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Investigating the association between intralimb strength ratio, interlimb strength and range of motion asymmetry index, and functional limitations with fall incidence among older adults: protocol for a prospective cohort study

Zahra Nasiri,[1] Amir Letafatkar ,[1] Mahdi Hosseinzadeh [2]

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[1]Department of Biomechanics and Sport Injuries, Kharazmi University, Tehran, Iran (the Islamic Republic of)
[2]Department of Sport Injuries and Corrective Exercises, Sport Sciences Research Institute, Tehran, Iran

Correspondence to
Dr Mahdi Hosseinzadeh; Metti@ssrc.ac.ir

ABSTRACT

The present study aims to identify the intralimb strength ratio, interlimb strength and range of motion asymmetry index in elderly individuals and then investigate the association between these asymmetry indices and functional limitations among older adults. 200 eligible elderly individuals will participate in this study. Muscle strength and range of motion will be assessed for eight lower limb muscle groups. The asymmetry of muscle strength and range of motion will be calculated. The variables of functional limitations, for example, falling, walking, static balance and dynamic balance status, will be evaluated. The significance of risk factors for fall incidence and functional limitations will be investigated using the multiple linear regression analysis, which will create a separate model with each of the strength and range of motion asymmetries variables. Predictive performance of strength and range of motion asymmetries for fall incidence and functional limitations will be conducted by the corresponding receiver-operating curve to define a cut-off for strength and range of motion asymmetries. This prospective cohort will provide important data on interlimb strength and range of motion asymmetry with functional limitation and fall incidence in elderlies. If successful, the potential benefits from reducing between-limb asymmetry in selected muscle strength or range of motion will be of high interest to the professionals and researchers who work with elderly adults. Finally, the holistic picture of the imbalances/asymmetries this cohort provides will potentially have implications for improving functional capacity and reducing fall incidence in the elderly population.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Interlimb strength and range of motion (ROM) asymmetry are normal in human physiology but tend to become more pronounced with ageing.
⇒ These asymmetries can lead to compensatory movement patterns, increasing the risk of falls, joint pain and overall functional decline.
⇒ There is a lack of studies identifying the interlimb strength and ROM asymmetry index in elderly individuals and investigating the association between these asymmetry indices with functional limitations and fall incidence among older adults.

WHAT THIS STUDY ADDS

⇒ This study will assess the intralimb strength ratio, interlimb strength and ROM asymmetry index in elderly individuals.
⇒ It will further investigate the association between these asymmetry indices, functional limitations and fall incidence.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The holistic picture of the imbalances/asymmetries provided by this cohort will potentially have implications for improving functional capacity and reducing fall incidence in the elderly population.
⇒ Targeted exercises, rehabilitation and lifestyle modifications can be designed as appropriate interventions to address asymmetry and functional limitations investigated in this study.

INTRODUCTION

Background and rationale

Interlimb strength and range of motion (ROM) asymmetry refer to the differences in muscular strength and joint flexibility between the left and right limbs.[1] These asymmetries can be a normal part of human physiology but tend to become more pronounced with ageing, contributing to functional limitations and increased risk of falling-related injury in older adults.[2] Strength asymmetry occurs when one limb is significantly stronger than the other. In older adults, this can result from disuse, muscle atrophy, neurological

conditions or the natural ageing process.[3] Strength asymmetry can lead to compensatory movement patterns,[4] increasing the risk of falls,[5 6] joint pain[7] and overall functional decline.[6] ROM asymmetry, for example, differences in flexibility and joint ROM between limbs, can stem from joint degeneration, previous injuries or chronic conditions such as arthritis.[8] ROM asymmetry can affect gait, balance and the ability to perform daily activities.[3 9]

Interlimb strength and ROM imbalances can lead to functional limitations among older adults.[9] Functional limitations refer to difficulties performing activities necessary for independent living, such as walking, climbing stairs, dressing and bathing.[10] These imbalances can further impair walking patterns (gait),[11] making movements less efficient and increasing the risk of trips and falls.[5 11] This can limit an older adult's ability to move freely and confidently. Asymmetry in strength and ROM can make it challenging to perform daily activities requiring bilateral coordination, such as carrying groceries, getting out of a chair or reaching overhead. This can lead to a decrease in independence and quality of life. Limb strength and flexibility differences can disrupt balance and postural control.[7] Older adults may then experience difficulties with balance, increasing their fall risk and leading to potential injuries.[5–7]

Interventions to address asymmetry and functional limitations typically involve targeted exercises, rehabilitation and lifestyle modifications.[12 13] Focused resistance exercises help balance strength between limbs, improve muscle mass and enhance functional abilities. Furthermore, stretching and mobility exercises can address ROM asymmetry, improving joint function and overall flexibility. Personalised therapy programmes can address specific asymmetries and functional limitations, often incorporating a combination of strength, flexibility and balance training. Early detection and intervention are crucial in managing interlimb asymmetry and preventing functional decline. Regular assessments and personalised exercise programmes can help maintain functional independence and enhance the quality of life for older adults. However, to the authors' best knowledge, there is a lack of studies to identify the interlimb strength and ROM asymmetry index in elderly individuals and investigate the association between these asymmetry indices with functional limitations and fall incidence among older adults.

OBJECTIVES

Hence, the purpose of this study will be twofold (1) to assess the intralimb strength ratio, interlimb strength and ROM asymmetry index in elderly individuals in Tehran and then (2) to investigate the association between these asymmetry indices, and functional limitations and fall incidence, for example, to which extent functional limitations and fall incidence would be determined (ie, regressionally predicted) by selected measures of strength and ROM and/or by the degree of intralimb, interlimb asymmetry in these parameters.

The authors hypothesised that the intralimb strength ratio, interlimb strength and ROM asymmetry indices would be significantly greater in elderly faller individuals with functional limitations and that these parameters could predict the functional limitations and fall incidence.

METHODS AND ANALYSIS

This observational, longitudinal prospective cohort study with a 1-year follow-up is designed in agreement with Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[14]

Study setting and participants

This study will be conducted at the sports medicine laboratory of the Biomechanics and Sports Injuries Department of Sport Sciences Research Institute, Tehran, Iran. A cohort of approximately 200 elderly adults will be recruited. All participants will receive written and verbal information about the study setting and potential risks and will fill in their written consent following the Declaration of Helsinki II before participating. Participation in the study is voluntary, and participants can withdraw or leave the study without any further notice. Recruitment will be conducted via social media advertisements, presentations at senior centres in the Tehran municipality and public events.

Eligibility criteria

Inclusion criteria include 100 males and 100 females' older adults aged between 60 and 85 years who can ambulate. Participants will be excluded if they are care dependent, suffering disability in lower limb, medical conditions potentially preventing them from safely completing the physical-functional testing of the study including: (A) arthritis or arthrosis in knee or hip joints, arthritis requiring medication or other rheumatic diseases potentially affecting joints or muscles; (B) diagnosed or suspected knee osteoarthritis; (C) bilateral knee alloplastic and hip alloplastic material; (D) connective tissue disorders; (E) severe chronic obstructive pulmonary disease; (F) unstable cardiac arrhythmias or decreased left ventricular ejection fraction (<60%); (G) surgical diseases affecting ability to conduct heavy load strength exercise; (H) embodied magnetic metal; (I) endocrinological diseases potentially affecting muscles (diabetes mellitus, growth hormone-treated, sex hormone-treated or untreated thyroid diseases); (J) alcohol consumption >21 U/week for men and 14 U/week for women (1 U=15.2 mL of alcohol); (K) medications: systemic corticosteroids, sex hormone therapy, antisex hormone therapy, anticoagulants; (L) >1 hour of weekly heavy strength training; (M) dementia or other severe cognitive impairment and (N) not holding Iranian citizenship or not fluent in Farsi.[15]

Who will take informed consent?

The chief investigator retains overall responsibility for the informed consent of participants and will ensure that all those with delegated responsibility are authorised, trained and competent to participate according to the protocol, principles of Good Clinical Practice and Declaration of Helsinki.

Additional consent provisions for the collection and use of participant data and biological specimens

There are no additional consent provisions for collecting and using participant data. No biological samples will be collected.

Procedures: baseline and follow-up measurements

Data collection on the sociodemographic and medical history status, physical-functional limitations, ROM and strength status, and anthropometric indicators will be organised by the principal investigator (MH). It will be collected by an independent specialist of the research team (properly trained with more than 5 years of experience working on elderlies). The same evaluator will collect data for all the participants to minimise differences in data collection procedures. The initial evaluation will occur on 2 days separated by an interval of 2–7 days.[16] Participants' characterisation data will be collected on the first day, and the participants will get familiarised with the isometric manual muscle testing (Lafayette Instrument Company, Lafayette, Indiana, USA). Then, the ROM status and the senior physical and functional fitness test scores will be collected. The participants' lower limb peak torque (PT) during the maximum voluntary isometric contractions will be collected on the second day of the initial measurements. The PT will be evaluated during the isometric contraction since it is safer and more reproducible among older adults with limited ROM, pain and greater compensations in dynamic contractions.[17] The test–retest reliability of the assessment of each muscle group will be determined by calculating the intraclass correlation coefficient (ICC) using the two-way mixed effects model, considering the mean PT on the first and second day of the initial assessments in a smaller sample of the participants (approximately 50 participants).[17]

After the initial evaluation, the participants will be monitored by monthly telephone contact over the 12-month follow-up period of the study to collect fall incidence. The fall incidence was defined as the occurrence of any unintentional event that would result in a change of position of an individual toward a lower level than his initial position.[18] For appropriate fall incidence reporting during the study's follow-up period, the participants will be duly clarified for this concept on the first day of the evaluation.

Sociodemographic status

Information on chronological age (continuous variable), marital state (assessed as a four categories variable: single, married, widowed and divorced), level of education (elementary school or less, middle school, high school, university education) and medical history status will be collected for each participant. Participants will further report the number of times they fell during the past year using a self-report form. Participants will be considered 'fallers' if they reported one number of falls in the past year.

Anthropometric measurements

The standardised procedures described by Lohan *et al*[19] will be followed for the collection of anthropometric data, including body mass weight determined using a portable scale (Seca, model 770, Germany) with a precision of 0.1 kg, height determined using a portable stadiometer (Seca Body meter, model 208, Germany) with a precision of 0.1 cm, and body mass index (BMI), calculated according the formula (BMI=weight/height^2). Weight and height will be assessed with the barefoot older adults wearing shorts and a light T-shirt.

Independent outcomes (predictors)

Lower limb muscle strength status

A Lafayette Manual Muscle Testing System Model-01165 (Lafayette Instrument Company) will assess the lower limb isometric strength status. The device will be set to record the force in kg and calibrated once at the start of the study.

The previous researchers have not agreed on the methodologies used for lower limb assessment. Based on prior research, we will implement the procedures explained by.[20] These testing positions have shown strong reliability for the measurement of isometric strength in previous studies for the hip,[21] knee[22] and ankle[22] muscle groups. Isometric muscle strength will be assessed with the participants in three positions (seated, supine and prone). Hip flexors (with the participant seated and hips and knees flexed at 90°. Dynamometer placed on the anterior aspect of the thigh, proximal to the knee joint), knee extensors (with the participant seated and hips and knees flexed at 90°. Dynamometer placed on the anterior aspect of the shank, proximal to the ankle joint) and knee flexors (with the participant seated and hips and knees flexed at 90°). Dynamometer placed on the posterior aspect of the shank, proximal to the ankle joint); ankle plantarflexors (with the participant lying supine with the ankle in plantar grade and hips and knees extended. Dynamometer placed over the metatarsal heads on the sole of the foot), ankle dorsi-flexors (Ankle dorsi-flexors with the participant lying supine with the ankle relaxed and hips and knees extended. Dynamometer placed over the metatarsal heads on the dorsum of the foot), hip abductors (with the participant lying supine and hips and knees extended). Dynamometer placed on the lateral aspect of the shank, proximal to the ankle joint and hip adductors with the participant lying supine and hips and knees extended. Dynamometer placed on the medial aspect of the shank, proximal to the ankle joint; hip extensors with the participant lying prone and hips and knees

extended. Dynamometer placed on the posterior aspect of the shank, proximal to the ankle joint. These positions will be chosen to minimise changes in position by the participant to enhance the feasibility of testing in a clinical setting. All tests will involve maximal voluntary isometric contractions (MVIC). To assist the assessor in overcoming the force produced by the participant, the laboratory table will be placed close to a wall, which will aid the assessor in their resistance to the participants' contractions for muscle groups.[20] Each muscle group will receive a submaximal practice trial to ensure the participant understands the contraction required.[20] Participants will perform three MVICs separated by 30–45 s of rest. Participants will be instructed to contract as hard and fast as possible with strong verbal encouragement for approximately 4 s. The trial with the highest PT will be selected for further analysis. Attempts containing an initial countermovement will be disqualified, and a new trial will be performed.[15]

Intralimb strength ratio analysis

Following the primary goal of the study, the intralimb ratio will be determined on the basis of the so-called conventional H/Q ratio (hamstring-to-quadriceps ratio), which is calculated by dividing the concentric hamstring MVIC by the concentric quadriceps MVIC of the same limb[23]:

H/QCON ratio=HCON/ QCON.

Interlimb asymmetry analysis

Interlimb strength asymmetries for all isometric test variables (hip flexors, hip extensors, knee extensors, knee flexors, ankle plantar flexors, ankle dorsi-flexors, hip abductors and hip adductors) will be quantified as the percentage difference between the two limbs using the following equation (15):

(([strongest–weakest]/strongest)×100).

Lower limb ROM

Active ROM measurements will be selected because older adults' voluntary postural balance maintenance and motor control are related to falling. At the same time, passive ROM assessments do not reflect voluntary muscle activity. A double-arm (30 cm) stainless steel goniometer (Tsutsumi Corp., Kamagaya City, Chiba, Japan) will be used to measure all lower extremity ROMs.[24] Since most fall incidences happen during daily life and not during sports activities, especially at home more than away from home, participants will not be allowed to perform conventional warm-ups.[24] Participants will be notified to perform each ROM movement, provided time to rest between ROM measurements and then resume when they report they are ready to continue. To measure maximum ROMs, participants will be notified to move through full ranges of joint motions without pain, as far as possible, at comfortable speeds. ROM measurements will be initiated when participants are familiar with each ROM movement. ROM measurements will be performed in the following order: supine (hip flexion, abduction and adduction ROMs), prone (hip extension and knee flexion ROMs) and seated positions (internal and external hip rotation ROMs and ankle dorsiflexion and plantar flexion ROMs). The evaluator will closely observe whether compensatory movements (posterior pelvic tilt or anterior pelvic tilt) occur or not during measurements; if movements are present, measurements will be redone. When a fixed arm of the goniometer is placed perpendicular to the floor, the evaluator will confirm the position with his eyes. The positions within the anatomic landmarks required for ROM measurements will be confirmed with his hands. Those of the right lower extremity will follow the left lower extremity measured at each position at the same positions. All ROMs will be measured twice in degrees, and the best values of each motion's right and left sides, respectively, will be used for analysis.[24] The same formula for calculating the interlimb strength asymmetries for the isometric test variables will be acquired for the interlimb ROM asymmetries.

Dependent outcomes (criterion variables)

Functional limitation outcomes

Timed up and go test

The agility and dynamic balance are evaluated with the timed up-and-go test (TUG). The TUG test is a timed test that requires the participants to stand up from a chair with an armrest, walk 3 m to a line on the floor, turn around, return to the chair and sit down. Previous studies have suggested that a cut-off time of 13.5 s should be used as a threshold for identifying community-dwelling older adults with an increased risk of falling.[25 26]

The 10 m walk test

The valid and reliable 10m walk test[27 28] will be carried out to assess walking velocity. A 20 m walkway, including 5 m for acceleration and 5 m for deceleration, will allow participants space to accelerate/decelerate outside the data collection area. Each participant will complete three consecutive trials for each walking test. Participants will be instructed to 'walk at their comfortable, usual pace' until they reach the end of the marked path. The fastest trial will be recorded.

Tinetti Performance Oriented Mobility Assessment

Performance Oriented Mobility Assessment (POMA) is an assessment consisting of two parts: gait and balance. The gait evaluation section consists of 12 points while the balance evaluation comprises 16 points. Gait and balance scores are combined for a total possible score of 28 points, with higher scores representing better function. To determine the participant's gait quality, the assessor asked the participant to walk 25 feet each way across the room while assessing any hesitation, step length and height, leg distance, step symmetry and step continuity. For the balance part of the Tinetti assessment, the assessor observed the quality of the movements and the ability of the participant to maintain balance in different

positions, including sitting on a chair, standing up from a chair, standing balance, standing balance while tapping on the chest, 360° rotation, standing balance with closed eyes, and sitting.[29] The POMA test is reliable in older adults (ICC=0.75–0.97).[30]

The 30 s chair-stand test

The participants will be asked to rise and sit back down in a chair as many times as they can for 30 s, maintaining arms crossed at the level of the chest with wrists resting against it. The total number of stand-ups will be counted.[31]

Standing stork balance test

The standing stork balance test was used to measure the static balance of the participants, who were required to maintain a one-leg standing position on the non-dominant leg,[32] with the opposite foot against the inside of the supporting knee and both hands on the hips. The stopwatch was started as the heel was lifted from the floor, and the time spent in this position was measured.[33] The recorded time ended when one or both hands separated from the waist, the support foot changed position (moved) or the foot resting on the opposite knee lost contact.[34] The standing stork balance test is reported as a reliable indicator of balance.[35] In the instance where someone could not perform the test due to poor balance, they scored 0 s.

Composite functional limitation measure

The composite sum of the Z-scores of the five tests mentioned above parameters will be calculated to provide a global index for functional limitation, which will be used in the subsequent statistical analysis.

Sample size estimation

A sample size calculation was conducted using G*Power (University of Kiel, Germany). The specific parameters for this calculation were as follows: an exact test within the bivariate normal model, employing an a priori approach to compute the required sample size based on the specified α, power and effect size. Using a two-tailed test with an expected effect size (r H1) of 0.2, the significance level (α) was set to 0.05 and the desired power (1–β) to 0.8. The null hypothesis correlation (r H0) was set to 0.00, indicating no correlation. Using these parameters, the minimum sample size needed for adequate power was 193 participants. A conservative sample of 200 participants will then be recruited.

Data management

The recorded data will be sent to the chief investigator immediately after recording (on a daily base), and he will make sure to have a backup of the raw data on three different secure storages. The cohort data will be stored in secure storage at the study centre for 10 years after the completion of the study. All the deidentified data will be handled only based on the reasonable request from the chief investigator.

Confidentiality

All data from the study will be accessed exclusively by research team members trained based on the Sport Sciences Research Institute of Iran (SSRI) ethics protocols and have taken an oath of confidentiality. Each participant will be given a study ID number, which will collect deidentified information without the participant's name, including demographic information and physical-functional test results. No information concerning the study or the data will be released to any unauthorised third party without the ethics committee's prior approval at the SSRI. All research activities will be conducted in as private a setting as possible. Study participant contact information will be securely stored at a secure storage (at the disposal of the chief investigator only) for internal use during the study.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis

There is no collection, laboratory evaluation or storage of biological specimens for genetic or molecular analysis in the current study and for future use in ancillary studies.

Statistical methods

Statistical methods for primary and secondary outcomes

Group characteristics will be compared using unpaired t-tests or Wilcoxon rank-sum tests for Gaussian and non-Gaussian distributed data. Unilateral strength and ROM for the strongest and weakest leg will be analysed using multiple linear regression with sex, strongest/weakest limb and age as independent variables. Relationships between dependent variables (Composite Z-score) and independent variables (various muscle strength and ROM parameters), including covariables (sex, age, falling incidence and BMI), will be performed using multiple linear regression analysis. Robust SEs will be calculated when linear regression models show heteroscedasticity. Between-sex comparisons for intralimb and interlimb asymmetry will be performed using Wilcoxon rank-sum tests (assuming non-Gaussian distributions). The significance of risk factors for functional limitations will be investigated using the multiple linear regression analysis, creating a model with each of the strength and ROM asymmetries variables. Predictive performance of strength and ROM asymmetries for functional limitations will be conducted by the corresponding receiver operating curve to define a cut-off for strength and ROM asymmetries. Results will be reported as mean±SD unless otherwise assumed, and the significance level will be set as $p<0.05$ (two-tailed testing). All statistical analyses will be performed by using SPSS V.26.

Interim analyses

The data monitoring committee, interim analyses or stopping guidelines are not included in this study because all the testing approaches applied in this study are already in daily practice, and the results have been acceptable. However, any unexpected adverse events during the

testing period will be reported to a highly experienced physiotherapist who will not be involved in the execution of the cohort. This physiotherapist will be available to decide to terminate the assessment in case of unanticipated harm.

Plans to give access to the full protocol, participant-level data and statistical code

Deidentified data will be made available to all investigators whose proposed use of data has been approved by the SSRI ethics committee and with a signed data-sharing agreement between all parties. As chief investigator, MH will be primarily responsible for data management. Data analysis will occur independently. Data will not be released to any third party (including the SSRI) before completing the cohort. Deidentified participant data will be available on request from the chief investigator. Statistical code will also be available on request following the publication of the results.

Dissemination plans

A written summary of the results will be disseminated to participants at the end of the study. Following their enrolment in the study, participants can request to receive a copy of their assessments after finishing the study. We will disseminate the findings through peer-reviewed publications and conference presentations and send them to participants. Finally, participants will not be invited to contribute to the writing or editing of any possible manuscript based on the findings of this study for readability or accuracy.

Time plan

Elderly adults will be recruited starting in July 2024, and participants will be included until we reach over 200 participants.

Contributors MH is the chief investigator and the guarantor; he conceived the study and led the proposal and protocol development. ZN and AL contributed to the study design and the development of the proposal. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and the study is approved by the ethics in research committee of the sport sciences research institute of Iran (IR.SSRC.REC.1401.057). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Once collected, the data will be available from the corresponding author on a reasonable request.

Author note MH (Metti): Metti is PhD holder of Biomedical engineering from AAU, Denmark, and Assistant Professor of Sport Injuries at Department of Sport Injuries and Corrective Exercises in Sport Sciences Research Institute of Iran (SSRI). He is also director of international affairs at SSRI. Metti's research interest is in developing scientific research projects in the subjects like: Screening Tests; Senior Functional Tests; Exercise Training for older adults; Predicting Elderly Related Disorders; Pain (Assessment/ Quantification), Exercise Induced Hypoalgesia and Exercise based Rehabilitation; High performance; Sports Injury Surveillance System and Sports Injury Prediction and Prevention. He is involved in reviewing several both national and international peer-reviewed journals.

ORCID iDs
Amir Letafatkar http://orcid.org/0000-0002-5612-8340
Mahdi Hosseinzadeh http://orcid.org/0000-0001-6019-8205

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