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Effect of motor control training and breathing exercises on pain, disability and core muscle activity in women with postpartum lumbopelvic pain: a study protocol for randomised controlled trial study

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ABSTRACT

Introduction Postpartum lumbopelvic pain (LPP) is a prevalent condition among women following childbirth. Due to the importance of respiratory muscles in lumbopelvic stability, and the changes they undergo during pregnancy, this study aims to assess the effects of motor control training and breathing exercises on pain, disability and core muscle activity in women suffering from LPP after childbirth.

Methods and analysis 52 women with postpartum LPP will participate in this two-parallel-armed, superiority randomised controlled trial, comprising 24 treatment sessions. The intervention group consists of motor control training and breathing exercises, and the control group includes motor control training. The diaphragm excursion, pelvic floor and abdominal muscle activity, pain and disability will be evaluated using ultrasound imaging, visual analogue scale and Oswestry Disability Index, before and after the intervention, respectively.

Ethics and dissemination Ethical approval was obtained from the human research ethics committee of the Iran University of Medical Sciences (IR.IUMS.REC.1403.017). The study results will be submitted to a relevant journal and conferences.

Trial registration number This clinical trial has been registered in the Iranian Registry of Clinical Trials on 21 May 2024 (registration number: IRCT20180916041051N2).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of a parallel, randomised controlled trial design, concealed allocation and assessor blinding strengthens the study's methodological quality.
⇒ Exercises outlined in this study are simple and cost-effective, with low incidence of adverse effects.
⇒ Blinding of the investigators and participants is not possible, which may lead to bias.

BACKGROUND AND RATIONALE

Lumbopelvic pain (LPP) is a prevalent musculoskeletal issue among women during pregnancy and the postpartum period. It is characterised by pain in the lumbar spine (low back pain (LBP)), pelvic girdle or both areas. In the majority of women, symptoms typically diminish within 3 months postpartum. However, existing literature indicates that between 2% and 75% of women may experience persistent back pain for up to 3 years following pregnancy, which contributes to disability and associated economic costs.[1 2]

The precise mechanisms underlying the development of postpartum LPP remain controversial.[3] A most plausible hypothesis posits that mechanical and hormonal changes during pregnancy may influence the dynamic stability of the lumbopelvic region.[3] Optimal stability in the lumbopelvic region relies on the effective interaction of active, passive and neural subsystems.[4]

As a part of the active subsystem, the lumbopelvic muscles synergistically stabilise the lumbopelvic region and play a role in respiration.[5] Pregnancy can impair the function of these stabilising muscles.[6] The progressive enlargement of the uterus results in the stretching of abdominal muscles, which may lead to muscle weakness, diminished functional capacity and decreased pelvic stability.[6 7] Simultaneously, the enlargement of the uterus elevates the diaphragm, increasing its length and altering its zone of opposition with the rib cage.[8 9] Pelvic floor muscles (PFMs) are another component of the active stabilising system, which together with abdominals and diaphragms play a crucial role in maintaining lumbopelvic stability.[10 11] These muscles

undergo significant stretching during vaginal delivery, which can result in PFM disorders.[10]

Given that lumbopelvic instability and muscular impairments may contribute to postpartum LPP, exercise programmes as a non-invasive intervention[12] are essential for enhancing proper muscle activity and lumbopelvic stability in postpartum LPP management. One form of exercise known as motor control training has been shown to reduce pain and disability levels in subjects with LPP.[13 14] Motor control exercises focus on activating the deep lumbopelvic muscles to restore their control and coordination. Several studies have demonstrated the efficacy of this exercise method in LPP management.[13 15 16]

In healthy subjects, in addition to the respiratory function of the diaphragm muscle, it provides lumbar spinal stability through simultaneous contraction with the abdominal muscles and PFMs. Respiratory demand increases during pregnancy, since both mother and fetus should use a single breath. Increased demand for one of the diaphragm's functions will inevitably compromise its other functions and often diminish the respiratory muscles' capacity to fulfil their postural responsibilities. Breathing exercises facilitate muscle activation, thereby strengthening core muscles, including the diaphragm, abdominal muscles and PFMs, and improve spinal stabilisation through the co-contraction of these muscle groups.[17 18] Furthermore, breathing exercises enhance the patient's pulmonary function by increasing forced vital capacity and other indicators of oxygenation and blood volume. This improvement facilitates the development of more effective breathing patterns, which can alleviate LPP and improve muscle activity.[19–21] Consequently, it can be hypothesised that a treatment programme targeting respiratory muscles may enhance lumbopelvic stability and alleviate clinical symptoms in women with postpartum LPP.

Clinical studies have demonstrated the effectiveness of adding breathing exercises to motor control exercises in treating LBP.[18 22] Despite the existing body of research, no investigation has been conducted into the effects of these exercises on women experiencing postpartum LPP. Given the physiological changes during pregnancy, particularly in the diaphragm, abdominal muscles and PFMs, the applicability of findings from studies conducted on the general population with LBP to postpartum women with LPP is questionable.

OBJECTIVES

This study aims to investigate the effects of motor control training and breathing exercises on pain, disability and core muscle activity in women with postpartum LPP.

TRIAL DESIGN

This study is a two-parallel-armed, assessor-blind, superiority randomised controlled trial (RCT), designed to investigate the superiority of motor control training in conjunction with synchronous breathing exercises against motor control training alone on improving pain, disability and core muscle activity in women with postpartum LPP. This RCT employs a one-to-one allocation in two parallel groups: the intervention group receives motor control training and synchronous breathing exercises, and the control group is assigned to motor control training alone.

The primary outcome is diaphragm muscle excursion. Secondary outcomes include pain, disability, PFMs and abdominal muscle activity, which will be assessed before and after the interventions.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting

Data will be collected in the physiotherapy department laboratory of Iran University of Medical Sciences, Tehran, Iran. Patients were diagnosed with postpartum LPP without neurologic signs.

Patients diagnosed with postpartum LPP will be referred by midwives, obstetricians/gynaecologists or orthopaedic specialists from the Iran University outpatient clinics or contacted based on previously available records.

ELIGIBILITY CRITERIA

The inclusion criteria are as follows:

- Women aged 20–40 years, with a history of vaginal delivery within the past 3–12 months.
- Diagnosis of non-specific LBP, pelvic pain or LBP and pelvic pain together, with the onset occurring during pregnancy or at least 3 weeks postpartum.
- Positive active straight leg raise (ASLR) test, and having a positive result on at least three of six sacroiliac provocation tests (including distraction, compression, posterior shear test (thigh thrust test), Gaenslen provocation test (right), Gaenslen provocation test (left) and sacral thrust test).[23 24]
- The pain intensity at the time of the test or during the last 2 weeks should be between 3 and 7 on the visual analogue scale (VAS).[25]
- Body mass index <30 kg/m^2.

The exclusion criteria are as follows:

- Spinal deformity or pathological condition (canal stenosis, scoliosis, spondylolisthesis, fractures, spinal or pelvic tumours, etc).[26]
- History of neurological, cardiovascular, respiratory, renal diseases or rheumatoid arthritis.
- History of surgical intervention in the lumbopelvic region.
- Postpartum urinary dysfunctions (including urinary incontinence and/or urinary retention).
- Urogenital prolapse above grade 3.[27]
- History of caesarean section or more than two vaginal deliveries.
- Refusal to participate in the study.

Who will take informed consent?

Informed consent forms will be developed following the ethics committee of Iran University of Medical Sciences guidelines. At the baseline visit, a trial staff member will obtain written informed consent from eligible participants. All eligible participants will receive a comprehensive explanation of the interventions and possible adverse effects before signing the consent form.

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

Not applicable—Biological specimens will not be collected or stored.

Interventions

There are two arms in this trial:

- Intervention arm: motor control training plus breathing exercises.
- Control arm: motor control training.

The exercise sessions will be conducted over 8 weeks, three times a week, for 24 sessions under the supervision of a physiotherapist in both groups.

Each treatment session is estimated to last 50–60 min. If a session is missed, a make-up session can be scheduled.

Intervention description

A warm-up and cool-down exercise will be performed before and after the sessions. The warm-up activity takes 5 min, including the general full-body stretching (the upper limb, lower limb and trunk muscle groups). Participants will perform 5 min of jogging and walking, as cool-down exercises.[28]

Motor control exercise

Both groups will be given the motor control exercise programme. For the first 4 weeks, four commonly prescribed progressive motor control exercises have been selected to enhance the stabilisation of trunk muscles, consisting of curl up, dead bug, Superman and bird dog. The exercises have been chosen based on a thorough review of various core-strengthening exercises identified in previous studies.[29–31] The curl up and dead bug exercises will be performed in the supine position. The Superman exercises will be performed in the prone position and the bird dog in the quadruped position.

During the second 4-week period, in addition to the exercises of the first 4 weeks, the training programme will incorporate bridging exercises that emphasise functional movement patterns.[29 32]

Most exercises will be performed for 20 s, with exceptions for the dead bug exercise during the 3rd week and the 4th–8th week, as well as the bird dog exercise during the 4th–8th week. Exercises are performed in three sets, with five repetitions in each set, 20 s of rest between repetitions and 1 min of rest between sets.[29] For exercise progression, additional loads will be placed on the spine through various upper and lower extremities and trunk movement patterns each week.[29] Exercise progression depends on the correct performance of previous exercises without pain. The physiotherapist responsible for the interventions will monitor each participant and make decisions regarding exercise progression. If a participant experiences pain or fails to perform the exercises correctly, she will retrain on the previous exercise until she achieves proper execution.[33 34]

Curl up exercise: the participant performs the curl up in a supine position with the knees flexed, aiming to bring the shoulder blades towards the knees, thereby flexing the trunk through a limited range of motion. It begins with the hands held across the waist, progressing to fingers interlaced behind the head.[35] Each week's curl up exercises will be as follows: first week: the participant performs abdominal bracing with knees bent and feet flat on the floor, flexing her neck and directing her chin towards the chest. Second week: while performing the first-week exercise, the participant performs a trunk curl, holding her hands near the knees. Third week: while performing the trunk curl, the participant positions her hands on opposite shoulders. Fourth to eighth week: while performing the trunk curl, the participant positions her hands behind the head, interlocking her fingers.[30]

Dead bug exercise: the participant performs the dead bug in a supine position with the knees flexed, while maintaining the abdominal draw-in manoeuvre and arms fully extended. Its performance involves alternately moving the arms and legs. Each week's dead bug exercises will be as follows: first week: the participant lies supine, with her knees bent and arms fully extended, continuously alternates her arms, lifts one leg and holds it. Second week: the participant performs the exercise while alternating both the arms and legs for 20 s. Third week: the participant performs the second-week exercise for 25 s. Fourth to eighth week: the participant performs the second-week exercise for 30 s.[29 30]

Superman exercise: the participant lies prone with the legs and arms extended. The exercise begins with lifting one arm and progressing to lifting both arms and legs off the floor. Each week's Superman exercises will be as follows: first week: the participant lies prone with extended legs and arms and lifts one arm. Second week: while lying in the prone position, the participant lifts one leg. Third week: while lying in the prone position, the participant lifts one arm and the opposing leg. Fourth to eighth week: participant lifts both arms and legs off the floor.[29 30]

Bird dog exercise: the participant performs the bird dog exercise from the quadruped position, which involves simultaneous elevation of the contralateral upper and lower extremities. It begins in quadruped and progresses to three-point and then two-point contact with the surface. Each week's bird dog exercises will be as follows: first week: the participant maintains a quadruped position while elevating one arm until it is aligned with the body. Second week: while performing the quadruped position, the participant lifts her leg until it is aligned with the body. Third week: while performing the quadruped position, the participant lifts one arm and the opposing

leg. Fourth to eighth week: the participant performs the third-week exercise for 25 s.[29 30 36]

Bridging exercise: the participant lies supine with flexed knees, places hands horizontally on both sides, and raises the hips. The exercise begins with the floor bridge and progresses to the double and then single-leg ball bridge.[29] Each week's bridging exercises will be as follows: fifth week: the participant lies supine with flexed knees, places hands horizontally on both sides and raises the hips. Sixth week: while performing the first-week exercise, the participant lifts one leg and holds it. Seventh week: the participant lies in a supine position, placing her hands horizontally on both sides, then brings her legs together, positions them on the Swiss ball, and raises her hips to maintain balance on the ball. Eighth week: the participant performs the seventh-week exercise by placing one foot on the ball.[37]

Breathing exercise

Breathing exercises will be performed with motor control training in the intervention group. An inspiratory muscle training device will be used to perform breathing exercises (POWERbreathe classic device; POWERbreathe International, England). This device consists of a silicon mouthpiece and a valve that regulates ventilation. It is designed to improve the strength of the respiratory muscles by generating optimal pressure levels ranging from 10 to 15 mm Hg. During the initial session, participants in the intervention group will receive guidance on using the device under the supervision of a physiotherapist. Participants' perceived force will be controlled to keep it below 14 during the intervention.[18 38] The breathing exercises will be performed along with the motor control exercise. The breathing exercises for the intervention group will be conducted over 8 weeks, three times per week, under the supervision of a physiotherapist.

Participants will be instructed to discontinue the intervention immediately if they experience dizziness or dyspnoea.

Criteria for discontinuing or modifying allocated interventions

Participants can withdraw from the study at any time and for any reason, without any consequences.

Strategies to improve adherence to interventions

The rehabilitation protocol will be offered at no cost to enhance patient motivation. There will be an opportunity for the participants to ask questions, and their questions will be answered satisfactorily. A physiotherapist will also closely supervise each treatment session and provide feedback.

Relevant concomitant care permitted or prohibited during the trial

Concomitant or confounding care or interventions that potentially could affect the study outcomes will not be allowed. Participants expected to require analgesics or other physiotherapy interventions during the intervention phase will be deemed ineligible and excluded from the study.

Provisions for post-trial care

Participation in the trial is not expected to cause harm, and no compensation is available for trial participation or post-trial care.

Outcomes

All outcomes will be assessed at two measurement time points: at baseline and following the final treatment session (after 8 weeks) by a physiotherapist. An ultrasound unit (SONOACE R7; Samsung Medison, Korea) with a bandwidth frequency of 5–8 MHz (penetration frequency) will be used to assess diaphragm excursion, pelvic floor and abdominal muscle activity. Ultrasound imaging is a reliable and valid tool for core muscle activity assessment and has been used in several studies to evaluate these muscles during different tasks.[39–41]

Women in both groups will be evaluated under the following test conditions: at rest, during deep respiration and while executing the ASLR. During rest and deep respiration, the participant will be in a crook-lying posture, with approximately 60° of hip and knee flexion while maintaining a neutral lumbar spine position.

During deep respiration, participants will be instructed to breathe in and out as forcefully as possible without any additional prompts, to prevent alterations in their breathing patterns. To execute the ASLR, participants will be instructed to lie in a relaxed supine position and lift their right leg 20 cm above the table. The leg was held in the elevated position for 10 s, at which point the image would be captured. The ASLR is a reliable and valid test suggested as a clinical measure of lumbopelvic stability, in both pregnant and postpartum populations.[42–44]

Primary outcome

The primary outcome is the diaphragm excursion (activity). The choice of diaphragm excursion as the primary outcome variable is based on the results of a previous study that showed the diaphragm excursion differed between women with and without postpartum LPP during postural and respiratory tasks.[8] The diaphragm excursions will be recorded in motion mode (M-mode) using a convex probe. The probe will be positioned between the midclavicular and anterior axillary lines, oriented medially, cranially and dorsally to enhance visualisation of the posterior third of the right diaphragm. In M-mode imaging, the diaphragm is visualised as an echogenic line that exhibits free movement during inspiration and expiration. During the M-mode tracing, inspiration is defined as an upward motion. The excursion will be measured along the vertical axis, from the baseline to the peak of the trace. The excursion of the right hemidiaphragm will be recorded during deep respiration and ASLR.

Secondary outcomes

Secondary outcomes are PFMs and abdominal muscle activity, pain and disability.

PFM activity

The displacement of the bladder base will be considered to assess PFM activity. Before the test, participants will consume 600 mL of water to ensure the acquisition of clear images of the bladder base. Transabdominal ultrasound will be conducted using M-mode, with the convex probe positioned transversely along the midline of the suprapubic region. The inferior border of the bladder will serve as a reference point, indicated by the termination of the anechoic margin, while the beginning of the hyperechoic line representing the pelvic floor deep plane will be identified at the junction of the anechoic margin and the hyperechoic line.[45 46] The vertical distance of bladder base displacement, defined as the difference between the maximum displacement of the bladder base during deep expiration/following a 10 s hold of the ASLR and the initial position of the bladder base at rest, will be regarded as an indicator of PFMs activity.

Abdominal muscle activity

A linear probe will be used to assess the abdominal muscle activity, and the ultrasound unit will be set to B-mode. The ultrasound probe will be positioned at the midpoint between the 12th rib and the iliac crest along the anterior axillary line. All measurements will be taken from the right side of the abdominal wall. The thickness of abdominal muscles will be measured at rest and then compared with the measurements obtained at the end of deep respiration and after a 10 s hold of the ASLR. Measurements will be taken 15 mm from the right transversus abdominis (TrA) musculoskeletal junction to ensure the standardised location. At this point, the abdominal muscles' thickness is measured between the edges of the fascial bands. The thickness of the abdominal muscles, including the TrA, internal oblique and external oblique, will be assessed during deep expiration following a 10 s hold of the ASLR. These measurements will be expressed as a percentage of the thickness at rest, calculated using the formula: (thickness during deep expiration and ASLR/thickness at rest)×100. The percentage change in muscle thickness is considered an indicator of muscle activity.[24 47]

Pain intensity

Pain will be measured by the VAS. It is a self-administered scale, ranging from 0 points indicating no pain to 10 points for the maximum pain intensity.[48] Participants will rate their average pain intensity over the past 2 weeks using VAS.

Disability

Disability will be assessed using the Oswestry Disability Index (ODI). The ODI is a self-administered, 10-item questionnaire designed to evaluate pain-related disability in subjects with LBP. Each item is scored on a 0–5 scale, where 0 indicates no disability and 5 signifies the highest level of disability. The total score ranges from 0% to 100%, with higher scores reflecting greater disability. The Persian version of the ODI, which has demonstrated reliability and validity properties in individuals with LBP, will be used in this study.[49]

Project timeline

The timeline is presented in figure 1.

Sample size

This study is the first to compare the effects of motor control training combined with breathing exercises against motor control training alone on the improvement of pain, disability and core muscle activity in women with postpartum LPP. In light of the absence of prior studies, the Cohen standardised effect size was employed to calculate the sample size. The sample size was calculated using the G*Power software (V.3.1.9.4). Taking into account a power of 0.80, an alpha level of 0.05 and Cohen's effect size of 0.8, the necessary sample size is determined to be 42. Considering a dropout rate of 20%, a total of 52 women with postpartum LPP will be included in the study, with 26 participants allocated to each group. The sample size will be recalculated at the end of the trial to ensure that it is adequate.

Recruitment

Participants will be recruited from Iran University outpatient clinics through referrals from midwives, obstetricians/gynaecologists or orthopaedic specialists. Participants will also be recruited through brochures/poster advertisements in midwifery, obstetrics/gynaecology clinics, ultrasound clinics and community sites such as libraries, coffee shops and on Instagram.

Data will be collected in the physiotherapy department laboratory at Iran University of Medical Sciences in Tehran, Iran. A physiotherapist will evaluate patients for eligibility and confirm their final eligibility status. The treatment protocol will be explained to the patients, and those who provide informed consent to participate in the study will be included.

Assignment of interventions: allocation

Sequence generation

Participants will be randomly assigned to one of two groups (the experimental group or the control group) in a 1:1 ratio, employing the balanced block randomisation method. The freely available online platform https://randomizer.org/ will be used for this allocation process.

Concealment mechanism

Sealed envelopes will be used to securely store the randomisation results for each participant.

Implementation

A study investigator enrols participants and accesses the website with a personal ID and password, thereby becoming aware of the intervention assigned to each participant. Before the intervention, participants will

	Enrolment	Allocation	Intervention							
TIMEPOINT	$-t_1$	0	t_1= Week 1	t_2= Week 2	t_3= Week 3	t_4= Week 4	t_5= Week 5	t_6= Week 6	t_7= Week 7	t_8= Week 8
ENROLMENT:										
Eligibility screen	X									
Informed consent	X									
Allocation		X								
INTERVENTIONS:										
Motor control exercise plus breathing exercise (Intervention group)			←	—	—	—	—	—	—	→
Motor control exercise (Control group)			←	—	—	—	—	—	—	→
ASSESSMENTS:										
Diaphragm muscle excursion		X								X
PFM activity		X								X
Abdominal muscle activity		X								X
Pain		X								X
Disability		X								X

Figure 1 Schedule of enrolment, intervention and assessments. PFM, Pelvic Floor

select one of the sealed envelopes and hand it to the study investigator. On opening the envelope, the study investigator will administer the allocation immediately prior to the intervention.

Assignment of interventions: blinding

Who will be blinded?

The nature of this study will not allow the blinding of the enrolled women and the physiotherapist who will perform the interventions. However, the physiotherapist performing the outcome assessments and the statistician will remain blinded to the allocation of study arms.

Procedure for unblinding if needed

Given the nature of the intervention, unblinding is not necessary.

Data collection and management

Plans for assessment and collection of outcomes

Assessments are conducted at two points: at baseline and following treatment sessions, by a physiotherapist with sufficient experience. Additionally, a staff member will gather demographic information during the initial session. Detailed descriptions of the outcomes and assessments are provided in the 'Outcomes' section.

Plans to promote participant retention and complete follow-up

During the initial session, all potential participants are informed of the importance of attending all treatment sessions throughout the trial. This ensures that only individuals who are capable of committing to the entire protocol are enrolled. Also, participants will receive a reminder message the day before the intervention sessions, informing them of the precise time and requesting confirmation of their attendance. Participants

who do not respond to the message will receive a phone call. Data of patients who withdraw from the study are considered as dropouts.

Data management

Each participant will be assigned a unique study ID to replace their identifying information on enrolment. Participants will be identified using their ID, the initial letter of their last name and their first name. Data will be collected on paper and stored in folders in an office within the physiotherapy department laboratory at Iran University of Medical Sciences. A research staff member will enter the data into Excel software two times.

Confidentiality

Identifying information (full name, date of birth, contact information and written informed consent), medical history and participants' ID will be recorded in a document maintained by the corresponding investigator. Only research team members have access to the participants' data. Participants' private data will remain confidential and not be disclosed in the publication.

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

Not applicable. No biological samples will be collected or stored.

Statistical methods

Statistical methods for primary and secondary outcomes

Data analysis will be performed using SPSS V.24. The primary and secondary outcomes analysis will be based on an intention-to-treat approach, including withdrawals and dropouts. Data normality will be assessed using Shapiro-Wilk tests, histograms, skewness and kurtosis evaluations. According to the data distribution, quantitative variables will be described using mean (SD) or median (first and third quartiles). Categorical variables will be reported as frequencies and percentages.

The demographic variables will be compared between the two groups using an independent t-test or the non-parametric Mann-Whitney U test. An independent t-test will be used to compare groups for variables that meet normality assumptions. In cases of non-normal distribution, the Mann-Whitney U test will be used. The variables in each group will also be compared between before and after intervention based on data distribution. Two-tailed p values of ≤ 0.05 will be considered significant.

Artificial intelligence algorithms may also be used to discover the relationship between the variables of pain and disability, PFMs activity, abdominal muscle activity and diaphragm muscle excursion, which have a synergistic and non-linear effect on each other.

Interim analyses

The planned interventions are non-invasive, free and do not qualify as expensive, so no interim analyses will be conducted.

Methods for additional analyses

Subgroup analyses are not planned.

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

The primary analysis of this study will employ the intention-to-treat approach, which ensures that all participants are included in the final analysis based on their random allocation, irrespective of whether they completed the study. The study will report the rate of missing data, and no imputation will be performed to replace any missing values.

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

Following the publication of the study results, a deidentified version of the complete trial protocol will be made available on reasonable request to the corresponding author.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee

The coordinating study centre is the department of physiotherapy, Iran University of Medical Sciences, Iran.

The trial steering committee consists of the corresponding investigator, a physiotherapist (PhD candidate), other authors of the study (MD, SND, and MNF) and a statistician. The corresponding investigator will be fully responsible for the research and its management. Steering committee members will be responsible for the day-to-day running of the trial, providing organisational support and data analyses. The administrative secretary of the physiotherapy clinic is responsible for managing daily patient contact and scheduling appointments. Meetings will be held every 2 weeks, during which all authors will discuss the study's progress and strategies for enhancing trial management.

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

The separate data monitoring committee is not deemed necessary, as the interventions are not anticipated to pose any risk of harm to participants.

Adverse event reporting and harms

Given that the proposed interventions in this study are considered safe, no severe adverse events related to the interventions are anticipated. However, all study participants will be instructed to report any adverse or serious events to the physiotherapist responsible for the interventions. Dizziness or fatigue may occur following the intervention; however, the literature does not document any serious side effects. The corresponding investigator will inform the institution's research ethics committee of any adverse events.

Frequency and plans for auditing trial conduct

The trial steering committee will meet every 2 weeks to review the trial's progress. The committee reviews the adherence to the study protocol, approves protocol modifications, monitors study recruitment and the overall timetable, guides on specific scientific issues as they arise, ensures compliance with relevant legislation and approves strategies for publication and dissemination.

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

The ethical committee of the Iran University of Medical Sciences must approve modifications to the study protocol and then update it in the Iranian Registry of Clinical Trials.

Dissemination plans

Research results will be published in a relevant journal and presented at physiotherapy, gynaecology and obstetrics conferences.

DISCUSSION

The present study will investigate the effect of motor control training and breathing exercises compared with motor control training alone on pain, disability and core muscle activity in women with postpartum LPP.

Postpartum women may experience LPP as a result of mechanical and hormonal alterations that occur during pregnancy and childbirth, which can affect the dynamic stability of the lumbopelvic region. Motor control exercises strengthen the deep lumbopelvic muscles, thereby improving lumbar stability.

Previous studies have shown that the general population with LBP is susceptible to respiratory muscle weakness and atrophy and that breathing patterns, core stability and respiratory function may be related to LBP.[50 51] Moreover, during pregnancy, the diaphragm's higher position due to the uterus's enlargement and the increased respiratory demand can affect the diaphragm's stabilising role. A recent study also reported reduced diaphragm excursion in women with postpartum LPP compared with controls.[8] Based on prior theories suggesting that respiratory exercises can enhance core muscle activity and spinal stability, it can be hypothesised that incorporating breathing exercises with motor control exercises may yield greater improvements in pain, disability and core muscle activity than motor control exercises alone in women experiencing postpartum LPP.

Compared with other cost-effective non-pharmacological treatments (eg, spinal manipulation, acupuncture or interdisciplinary rehabilitation), the exercises outlined in this study are characterised by their simplicity and low incidence of adverse effects. This enhances the therapy's acceptability among women with postpartum LPP who are seeking assistance. If the findings are conclusive, the present study could help establish a scientific basis for the use and effectiveness of motor control training and breathing exercises for improving pain, disability and core muscle activity in women with postpartum LPP.

The study's results will be relevant to physiotherapists, midwives, clinicians and administrative stakeholders. If motor control training combined with breathing exercises is more effective than motor control training alone, the study results are expected to have substantial implications for the rehabilitation of women with postpartum LPP. This may enhance the scientific foundation and facilitate the successful implementation of effective physiotherapy programmes in clinical settings.

The present study has some limitations. The inclusion and exclusion criteria set in this study may limit the generalisability of the findings. Another limitation is that the women participating in this study are motivated to exercise, so the findings cannot be generalised to others with postpartum LPP who are not interested in participating in exercise training programmes. Further, it is not feasible to blind investigators and participants because of the nature of the intervention, which may lead to bias in the results.

TRIAL STATUS

The current protocol represents protocol V.1.0. The recruitment for the trial began on 21 May 2024 and is expected to be completed in November 2025.

ETHICS AND DISSEMINATION

The Iran University of Medical Sciences Human Research Ethics Committee has approved the study protocol (IR.IUMS.REC.1403.017). The study has been prospectively registered in the Iranian Registry of Clinical Trials (IRCT20180916041051N2). Research results will be submitted to relevant scientific journals and international conferences. A summary of the study results will be provided to study participants following the completion of the study.

Contributors SSA and MD led the protocol development with support from all coauthors (SF, SND and MNF) who will provide expert input on trial design and intervention content. SF will assess the outcome measures. SSA and SF drafted the protocol manuscript. Guarantor: SSA. 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, conduct, reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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