Research Protocol

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Physiotherapy Section

Effect of Pelvic Floor Exercises and Diaphragmatic Activation versus Split Tummy Exercise Program on Inter-recti Distance, Strength and Quality of Life in Diastasis Recti: A Research Protocol

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ABSTRACT

Introduction: Diastasis Recti Abdominis (DRA) is characterised by an increased separation of the rectus abdominis muscles, which is accompanied by the extension of the linea alba tissue and weakness of the abdominal wall. Among women, DRA is prevalent both during pregnancy and in the postpartum period. There is a lack of knowledge regarding the prevalence, risk factors and rehabilitation of this condition.

Need of the study: Diastasis Recti can lead to an increased distance between the rectus abdominis muscles and weaken the abdominal muscles, which may contribute to pelvic floor dysfunction and affect its function, ultimately resulting in a reduced quality of life. It has also been noted that Urinary Incontinence (UI), Pelvic Organ Prolapse (POP) and faecal incontinence occur more frequently in women who have DRA. In this study, the combined effect of pelvic floor exercises with abdominal activation and the Split Tummy Exercise Program (STEP) can be a more effective management strategy in reducing diastasis recti and thereby improving abdominal muscle strength and quality of life.

Aim: To compare the effects of pelvic floor exercises with diaphragmatic activation and the Split Tummy Workout Program on strength, overall quality of life and inter-recti distance in patients with diastasis recti.

Materials and Methods: The present study is a comparative study in which a simple random sampling technique will be employed on participants allocated by a sequentially numbered opaque sealed envelope technique. The total duration of the study will be one year from June 2024 to June 2025, with a total of 60 participants conducted at Datta Meghe Institute of Higher Education and Research, Deemed to be University, Wardha, Maharashtra, India. This research will be conducted in the Department of Community Health Physiotherapy and the Department of Obstetrics and Gynaecology, based on the inclusion criteria of the study. Group A will receive a four-week exercise program that includes pelvic floor exercises combined with abdominal activation, while Group B will follow the STEP program. Outcome measures will include a Digital Calliper, Posterior Pelvic Pain Provocation Test, Visual Analogue Scale (VAS), Sphygmomanometer and Health-Related Quality of Life Scale (HRQOL), which will be performed at baseline and at the last session after four weeks of rehabilitation.

Keywords: Postpartum, Physiotherapy rehabilitation, Pelvic floor exercises program

INTRODUCTION

The postpartum period, also referred to as the puerperium, occurs after the delivery of the newborn and placenta, lasting up to 6-8 weeks. During this time, the structural and physiological changes brought on by pregnancy are gradually reversed [1]. According to the World Health Organisation (WHO), the postnatal period is the most important yet often the most ignored stage of a mother's and baby's lives. Pregnancy is typically accompanied by a number of physical changes, including a shift in the centre of mass of the body, an increase in pressure on key internal organs, and an increase in body weight, which can frequently lead to back and pelvic discomfort [2].

Pregnancy and the postpartum period are marked by significant hormonal and social changes [3]. According to several studies, 50% of pregnant women experience back and pelvic discomfort and in 9-15% of those cases, the pain is classified as severe [4]. Diastasis recti is one of the common conditions occurring after pregnancy. It refers to the separation of the rectus abdominis muscle at the linea alba, which connects the two parts of this muscle. Pregnant women are commonly affected by this condition, typically during the third trimester [5]. It is also seen most frequently in the early postpartum period. Studies suggest that DRA may affect between 30% and 70% of pregnant women, and in 35% to 60% of cases, it may persist for several months after giving birth [6].

Risk factors for diastasis recti include obesity, weight gain during pregnancy, prepregnancy weight, gestational age at delivery, type of birth and duration of labour. Women with DRA are thought to have had more pregnancies and births overall, and it is quite frequently seen in multiparous women. There is a substantial association between DRA during pregnancy and the frequent carrying and lifting of young children, which may increase pressure on the abdominal wall and contribute to already weakened abdominal muscles after multiple pregnancies [7].

DRA is brought about by mechanical stresses applied to the abdominal wall by the growing foetus, loss of abdominal organ support and elastic changes in connective tissue induced by relaxin, progesterone and oestrogen hormones. Hormonal shifts and the expansion of the uterus during pregnancy can lead to the stretching and weakening of abdominal muscles [8]. The abdominal wall is fundamental for respiration, trunk rotation, supporting abdominal viscera and maintaining good posture. An increase in inter-recti distance affects these functions and can weaken and impair the ability of the abdominal muscles to perform their roles.

This can lead to altered trunk mechanics, decreased lumbo-pelvic stability and altered posture, all of which increase the risk of injury to the lumbar spine and pelvis [9]. Research findings indicate that DRA can lead to various complications, including alterations in trunk biomechanics, limitations in daily task performance, shifts in pelvic stability, potential spinal injuries, decreased functional strength, compromised abdominal wall integrity, and, in severe instances, the development of abdominal hernias.

DRA is characterised by severe weakness of the abdominal muscles, which, if left untreated, may result in secondary complications in the core region. These complications can include postural imbalance, changes in breathing patterns, instability of the trunk and pelvis, and hypermobility in the lumbopelvic region. The aim of the exercise programmes is to increase abdominal muscle strength and to reduce the distance of DRA in postpartum mothers. A voluntary contraction of the pelvic floor muscles will cause the muscle fibres to pull and lift the internal organs, while tightening the openings of the anus, vagina and urethra.

DRA muscle is marginally linked to POP, potentially contributing to compromised health-related quality of life, diminished abdominal muscle strength and heightened severity of low back pain [10]. It is widely recognised that DRA does not directly cause discomfort or distress, but it could play a role in the onset of lumbar pain or issues with the pelvic floor. Previous studies have observed a higher incidence of UI, POP and faecal incontinence in women with DRA compared to those without it. An investigation revealed a correlation between DRA and pelvic floor dysfunction in urogynaecological patients. The study found that individuals with DRA have an increased likelihood of experiencing pelvic floor muscle weakness, which can consequently lead to UI and POP [11].

Diaphragmatic Aspiration (DA), performed with arms alongside the body and knees bent, involves exhaling gradually through the mouth while drawing in the belly, then holding the breath and pulling the abdomen upwards. During DA, the IRD was reduced when the abdomen was pulled up during aspiration, likely because the two rectus abdominis muscles come closer to each other due to the stretching of their fibres. DA performed without drawing in the belly could, therefore, potentially result in a significant reduction in IRD. This should be further investigated, considering that drawing in has been shown to reduce the distortion of the linea alba.

This combination reduced the inter-recti distance. Its effects on other aspects of abdominal function (strength, endurance, circumference, linea alba stiffness and distortion) as well as pelvic floor function (tonus, strength, endurance, UI, POP) deserve to be studied in future research. The formulation of STEP content stemmed from a comprehensive examination of existing literature concerning physical activity interventions tailored for postpartum women previously diagnosed with DRA during pregnancy. A panel of six experts was engaged to assess the suitability and practicality of implementing the exercise regimen [12].

There is a scarcity of literature asserting the impact of pelvic floor exercises combined with diaphragmatic activation and STEP on inter-recti distance, strength and quality of life in diastasis recti. Thus, there is a need to conduct a study on the independent effects of pelvic floor exercises with diaphragmatic activation on diastasis recti. Therefore, this study aims to examine the additional effect of pelvic floor exercises combining diaphragmatic activation and STEP to improve inter-recti distance, strength and quality of life in postpartum women diagnosed with diastasis recti.

Objectives

To determine the effect of pelvic floor exercises combined with diaphragmatic activation on inter-recti distance, strength and quality of life in postpartum women with diastasis recti.

To evaluate the effect of STEP on inter-recti distance, strength and quality of life in postpartum women with diastasis recti.

To compare the effect of pelvic floor exercises combined with diaphragmatic activation and STEP on inter-recti distance, strength and quality of life in postpartum women diagnosed with diastasis recti.

Alternate hypothesis: There will be a significant difference between the effects of pelvic floor exercises combined with diaphragmatic activation and STEP in reducing inter-recti distance and improving strength and quality of life in postpartum women diagnosed with diastasis recti.

Null hypothesis: There will be no significant difference between the effects of pelvic floor exercises combined with diaphragmatic activation and STEP in reducing inter-recti distance and improving strength and quality of life in postpartum women diagnosed with diastasis recti.

REVIEW OF LITERATURE

Charpot V, conducted a study to investigate the effect of abdominal strengthening exercises in women during the postpartum period. The study included a 39-year-old female diagnosed with severe diastasis recti one year after her last delivery. In this study, the finger palpation method was used to examine Diastasis Recti Abdominis Muscle (DRAM), and abdominal strengthening exercises were administered for eight weeks. The study concluded that abdominal strengthening exercises are not effective in reducing severe diastasis recti in the late postpartum period. However, there was a definite reduction in low back pain, suggesting that the prescription of abdominal strengthening exercises for severe diastasis recti in the very late postpartum period may not be supported [13].

Wang XQ et al., conducted a randomised control trial to evaluate the effect of core stability exercises versus general exercises for chronic low back pain. They concluded that, in patients with low back pain, short-term back-specific functional status and pain reduction were better achieved with core stability exercises than with general exercise [14].

Boxer S and Jones S, carried out a study on inter-rater reliability and concluded that rectus abdominis diastasis can be measured during the postpartum period with a high degree of reliability when assessed using a dial calliper. It has proven to be an uncomplicated, accurate and practical instrument for measuring diastasis recti [15].

Gluppe SB et al., performed a randomised control trial to examine the immediate effect of abdominal and pelvic floor muscle exercises on inter-recti distance in parous women with diastasis recti. They found that head lift and twisted curl-up exercises decreased the inter-recti distance both above and below the umbilicus, whereas maximal in-drawing and pelvic floor muscle contraction exercises only increased the inter-recti distance below the umbilicus. A randomised controlled trial is needed to investigate whether head lift and twisted curl-up exercises are effective in permanently narrowing the inter-recti distance [16].

Shohaimi S et al., conducted a study on the STEP for reducing diastasis recti in postpartum primigravidae and concluded that the large reduction in DRA size demonstrated in the STEP intervention group at eight weeks postpartum suggests that STEP is effective as part of a postpartum training programme for managing DRA [12].

MATERIALS AND METHODS

The present study is a comparative study in which a simple random sampling technique was used to allocate participants via a sequentially numbered opaque sealed envelope method. The total duration of the study will be one year, from June 2024 to June 2025. Ethical approval was received from the Institutional Ethics Committee DMIHER (DU)/IEC/2024/180, and the study has been registered on clinicaltrials.gov with the CTRI Reference Number CTRI/2024/05/066765. All participants will provide written informed consent for the study. This study will include a total of 60 participants and will be conducted at the Datta Meghe Institute of Higher Education and Research, deemed to be a university. The research will

be carried out in the Department of Community Health Physiotherapy and the Department of Obstetrics and Gynaecology ward.

The ethics council of the Datta Meghe Institute of Higher Education and Research approved the study, which was implemented in the obstetrics and gynaecology ward and the Department of Community Health Physiotherapy. Individuals fulfilling the requirements for participation will be selected at random using opaque, sequentially numbered envelopes, and they will be assigned to either Group A or Group B. Before starting the intervention, each woman was provided with consent forms, which they filled out after being guided by the therapist on how to complete them. The entire procedure was explained to the participants by the therapist.

The baseline findings of all the participants were recorded using a digital calliper to measure diastasis recti, a sphygmomanometer to measure abdominal muscle strength and a VAS to assess pain. The posterior pelvic pain provocation test was utilised to evaluate lumbopelvic instability. Once the baseline readings were obtained by the assessor under the guidance of the Professor, they were noted in a data collection sheet. The study will be conducted under the guidance of the PG guide, HOD, principal and chief advisor of the research cell.

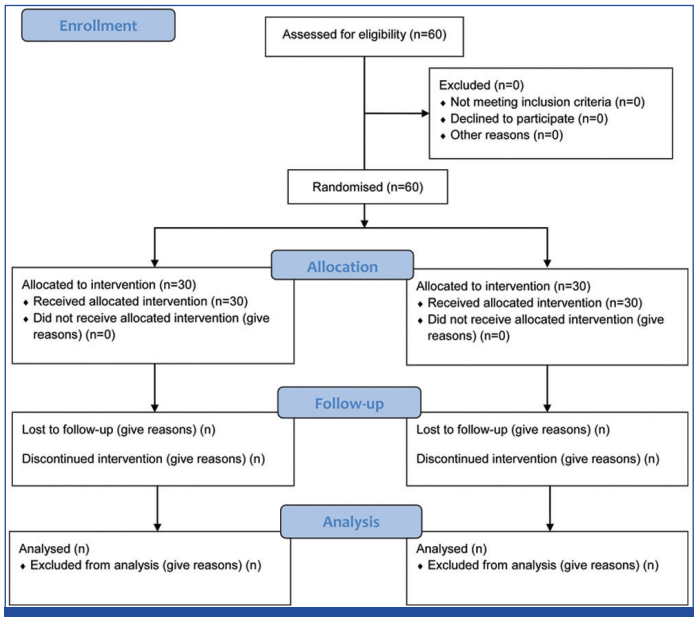
Inclusion criteria: Participants with age 25 to 40 years, multipara (two or more deliveries), full-term normal delivery and up to 6 weeks postpartum will be included in the study.

Exclusion criteria: Females with a previous history of abdominal surgeries, females with BMI >40 kg/m^2, subjects suffering from any heart or respiratory condition, any injury or fracture to the back or vertebra, and any neurological problems resulting in cognitive impairments that hinder their comprehension of instructions will be excluded fro the study.

Sample size calculation: The sample size will be calculated using Cohen's effect size by comparing two means (estimated). Considering a large effect size difference=0.8 (large effect size) at a 5% level of significance=1.96 at 80% power=0.84, with a ratio allocation (Group B/Group A) of 1, the sample size will be 26 per group. Considering a 15% dropout rate, the total required sample size is 30 samples per group.

Participant Timeline

Groups A and B will receive physiotherapy rehabilitation for a period of four weeks. Both Group A and Group B will be treated conventionally. In addition to standard therapy, Group A will undergo pelvic floor exercises combined with abdominal activation. The STEP will be administered to Group B in addition to standard treatment. The CONSORT flow chart is mentioned in [Table/Fig-1] [17].



[Table/Fig-1]: CONSORT flow chart [17].

Safety outcomes:

A report of any adverse incidents will be documented each time.

Methods: Assignment of Interventions

1. **Allocation**
   - A) Sequence generation: Computer-generated random numbers will be used for the study.
   - B) Allocation concealment mechanism: Simple random sampling using computer-generated random numbers will be employed to randomise the study subjects.
   - C) Implementation: The random number sequence will be generated by a blinded person without a healthcare background. The study's principal investigator will handle the enrollment and assignment of participants to the interventions.
2. **Blinding:**
   - A) Data collection methods: The assessment and collection of outcomes will occur in the preintervention stage after participants are assigned to the intervention groups. Postintervention data will be collected on the same day after completing the four-week intervention.
   - B) Data management: Frequencies and percentages for qualitative data, as well as means and standard deviations for quantitative data, will be used to summarise the information gathered.
   - C) Statistical methods: The demographic data (age and gender) will be analysed using descriptive statistics.

Group A will receive a four-week exercise programme that includes pelvic floor exercises combined with abdominal activation, while Group B received a four-week exercise programme that included STEP. Data will be collected and analysed statistically.

Participant Timeline

Each patient will be required to complete four weeks of rehabilitation after enrollment in the study. The evaluations will be performed at baseline and at the final session.

Group-A: Group A consisted of 30 participants.

Participants in Group A underwent aerobic training and pelvic floor exercises (as given in [Table/Fig-2]), combined with abdominal activation.

Precautions for Pelvic Floor Exercises:

1. Participants were instructed not to contract the gluteal muscles, hip adductors, or abdominal muscles.
2. Participants were instructed not to hold their breath while performing pelvic floor muscle contractions.

Additionally, the participants in Group A were taught the technique of DA, which involves deliberate, slow inhalation using the diaphragm, followed by complete exhalation and gradual engagement of the Transversus Abdominis (TrA) and intercostal muscles to lift the hemidiaphragm (DA). They were taught how to contract the pelvic floor muscles simultaneously with diaphragmatic activation while in a lying position.

Group B: Group B also included 30 participants.

This group also received aerobic training and STEP. This study is ongoing.

The STEP module comprises three phases: Facilitation, integration and strengthening of abdominal muscles, intended for postpartum use. It is recommended to participate in these exercises at least three times a week, with each session consisting of three sets of 10 repetitions. Flexibility is allowed regarding the duration and potential modifications of exercises if participants encounter difficulties. The exercise regimen emphasises enhancing abdominal strength through a series of exercises, including crunches, planks and Russian twists. During the crunches, individuals are instructed to raise their heads

	Position	Instruction	Duration of contractions/Repetitions/sets
Week 1	Supine lying with knees bent	Try to squeeze as if you are trying to hold urine, or stop wind from coming out. Do not use your abdominal muscles or your buttocks when you are doing this exercise. Your buttocks and legs should not move at all	(Slow twitch muscle fibres contraction): squeeze the muscles and hold for up to 10 seconds. If the patient is not able to hold the contraction for 10 sec, she shall try to contract the muscles for as long as she can. Once she can hold the contractions, gradually increase the duration up to 10 sec (Fast twitch muscle fibres contractions): Practice tightening the pelvic floor quickly and then relax. Fast contractions are done in the same way as slow contractions but when the patient squeezes the muscles, let go immediately so that one only feels a very quick lift in the pelvic floor. Practice hold and relax for 3 to 4 times/30 repetitions/3 sets.
Week 2	Patient was made to sit on a hard chair, leaning forward to support forearms on knees with hips abducted and thighs and knees apart	Try to squeeze as if you are trying to hold urine, and stop wind from coming out. Do not use your abdominal muscles or your buttocks when you are doing this exercise. Your buttocks and legs should not move at all	(Slow twitch muscle fibres contraction): squeeze the muscles and hold for up to 10 seconds. (Fast twitch muscle fibers contractions): Practice tightening the pelvic floor quickly and then relax. Fast contractions are done in the same way as slow contractions but when the patient squeezes the muscles, let go immediately so that one only feels a very quick lift in the pelvic floor. Practice hold and relax for 3 to 4 times/30 repetitions/3 sets.
Week 3	Standing position	Try to squeeze as if you are trying to hold urine, and stop wind from coming out. Do not use your abdominal muscles or your buttocks when you are doing this exercise. Your buttocks and legs should not move at all	(Slow twitch muscle fibers contraction): squeeze the muscles and hold for up to 10 seconds. (Fast twitch muscle fibers contractions): Practice tightening the pelvic floor quickly and then relax. Fast contractions are done in the same way as slow contractions but when the patient squeezes the muscles, let go immediately so that one only feels a very quick lift in the pelvic floor. Practice hold and relax for 3 to 4 times/30 repetitions/3 sets.
Week 4	Women were instructed to start with the least weight and place the vaginal cone while standing. The passive cone was the largest weight that could be held for a minute without the subject's voluntary contraction of the pelvic floor. In order to keep the cone from slipping out of the vagina, the patient would next use the larger weight, which required a deliberate contraction of the pelvic floor. The active cone was the heaviest weight that could be sustained by a muscle contraction	Try to squeeze as if you are trying to hold urine, and stop wind from coming out. Do not use your abdominal muscles or your buttocks when you are doing this exercise. Your buttocks and legs should not move at all	Slow twitch muscle fibers contraction): squeeze the muscles and hold for up to 10 seconds. (Fast twitch muscle fibers contractions): Practice tightening the pelvic floor quickly and then relax. Fast contractions are done in the same way as slow contractions but when the patient squeezes the muscles, let go immediately so that one only feels a very quick lift in the pelvic floor. Practice hold and relax for 3 to 4 times/30 repetitions/3 sets.

[Table/Fig-2]: The pelvic floor exercise protocol for four weeks.

and direct their gaze towards the space between their thighs while lying supine lying on their knees backs with bent [12].

To perform the plank exercise, individuals lie down on their stomach, supporting themselves with their elbows, and aim to maintain the position for as long as they can. For the Russian twist, participants sit slightly leaned back with a straight spine, bending both legs, and proceed to rotate their bodies from side to side.

Conventional Therapy

Aerobic training recommendations: Before embarking on any exercise regimen, it is essential to secure proper medical clearance. After being cleared, an individual's exercise regimen and progression should be customised based on their prior activity level and any current medical conditions. Exercise after giving birth should be approached with caution, paying attention to symptoms such as extreme exhaustion, dehydration, pain, discomfort in the breasts, or vaginal bleeding. If any of these symptoms occur, stop exercising immediately and consult a doctor.

Upon resuming exercise safely, reduce both intensity and duration, scaling back to the level of the last successful session. A therapist should monitor the patient's development and adjust the plan as necessary. Aerobic training is provided for four weeks. It is recommended that women who are new to postpartum exercise begin with three days a week of 25-30 minutes of aerobic activity. Gradually work up to six days a week, aiming for at least 150 minutes of moderate-to-intense activity each week. Examples include brisk walking and activities that elevate heart rate while still allowing for conversation. Due to the demands of breastfeeding and childcare, it may be wise for previously sedentary individuals to begin with shorter sessions (e.g., 15-20 minutes) and slowly increase the duration over the initial three weeks to enhance adherence.

OUTCOME MEASURES

Primary outcome measure:

1. **Digital calliper:** The diastasis recti was measured with a digital calliper. The patient was placed in a supine position, with their hands by their sides and their hips and knees flexed to a 45° angle for the test. Three centimetres were subtracted and added to the measurement of the inter-rectus distance at the level of the umbilicus. The patients were instructed to slowly raise their heads and shoulders off the examination bed and move towards their knees to lift their shoulders off the floor. They were then asked to hold this position for approximately ten seconds to palpate the rectus abdominis muscle with their fingers and position the internal measuring arms of the calliper between the two bellies of the rectus abdominis. The examiner placed their fingers horizontally across the abdomen.

   Subsequently, the digital display's registration number was noted. Four weeks following the intervention and at the baseline were when the tests were conducted [15]. Digital callipers are easy-to-use, accurate and straightforward measuring instruments for determining the extent of diastasis in the rectus abdominis after childbirth. The reliability of the digital calliper is (r=0.97).

2. **Sphygmomanometer:** The sphygmomanometer can provide objective measures and is reasonably priced, making it a viable method. It is commonly acknowledged that this tool is valid and reliable for evaluating strength in a range of medical situations. The name of the tool is Baseline Evaluation Instrument (the monitor exercise feedback). The patient lies prone to evaluate the strength of their core muscles. The bottom edge of a modified sphygmomanometer is placed immediately below the Anterior Superior Iliac Spine (ASIS) and positioned horizontally beneath the abdomen. The patient is instructed to draw in their abdomen when the balloon is inflated to 70 mmHg. Maintaining the pressure decrease between 6 and 10 mmHg for up to 10 seconds is the proper protocol. After this, three consecutive readings are noted, from which the mean value is determined [18].

Secondary outcome measures:

1. **Visual Analogue Scale (VAS):** Test-retest reliability has been shown to be good and the instrument has strong validity and is frequently used. The suffering VAS is a unidimensional pain intensity metric that has been widely utilised in several adult populations. A millimetre-long measurement is made from the left end of the line to the patient's specified locations to

compute the VAS score. The score is determined by measuring the distance (mm) on the 10-cm line between the markers for no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm), and severe pain (75-100 mm). The VAS was assessed at baseline and four weeks following the intervention [19].

2. **Posterior pelvic pain provocation test:** For this test, the patient is placed supine with the hip flexed to 90° and the knee bent. The examiner applies posterior shearing stress to the sacroiliac joint through the femur. When the participant feels pain in her buttocks, both distal and lateral to the L5-S1 area, which is near the sacroiliac joints, the test is deemed effective. This test was administered both at baseline and during the four weeks of intervention. The posterior pelvic pain provocation test has a sensitivity of 0.88 and a specificity of 0.89 [20].
3. **Health-Related Quality of Life Scale (HRQOL):** The Short Form Health Survey (SF-36) would be a useful tool for assessment.

STATISTICAL ANALYSIS

Data analysis: All data will be summarised with baseline characteristics. The demographic data (age and gender) will be analysed using descriptive statistics. Descriptive statistics, including mean, standard deviation, n (%), Chi-square test and Independent t-test, will be used to check the homogeneity of the descriptive statistics. Inferential statistics between the two groups will be analysed with an unpaired t-test and group comparisons will be made using a t-test, utilising the software Statistical Package for the Social Sciences (SPSS) version 21.0. A p-value <0.05 will be considered significant. Demographic variables will be described by frequency and percentage for categorical data and with mean and standard deviation for continuous data. Outcome variables will be analysed over continuous variables, summarised with the minimum, maximum, mean, standard deviation, standard error, and 95% Confidence Interval (CI) for parametric data. Continuous outcome variables will first be tested for normality using the Kolmogorov-Smirnov test at a 5% level of significance (p-value ≤0.05). If rejected, data will be considered non normally distributed; otherwise, parametric tests will be used to find significance. A t-test will be used to find the significant difference at a 5% level (p-value ≤0.05) for comparative groups—STEP along with conventional physiotherapy (control group) against pelvic floor exercises and abdominal activation along with conventional physiotherapy (experimental group).

Non normal data will be described by mean, median, lower quartile, and upper quartile for the use of non parametric tests. The Mann-Whitney test will be employed to test for significance. Categorical variables will be summarised by frequency (N) and percentage values (%). Categorical variables (stunted and non-stunted) will be analysed using Fisher's exact test to find significant associations with different risk factors. All confounding variables will be analysed using multivariate analysis.

Data monitoring: The data will be monitored by the Data Monitoring Committee of Ravi Nair Physiotherapy College.

HARMS: Every instance of an adverse event will be reported to the Ethical Committee, the clinician overseeing the evaluation and management of both requested and unintentional adverse events, as well as any other unanticipated consequences of trial interventions or trial conduct.

Access to data: All data collected during or after the study will be stored and maintained by the study's Principal Investigator (PI). The PI will have access to the final trial dataset, which will be shared in a de-identified format after receiving a formal request for research and publication purposes only.

Ancillary and post-trial care: Care will be provided to study subjects in the event of harm resulting from trial participation by the PI in accordance with the policies of Ravi Nair Physiotherapy College and DMIHER.

Dissemination policy: Any data collected during or after the study will only be used for academic and research-related purposes, culminating in a publication in a reputed journal.

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