with no physical training. After 16 weeks, resting heart rate was lowered, maximal oxygen uptake was elevated and total fat mass decreased. [31]

For untrained men, (Krustrup et al. 2009) [29] have shown that recreational soccer training, organized as small-sided drills, has significant beneficial effects on health profile and physical capacity. In a study some aspects, it is superior to frequent moderate-intensity running training, after training performed for 1 h (two or three times per week) for 12 weeks; at an average heart rate of 82% and 82% (1%) of HR(max) for 36 healthy men in football group and running group. Recreational football stimulates both aerobic and anaerobic energy turnover and is an effective type of training leading to significant cardiovascular and muscular adaptations as well as performance enhancements throughout a 12-week training period [30]. Moreover, positive adaptations in cardiovascular fitness obtained over 12 weeks of regular recreational football training with further development in musculoskeletal fitness [39]. Also, (Andersen LJ et.al 2010) [7] have investigated whether football has favorable effects in the treatment of mild-to-moderate arterial hypertension. The study included 25 untrained males aged 31-54 years. They randomized to a football training group and a control group for 3 months. The results show that football as a treatment for hypertension can be an attractive non-pharmacological supplement to the treatment of mild-to-moderate arterial hypertension.

On the other hand, (Timmins et al. 2016) [48] studied the architectural adaptation of the long head of the biceps femoris after concentric or eccentric strength training in the adaptation period of training and detraining. The results show that short-term strength training can contribute to the architectural change in the long head of the biceps femoris. (Narici et al 2003) [36] examined the impact of aging on muscle architecture of the medial gastrocnemius in 14 young and 16 elderly physically active people, who have had the same height, body weight, and physical activity regime. Young people varied by age from 27 to 42 years and elderly people were 70–81 years old. Anatomical cross-sectional area and the volume of the medial gastrocnemius muscle were measured by computed tomography, and the length of the beams and pennation angle were measured by ultrasound. Anatomical cross-sectional area and the amount of muscle in the elderly amounted to 19.1 %, while in the young participants 25.4 %. Fascicle length and pennation angle also were smaller in the elderly group (10.2 % and 13.2 %, respectively). Another study Investigated whether increased tendon-aponeurosis stiffness and contractile strength of the triceps surae muscle-tendon units induced by resistance training would affect running economy. This study was conducted on an exercise group (n = 13) performed a 14-week exercise program. The results show After

resistant training intervention an increase in maximum plantarflexion muscle strength (a ~7 %) and an increase in triceps surae tendon-aponeurosis stiffness (a ~16 %). [2]

Another study [12] investigated the effects of sports training on muscle architecture; 8 female and 15 male athletes performed 4 weeks of sprint, jump, and resistance training in addition to their sports training (standardization) before adopting one of three different sports programs. Muscle size, fascicle angle, and fascicle length of the vastus lateralis and rectus femoris muscles (using ultrasound procedures) as well as 20-m sprint run, vertical jump, and strength performance changes were examined. Significant muscle size and architectural adaptations can occur in concurrently training athletes in response to a 5-wk training program, and these adaptations were possibly associated with the force and velocity characteristics of the training exercises. (Angelik et al 2019) has studied the rate of force development (RFD) and muscle architecture early adaptations in response to training with fast-or slow-velocity eccentric squats. Eighteen young novice participants followed six weeks (two sessions/week) of either fast-velocity (Fast) or slow-velocity (Slow) squat eccentric-only training. The results of this study suggest that fast eccentric resistance training may be more appropriate for increases in rapid force production compared to slow eccentric resistance training, and this may be partly due to increases in muscle fascicle length induced by fast eccentric training. Moreover, the main muscle architecture parameters, which were assessed through muscle ultrasound, were demonstrated some degree of alteration in the quadriceps femoris and gastrocnemius medialis, and each of these parameters may be theoretically useful for detecting the loss of muscle mass and functionality in geriatric patients. [47]

However, so far almost no studies compared the effects of football and running training interventions on the age-related decline of muscle strength and structure. This is the first study that aims at investigating the differential effects of football and running training response on muscle architecture, patella tendon properties, and thigh muscles. The proposed study should benefit participants physical, psychological and social dimensions. It is assumed that not only running and football training may result in the improvement of the aerobic capacity and systemic arterial blood pressure reductions, but also can improve the functional parameters, including increased explosive power strength, balance, agility, and functional capacity. As our primary hypothesis, we expect moderate differences between both groups in muscle architecture (Cross-Sectional Area, Fascicle Length, Muscle Thickness, Pennation Angle), knee range of motion, passive resistive torque, work, power and tendon length and thickness as football entails are broader and multimodal muscular stimulus compared to aerobic training alone. These may lead to overall decrease in obesity risk and stress, it could also prevent heart diseases, maintain muscle mass and reduce the risk of depression. Moreover, The training programs may enhance the tendon mechanical work and muscle architecture that causes a perceptible decrease in the probability of dynapenia and sarcopenia.

Trial status

The recruitment will start at 1/3/2020 and end at 15/03/2020.

Abbreviations

ROM: Range of motion, PRT: Passive resistive torque, MS: Isokinetic Muscular Strength Test, FL: Fascicle Length, MT: Muscle Thickness, CSA: Cross-section area, HR: Heart rate, ANCOVA: analysis of covariance, VO2max: maximal oxygen uptake, SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials.

Declarations

Funding:

The first researcher will finance the research, as it is part of his Ph.D. thesis. Please note that the researcher is delegated to Tishreen University in order to obtain Ph.D. degree. The first researcher will finance the research, as it is part of his Ph.D. thesis. Please note that the researcher is delegated to Tishreen University in order to obtain Ph.D. degree.

This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Protocol amendments:

Protocol amendments will be documented with the date and a description of the change.

Ethics approval and consent to participate:

All patients will provide written consent, prior to participation. This study has been approved by the Tishreen University ethical committee number 4406.

Consent for publication:

Not applicable.

Competing interests:

The authors declare that they have no competing interests.

Acknowledgements

Not applicable

Authors' contributions {31b}

LD conceived of the study. LD and GA initiated the study design. GA is responsible for the implementation of the practical section of research and the data collection. LD and GA provided statistical expertise in trial design and GA is conducting the primary statistical analysis. All authors contributed to refinement of the study protocol and approved the final manuscript.

Funding {4}

The first researcher will finance the research, as it is part of his Ph.D. thesis. Please note that the researcher is delegated to Tishreen University in order to obtain Ph.D. degree.

This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Availability of data and materials {29}

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

Ethics approval and consent to participate {24}

Human Research Ethics Committee approval has been obtained through the Tishreen University Ethics Committee on 08/04/2019. Number: 4406.

Consent for publication {32}

Not applicable

Competing interests {28}

The authors declare that they have no competing interests.

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Figures

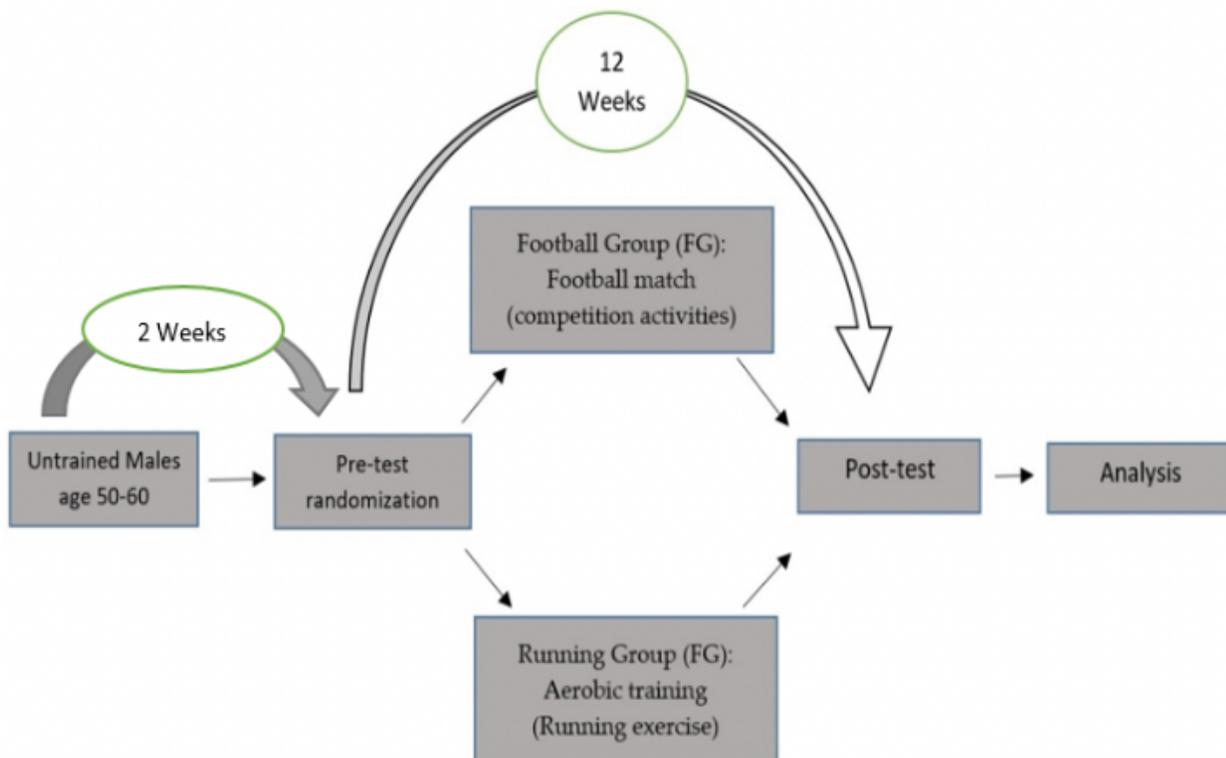


Figure 1

Participant timeline and study design.