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To compare the effect and durability of the effect of corrective exercise and manual therapy focused on the back versus hip on disability, function, pressure pain, pain map, health and psychological status of the elderly with chronic back and hip pain: protocol for a randomised controlled trial

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ABSTRACT

This paper presents a protocol for a randomised control trial to compare the effect and durability of the effect of corrective exercise, and manual therapy focused on the back versus hip versus back and hip on disability, function, pressure pain threshold, pressure pain mapping, health and psychological status of the elderly with chronic back and hip pain. A total of 75 elderly participants will be assigned randomly into three groups, including back-focused exercises (n=25), hip-focused exercises (n=25) and back-focused and hip-focused exercises (n=25). Primary outcomes (disability and function) and secondary outcomes (pressure pain threshold, pressure pain mapping, health status and psychological factors) will be evaluated before, immediately after and 6 months after the 8 week exercise intervention. The data will be analysed using a general linear model repeated measures analysis of variance including both within and between factors (three groups*three times) with Bonferroni adjustments used as a post-hoc test at a significant level of 0.05. This trial will demonstrate whether back versus hip versus back-focused and hip-focused manual therapy can better improve the disability, function, pressure pain threshold, pressure pain mapping, health and psychological status of the elderly with chronic back and hip pain. If successful, this study's findings and information will potentially have implications for addressing back and hip pain in the elderly population by an alternative multidisciplinary approach. Trial registration number: IRCT20220911055941N1.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Chronic back and hip pain significantly impacts the quality of life in the elderly and is associated with disability, reduced function and psychological distress. Corrective exercises and manual therapy have been shown to alleviate pain and improve function. Yet, there is limited evidence comparing their effects when focused on different anatomical regions (back vs hip vs both).

WHAT THIS STUDY ADDS

⇒ This study will directly compare the efficacy and durability of back-focused, hip-focused and combined back and hip interventions on disability, function, pain thresholds and psychological status in elderly individuals. By incorporating a 6 month follow-up, it evaluates the long-term effectiveness of these approaches, offering insights into the most impactful and sustainable intervention.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Findings from this trial may inform targeted, region-specific rehabilitation strategies for chronic back and hip pain in the elderly. The results could support the development of personalised, multidisciplinary care plans, influencing clinical practice and potentially guiding policy on non-invasive, cost-effective management for chronic pain in ageing populations.

INTRODUCTION

Background and rationale

Back and hip pain are common issues among the elderly population, often attributed to various factors such as age-related degeneration, chronic conditions, lifestyle and injury. As people age, the spine undergoes degenerative changes such as the loss of elasticity in spinal discs, osteoarthritis and bone spurs. These changes can lead to conditions like degenerative disc disease, spinal stenosis and facet joint osteoarthritis, resulting in back pain. Osteoarthritis is a common cause of hip

pain in older adults. It occurs when the cartilage cushions the hip joint and wears down over time, leading to pain, stiffness and reduced range of motion. Lack of physical activity can contribute to muscle weakness, joint stiffness and reduced flexibility, exacerbating back and hip pain. Ageing can cause muscle mass and strength loss, particularly in the core and hip muscles. Weakness and imbalance can contribute to poor posture, altered gait mechanics and increased stress on the back and hip joints.

Back and hip pain management in the elderly often involves a multidisciplinary approach, including physical therapy and exercise programmes to strengthen muscles, improve flexibility and enhance balance. Manual therapy, including techniques such as massage, mobilisation and manipulation, can also effectively address back and hip pain in the elderly population. Manual therapy can be a valuable component of conservative management for back and hip pain in elderly patients, promoting pain relief, improved function and enhanced quality of life. Manual therapy for back pain in the elderly includes massage therapy, mobilisation and manipulation. At the same time, manual therapy for hip pain in the elderly includes soft tissue mobilisation, joint mobilisation and stretching and range of motion exercises. Hicks *et al* investigated whether tailored, hip-focused physical therapy improves pain and functional limitations in the elderly compared with non-tailored, spine-focused physical therapy.[1] Their findings warrant further investigation before clinical implementation. Furthermore, with the best knowledge of the authors, there is a lack of studies investigating the effect and durability of the effect of corrective exercise and manual therapy focused on the back versus hip versus a combination of both these therapies on disability, function, pressure pain, pain map, health and psychological status of the elderly with chronic back and hip pain. The authors hypothesised that combining both these pain management programmes will have a better effect on improving disability, function, pressure pain, pain map, health and psychological status of the elderly with chronic back and hip pain.

Objectives

Primary aim

Comparison of the effect and durability of the effect of 8 weeks' corrective exercise and manual therapy focused on the back versus hip versus a combination of both these therapies on disability and function in the elderly with chronic back and hip pain.

Secondary aim

Comparison of the effect and durability of the effect of 8 weeks' corrective exercise and manual therapy focused on the back versus hip versus a combination of both these therapies on pressure pain threshold (PPT), pressure pain mapping, health status and psychological factors in the elderly with chronic back and hip pain.

Trial design

This study was a three-arm, assessor-blind, randomised controlled trial.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting

This study will be conducted at the sports medicine laboratory of the Biomechanics and Sports Injuries Department of Kharazmi University, Tehran, Iran.

Eligibility criteria

Inclusion criteria include male and female older adults aged between 60 and 85 years who are complaining of low back pain (LBP)>3 months for at least half of the days in the last 6 months,[2] moderate LBP intensity (>3 on 0–10), normalised isometric hip internal rotation strength<0.26, hip disability and osteoarthritis outcome score>5 on pain-related items P4–P8.[3] The exclusion criteria include previous hip fracture with repair, a hip fracture within the last 15 years without repair, total hip replacement, known spinal pathology other than spinal stenosis and/or osteoarthritis, severely impaired mobility (ie, requires the use of a wheelchair), Folstein Mini-Mental State Examination Score<24, severe visual or hearing impairment, red flags such as fever, significant unintentional weight loss>10 pounds, pain that awakens or keeps one awake at night, trauma that preceded the onset of pain or signs and symptoms of cauda equine, significant pain in legs greater than the back, acute illness (eg, COVID-19), inability to participate in the study for the whole time of the study (eg, moving residences), receipt of manual or exercise therapy for low back or hip within the last 3 month.[3]

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 (GCP) 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.

Interventions

Explanation for the choice of comparators

There is no current standard therapy recommended for patients suffering from lower back pain. The exercise protocol for controlling and strengthening the lumbopelvic muscles selected as corrective exercise and manual therapy focused on the back versus hip versus a combination of both these interventions in this study were therefore based on the study of Pugliese *et al*.[3] All the abovementioned protocols were demonstrated as fully appropriate protocols.

Intervention description

Corrective exercise and manual therapy focused on the back

Back-focused manual therapy includes two therapy sessions in the clinic under the supervision of a trained therapist and two home-based training sessions. Clinic sessions include 45 min of trunk muscle functional training, lumbar manual therapy and stationary cycling; the home-based training for this intervention includes lumbar flexibility exercises for 15 min. All exercises progress based on meeting a quota criterion (eg, 3 sets of 10 repetitions). A detailed description of these exercise trainings is displayed in table 1.[3]

Corrective exercise and manual therapy focused on the hip

Hip-focused manual therapy also includes two therapy sessions in the clinic under the supervision of a trained therapist and two home-based training sessions. Clinic sessions include 45 min of functional hip exercise training and hip manual therapy; the home-based training for this intervention includes hip strengthening and exercises with an elastic band for 15 min. All exercises progress based on meeting a quota criterion (eg, 3 sets of 10 repetitions). A detailed description of these exercise trainings is displayed in table 1.[3]

Corrective exercise and manual therapy focused on both the hip and back

The hip-focused and back-focused manual therapy includes a combination of both the abovementioned protocols. This protocol includes two therapy sessions of 90 min in the clinic and home-based training for 30 min on two non-therapy days. A detailed description of these exercise trainings is displayed in table 1.[3]

Criteria for discontinuing or modifying allocated interventions

If participants discontinued or deviated from intervention protocols for more than three sessions, they would no longer be included in the analysis.

Strategies to improve adherence to interventions

The research assistant will follow-up with all the participants via telephone to ascertain that they comply with all the home-based protocols. Suppose a participant discontinues or deviates from intervention protocols. In that case, the research assistant will follow-up to ascertain the reason for discontinuation and whether any assistance from the study team can help. The research assistant will check if the participant is still willing to continue with the appointed intervention and outcome measure assessments at the study time points.

Relevant concomitant care permitted or prohibited during the trial

N/A. No relevant concomitant care and interventions are permitted or prohibited during the trial.

Provisions for post-trial care

Patients will be treated during and after the trial and follow-up assessment with the best intentions. If malpractice has taken place, patients will be compensated by the chief researcher.

Outcomes

Primary outcome

Quebec Back Pain Disability Scale (QBPDS)

The Quebec Back Pain Disability Scale (QBPDS) contains 20 daily activities classified into six types of activities relevant to LBP, including bed/rest, sitting/standing, ambulation, movement, bending/stooping and handling large or heavy objects, and asks the patient to score the amount of difficulty in doing each activity from 0 (‘not difficult at all’) to 5 (‘unable to do’). The overall score is determined by a summary of the values for each item and ranges from 0 (‘not being disabled’) to 100 (‘being maximally disabled’).[4]

Hip Disability and Osteoarthritis Outcome Score (HOOS)

The Hip Disability and Osteoarthritis Outcome Score (HOOS) is an adaptation of the KOOS[5] intended to evaluate symptoms and functional limitations related to the hip. The HOOS consists of 40 items, assessing five separate patient-relevant dimensions: Pain (P) (10 items); Symptoms (S) including stiffness and range of motion (five items); Activity limitations living (A) (17 items); Sport and Recreation Function (SP) (four items) and Hip-Related Quality of Life (Q) (four items).[6]

Secondary outcomes

The 10-Metre Walk Test (10MWT)

The valid and reliable 10-m walk test[7 8] 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.

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.[9]

Pressure pain threshold (PPT)

PPT is determined by applying a mechanical stimulus to determine when the stimulus-induced sensation of pressure first changes to that of pain.[10] This allows the quantification of the PPTs of skin and muscle. A pressure algometer (Somedic Model 2, Sweden) will be used to apply pressure to sites close and far from the participants’ pain (lower back and biceps area). The reliability of PPT based on raters or measurement frequencies is reported to be relatively high.[11]

Table 1 A detailed description of the exercise interventions

Exercise intervention	Component	Description
Back-focused In-clinic exercise programme (45 min)	Lumbar manual therapy	► Central posterior–anterior oscillatory mobilisations (grades I–II) to L1–L5 levels ► Effleurage to thoracolumbar area
	Stationary cycling	► Stationary cycle without resistance for submaximal intensity
Home exercise programme (15 min)	Lumbar flexibility exercises	► Generalised stretches to enhance lumbar mobility
	Trunk muscle training exercises	► Bracing ► Anterior trunk (eg, curl-ups) ► Posterior trunk (eg, alternating arm lifts in quadruped)
Hip-focused In-clinic exercise programme (45 min)	Hip manual therapy	Four hip mobilisation techniques (bilateral) ► Long-axis distraction (grade III sustained) plus manipulation ► Anterior–posterior oscillatory mobilisations (grade III/IV) ► Lateral femoral glide (grade III sustained) with internal rotation oscillatory mobilisations (grade III/IV) ► Posterior–anterior oscillatory mobilisations (grade III/IV) Manual stretches (bilateral) ► Hamstrings ► Hip flexors
	Functional hip exercises	Two phases ► Visits 1–8: partial wall squats, hip abduction with an elastic band ► Forward step-ups ► Visits 9–16: wall squats, side-stepping with band, lateral step-ups
Home exercise programme (15 min)	Hip strengthening exercises with elastic band	► Hip abduction ► Hip extension ► Hip internal rotation ► Hip external rotation
	Trunk muscle training exercises	► Bracing ► Anterior trunk (eg, curl-ups) ► Posterior trunk (eg, alternating arm lifts in quadruped) ► Lateral trunk (eg, side bridges)
Combined back-focused and hip-focused In-clinic exercise programme (90 min)	Lumbar and hip manual therapy	► Central posterior–anterior oscillatory mobilisations (grade I–II) to L1–L5 levels ► Effleurage to thoracolumbar area ► Long-axis distraction (grade III sustained) plus manipulation ► Anterior–posterior oscillatory mobilisations (grade III/IV) ► Lateral femoral glide (grade III sustained) with internal rotation oscillatory mobilisations (grade III/IV) ► Posterior–anterior oscillatory mobilisations (grade III/IV) Manual stretches (bilateral) ► Hamstrings ► Hip flexors
	Functional back and hip exercises	► Visits 1–8: partial wall squats, hip abduction with an elastic band ► Forward step-ups ► Visits 9–16: wall squats, side-stepping with band, lateral step-ups ► Stationary cycle without resistance for submaximal intensity

Continued

Table 1 Continued

Exercise intervention	Component	Description
Home exercise programme (30 min)	Lumbar flexibility exercises	► Generalised stretches to enhance lumbar mobility
	Hip strengthening exercises with elastic band	► Hip abduction ► Hip extension ► Hip internal rotation ► Hip external rotation
	Trunk muscle training exercises	► Bracing ► Anterior trunk (eg, curl-ups) ► Posterior trunk (eg, alternating arm lifts in quadruped) ► Lateral trunk (eg, side bridges)

Modified table from Pugliese *et al*.[3]

Pressure pain mapping

The PPT measurements will be performed in one session. For the lumbar region, PPT will be measured at 27 points: five points located on the spinal processes between the first (L1) and the fifth (L5) lumbar vertebrae and 22 points located on the erector spinae muscles on each side of the spine (see figure 1). The distance between adjacent points in this region will be based on the distance between the L1 and L5 (d2). All horizontal distances will be one-fourth of d2, and vertical distances will be one-eighth of d2. A hand-held algometer (Somedic Algometer type 2, Sweden) with a 1 cm wide rubber tip will be used for the PPT measurements. The algometer will be pressed against the skin at a perpendicular angle at a constant slope of 30 kPa/s.[12]

Health status outcomes

Fear Avoidance Beliefs Questionnaire (FABQ)

The fear-avoidance beliefs questionnaire is one of the best measures for assessing fear-avoidance beliefs.[13] It is a 16-item back pain-specific self-report measure that assesses the extent to which pain is believed to be caused

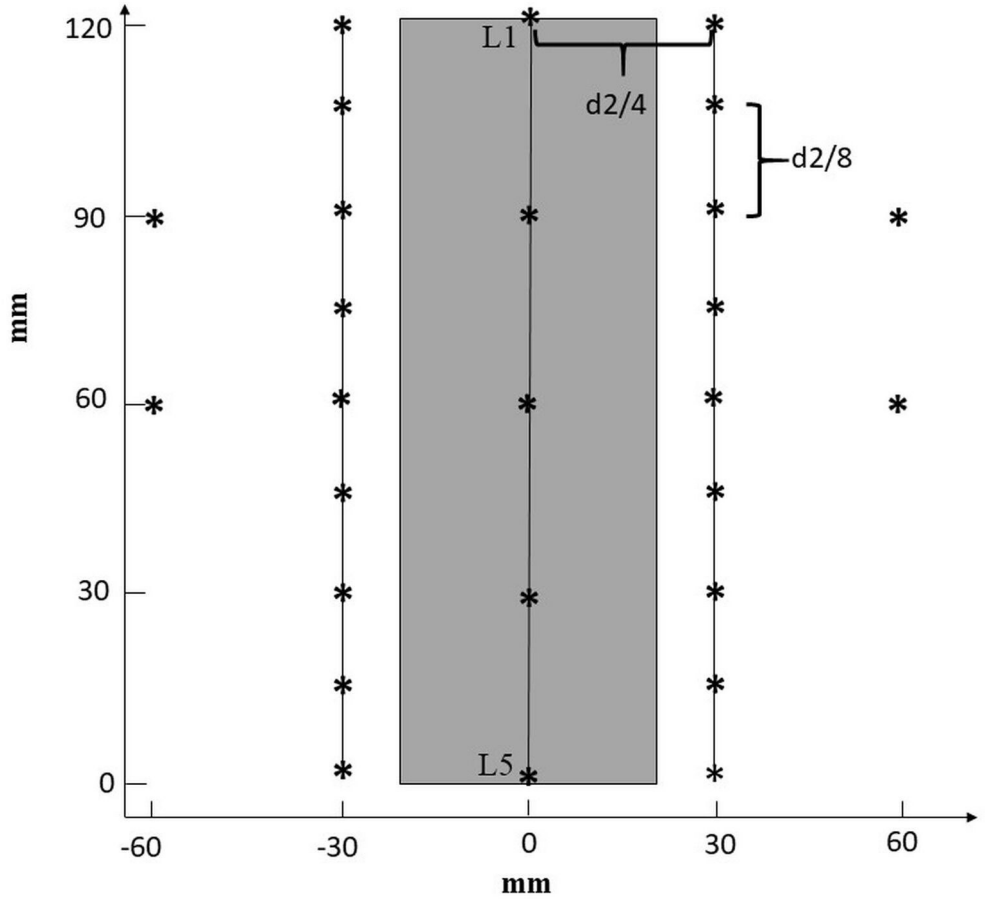

Figure 1 Schematic representation of the low back PPT recordings (27 points).[12] PPT, pressure pain threshold

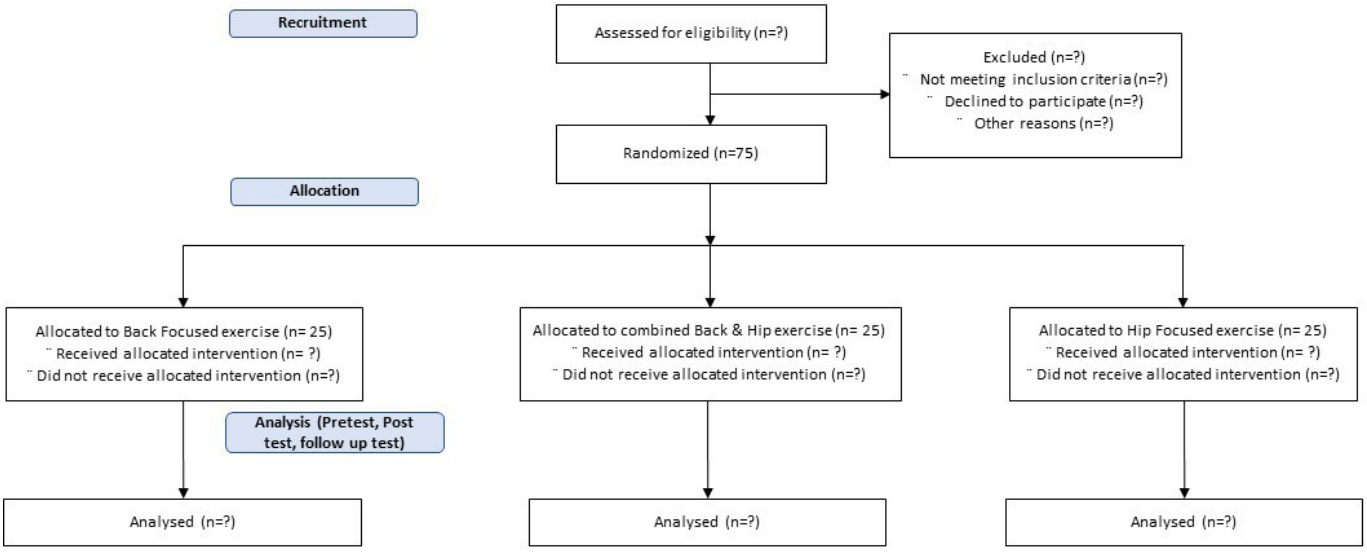

Figure 2 CONSORT flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

or aggravated by general physical activity (FABQ-PA) and work-related activities (FABQ-W). These represent the two subscales of the measure.[13] Summing the two subscale scores gives a total FABQ score of 66, with higher scores reflecting stronger fear-avoidance beliefs.[13]

Participant timeline

Figure 2 provides the Consolidated Standards of Reporting Trials (CONSORT) flow diagram, and figure 3 provides a schedule of enrolment, interventions and assessments in this study.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			
TIMEPOINT**	$-t_1$	0	*Pre-test*	*6 weeks*	*Post-test*	*Follow up*
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
[Home-based exercise + weight loss]			←	X	→	
[Home-based exercise]			←	X	→	
ASSESSMENTS:						
[QBPDS]			X		X	X
[HOOS]			X		X	X
[10MWT]			X		X	X
[30 s chair-stand test]			X		X	X
[PPT]			X		X	X
[PPT mapping]			X		X	X
[FABQ]			X		X	X

Figure 3 Schedule of enrolment, interventions and assessments. FABQ, Fear-Avoidance Beliefs Questionnaire; HOOS, Hip Disability and Osteoarthritis Outcome score; PPT, pressure pain threshold; QBPDS, Quebec Back Pain Disability Scale; –t1, baseline assessments; 10MWT, 10 m walk test.

Sample size

The software (G*Power, Franz Faul University of Kiel, Germany) was used to estimate the number of participants. A priori sample size was estimated based on performing a between-within interaction, effect size of 0.14, power of 0.80 and having three groups; therefore, 66 participants were estimated for the study. Considering a 10% dropout rate from completing the study procedures (back to the previous studies), we will recruit 75 participants for this study.

Recruitment

We will recruit patients through practitioners via flyers distributed at Kharazmi University, hospitals and physical therapy clinics. We will further use advertising posters in each centre and online advertisements in the media. Then, participants will be in charge of screening for inclusion and exclusion criteria, and a final decision will be made regarding the eligibility of the patients. Figures 2 and 3 show the CONSORT flow diagram and the study's timeline schedule.

Assignment of interventions: allocation

Sequence generation

In a simple randomisation, the concealed allocation will be performed using a computer-generated block randomised table of numbers (block size four) created before the start of data collection by a researcher assistant who will not get involved in the recruitment or treatment of patients and blind to the aim of the research.

Concealment mechanism

The random numerical sequence will be placed in sealed opaque envelopes. Next, another researcher assistant will open an envelope and process the treatment according to the group assignment.

Implementation

A researcher assistant who is not involved in the recruitment or treatment of patients and is blind to the aim of the research will enrol participants and assign them to interventions.

Assignment of interventions: blinding

Who will be blinded

When collecting the outcome measurements, the outcome measure assessor will be blinded from the treatment allocation. The patient will wear long-covered clothes during the follow-up visits and will be asked not to reveal the treatment. Blinding the treatment approach is impossible for the personnel executing the treatment approach or the patients. This study will use a pretest/post-test design, a blinded assessor and a data analyst.

Procedure for unblinding if needed

Suppose the research assistant (the assessor) unintentionally discovers a participant's allocation while recording the pretest and post-test measurements. In that case, the participant will be assigned to a different research assistant to record the data.

DATA COLLECTION AND MANAGEMENT

Plans for assessment and collection of outcomes

All the primary and secondary outcome measures explained in the 'Outcomes' section will be recorded 1 week before the start of the intervention protocols as the baseline pretest session and then 1 week after completing all the intervention protocols as the post-test measurements and again after 6 months as a follow-up session.

Plans to promote participant retention and complete follow-up

To ensure an adequate follow-up rate, the research team will maintain regular contact with participants after giving informed consent (regularly every 2 weeks). It will ensure that contact occurs the week before the baseline assessment (pretest) to ensure greater contact between consent and the intervention start. After randomisation, participants can meet a specific therapist and ask questions before the intervention starts. Participants receive treatment free of charge, monetary compensation for follow-up assessments and reimbursement for their transportation expenses.

Data management

The recorded data will be sent to the chief investigator immediately after recording (daily), and he will make sure to have a backup of the raw data in three different secure storages. Trial 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 in 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 clinical information and laboratory results. No information concerning the study or the data will be released to any unauthorised third party without prior written approval of the ethics committee 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 in this trial/future use

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

STATISTICAL METHODS

Statistical methods for primary and secondary outcomes

Data will be analysed using SPSS V.26. Kolmogorov-Smirnov will be used for checking the normal distribution of the outcomes. The homogeneity of the variations will be observed using the Levene test. Comparisons between the baseline demographic and clinical data will be made using the one-way analysis of variance (ANOVA).

A general linear mixed model will be used to compare outcome measures between groups over time (pretest, post-test, follow-up test) and group effects (back-focused exercises vs hip-focused vs combined back and hip groups). If a significant interaction effect was found between factors, post-hoc t-tests with Bonferroni correction will be applied to each dependent variable using a diagonal covariance matrix. Effect sizes will be expressed in partial eta squared (η^2_p), with values of 0.01, 0.06 and 0.14 representing small, medium and large effects, respectively.

Interim analyses

Data monitoring committees, interim analyses or stopping guidelines are not included in this study because all the treatment approaches applied in this study are already in daily practice, and the results have been acceptable. However, any unexpected adverse events that occurred during the intervention period will be reported to a highly experienced physiotherapist who will not be involved in the execution of the trial. This physiotherapist will be available to decide to terminate the trials in case of unanticipated harm.

Methods for additional analyses (eg, subgroup analyses)

The main conclusion will be drawn from the unadjusted analysis without performing any subgroup analysis of primary and secondary outcomes.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

The mixed-model ANOVA compares the within and between groups, and the effects allow for possible missed data. We will assume that data are missing at random. Study group and assessment time will be used as fixed factors, and patients will be used as random factors.

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, Dr Hosseinzadeh 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 the trial is completed. Deidentified participant data will be made publicly available after the initial publication of results on an open-access platform. They will also be available on request from the chief investigator. Statistical code will also be available on request following the publication of the results.

OVERSIGHT AND MONITORING

Composition of the coordinating centre and trial steering committee

The chief investigator will be responsible for the overall management of the project. The coinvestigator will promote participant retention, complete the follow-up and improve adherence to the intervention protocols where an intervention appointment is missed. Several research assistants will take care of the blinded randomisation. A highly experienced physiotherapist will be available to allow participants to ask questions before the intervention starts and decide to terminate the trial participation for a participant in case of unanticipated harm. Another blinded coinvestigator will take care of the statistical analysis.

Composition of the data monitoring committee, its role and reporting structure

The current trial does not have a formal data monitoring committee. Instead, research assistants will meet weekly with the principal investigator to review ongoing trial activities.

Adverse event reporting and harms

All the treatment approaches applied in this study are already in daily practice, and the results have been acceptable. No potential harm is therefore anticipated for the elderly participants of this study. All complications and harms (in case of any) will be reported to this highly experienced physiotherapist, who will be available to decide to terminate the trial participation for a participant in case of unanticipated harm. All the complications and harms (in case of any) will also be reported to the Research Ethics Committee. Major and minor complications (in case of any) will be listed in the safety consideration section.

Frequency and plans for auditing trial conduct

All procedures and instructions will be followed if the Research Ethics Board requests an audit. Currently, the study team has no plans for independent auditing of trial conduct.

Plans for communicating important protocol amendments to relevant parties (eg, trial participants, ethical committees)

In the case of modification of the study protocol, all changes will be reported to the institutional ethics committee at SSRI and will be updated by the Iranian Registry of Clinical Trials.

Dissemination plans

A written summary of the results will be disseminated to participants at the end of the study. Following their enrolment in the trial, 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 any possible manuscript based on the findings of this study for readability or accuracy.

DISCUSSION

There is no consensus standard or comprehensive approach that can effectively address back and hip pain, specifically in the elderly population. This study will aim to determine the most appropriate multidisciplinary approach for managing back and hip pain in elderly individuals. Our suggested alternative approach includes lifestyle modifications for staying physically active, manual therapy, muscle strengthening and flexibility improvement. This is a single-blind randomised clinical trial, in which we cannot blind the exercise intervention assigned to the participants, including the athletic trainers providing the treatments and the elderly individuals participating in the study. We plan to mitigate this limitation by blinding the outcome measure assessor from the treatment allocation when collecting the outcome measurements. Furthermore, the participants will be wearing long-covered clothes during the follow-up visits. They will be asked not to reveal the treatment to mask their allocation. This prospective trial is expected to contribute towards refining guidelines for GCP and may be used as a basis for health authorities' recommendations. If successful, this study's findings and information will potentially have implications for addressing back and hip pain in the elderly population by an alternative multidisciplinary approach.

Trial status

This is the first version of this clinical trial protocol, dated 22 July 2023. Trial Status is 'in progress'.

Contributors MH is the chief Investigator and the guarantor; he conceived the study and led the proposal and protocol development. MK and AL contributed to the study design and the development of the proposal. MK wrote the draft of the manuscript. MH and AL edited the manuscript. 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 was approved by ethical committee of the Sport Sciences Research Institute (IR.SSRC.REC.1401.052). 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 upon reasonable request.

Author note Mahdi Hosseinzadeh (Metti): Metti holds a PhD in biomedical engineering from AAU, Denmark and is an assistant professor of Sport Injuries at the Department of Sport Injuries and Corrective Exercises in Sport Sciences Research Institute of Iran (SSRI). Metti's research interest is in developing scientific research on the areas of: 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 a scientific reviewer for national and international peer-reviewed journals.

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