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RCT - Protocol

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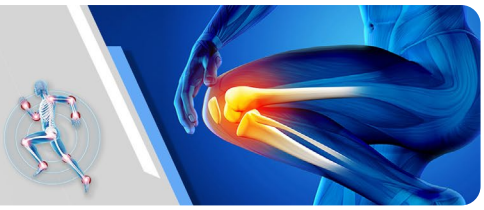

Effectiveness of Core Stabilization Exercise along with Conventional Physiotherapy on Pain, Proprioception and Disability in Patients with Chronic Low Back Pain: A Randomized Control Trial Protocol

Md Waliul Islam[1], Md Tanzir-Uz-Zaman[1], Md Golam Kibria[2], Md Mostafijur Rahman[3], Md Jubair Hassan[4], Saddam Hossain[5], Md Kutub Uddin[6], Mohammad Ainur Nishad Rhajib[1], Md Zakir Hossain[3], Abdullah Ibn Abul Fazal[3] and Mohammad Anwar Hossain[7]*

Abstract

Background/Purpose: Currently, there is significant emphasis on importance of core muscle in rehabilitation of musculoskeletal pain like low back pain. Therefore, this study aim to investigate where additional core muscle training improve clinical outcomes.

Methods: In a randomized controlled trial 60 patient will be randomly allocated to two groups of conventional physiotherapy and core stability exercise with conventional therapy. Single blind randomize control trial design will be used in this study. Total treatment session will be 4 sessions per week for 12 weeks.

Outcome Measurement: The investigator will assess the pain before and after intervention with Numeric Pain Ratting Scale (NPRS) and disability with Oswestry Low Back Pain Disability Index. Intermediate assessment will be performed after 6 weeks of intervention.

Discussion: This study will provide evidence for additional effect of core stability exercise on pain and functional disability for patient with low back pain.

Keywords: Chronic Low back pain; Core stabilization exercise; Conventional physiotherapy

Introduction

Low Back Pain (LBP) is a widespread health and socioeconomic issue that significantly contributes to disability worldwide. LBP scored as the most severe handicap in terms of years lived with disability, according to Global Burden of Disease 2010 research [1]. Furthermore, according to Hoy et al. [2] estimated the mean point prevalence, 1-year prevalence, and lifetime prevalence of LBP were, respectively, 18.3%, 38.0%, and 38.9%.

Lower extremities discomfort may or may not accompany low back pain, which causes pain that is localized between the costal margins and the inferior gluteal folds [3]. Nonspecific LBP (NSLBP), which has no known etiology or pathology, makes for more than 85% of LBP cases [4,5]. Patients with NSLBP have reduced postural control, which is necessary for performing functional activities [6]. The ocular, vestibular, and somatic sensory systems all contribute sensory information to the complex neuromuscular process of postural regulation [6-8].

Postural control requires both cerebral processing and motor output [9]. Proprioception is significantly affected in individuals with chronic LBP than in healthy controls, according to a comprehensive study [10]. LBP may have a potential mechanism involving proprioceptive deficits altering the motion of the lumbar spine [11,12]. Reduced proprioceptive acuity may affect a population's ability to achieve and maintain a neutral spinal position, muscle coordination, and consequently diminish balance control. Patients with LBP may experience discomfort, impairment, and recurrences of injury because of decreased postural control. Accordingly, impaired sensorimotor control may result from diminished proprioception in patients with LBP, which has been suggested to be either or both a cause and a result of their pain [13,14].

Affiliation:

[1]*Senior Clinical Physiotherapist, Centre for the Rehabilitation of the Paralised, Bangladesh*

[2]*Junior Consultant of Physiotherapy, Centre for the Rehabilitation of the Paralised, Bangladesh*

[3]*Clinical Physiotherapist, Centre for the Rehabilitation of the Paralised, Bangladesh*

[4]*Physiotherapist and Rehabilitation officer, Handicap International (Humanity and Inclusion)*

[5]*Consultant Asia Digital Physiotherapy and Orthopedic Rehabilitation Centre, Bangladesh*

[6]*Lecturer, SAIC College of Medical Science & Technology, Dhaka, Bangladesh*

[7]*Associate professor, Bangladesh Health Professions Institute (BHPI), Dhaka, Bangladesh*

***Corresponding author:**
Mohammad Anwar Hossain, Associate Professor, Bangladesh Health Professions Institute (BHPI), Dhaka, Bangladesh.

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For patients with LBP, several types of therapeutic exercises are employed in clinical settings. The co-activation of the Transversus Abdominis (TrA) and LM muscles is emphasized in Core Stability Exercises (CSE), which are based on the motor learning method. By increasing intra-abdominal pressure, these deep stabilizing muscles stiffen the lumbar spine and give the spine segmental stability [15]. They link to the thoracolumbar fascia. Additionally, CSE can improve muscle behavior, undo pain-related restructuring in the motor cortex, and retrain local trunk muscles' critical role in the neuromuscular regulation of spinal stability [16]. In LBP patients, stabilization exercises have been shown to increase stability index, successfully correct postural abnormalities, and reduce pain and disability [17-20].

Treatment for patients with LBP frequently involves Strengthening Exercises (STE). For patients with subacute or chronic NSLBP, strengthening activities are appropriate because they activate the superficial trunk muscles that enable shock absorption of loads [21,22]. These exercises are meant to improve overall spinal stability by strengthening and controlling the global trunk muscles. In patients with NSLBP, these exercises may lessen discomfort and physical impairment while increasing trunk muscular activation [22]. Docherty et al. [23] claim that strength training can improve joint position awareness and strength in the ankle. A combination of central and spindle mechanisms or an improvement in the central mechanisms of motor control may result from strengthening training regimens [24,25]. No prior research has reported the effects of strengthening exercises on proprioception related to either the subacute or chronic stages of LBP.

Therefore, our primary purpose is to compare the effects of conventional and conventional with core stabilization exercise on pain and disability in patients with chronic low back pain. Our secondary purpose was to compare the effects of conventional and conventional with core stabilization exercise on pain and disability.

Methodology

An assessor-blinded randomized controlled trial will be performed after receiving the ethical permission of Ethics Committee; the study proposal will follow the CONSORT checklist and will be submitted for trial registration. It will be conducted at the Tertiary level rehabilitation centre. The intentions and processes of the study will be explained to the eligible participants, and they were asked to sign an informed consent form before their participation. The participants will be allocated into two groups, conventional physiotherapy group and the core stability group. An initial assessment will be done before and after intervention and after 4 weeks of treatment.

Inclusion and Exclusion Criteria: The inclusion criteria are: (a) male and female between 18 years and above, (b) primary complaint of LBP experienced at least over the previous 3 months, and (c) ability to cooperate with investigator. The participants exclusion criteria is: (a) previous history of thoracic spine or lumbosacral spine surgery, (b) Any neurological deficit or presence of red flag, (c) evidence of serious spine pathology (e.g., tumor, infection, fracture, spinal stenosis, inflammatory disease), (d) Unstable or severe disabling chronic cardiovascular and pulmonary disease, (e) History of serious psychological or psychiatric illness, and (f) current pregnancy.

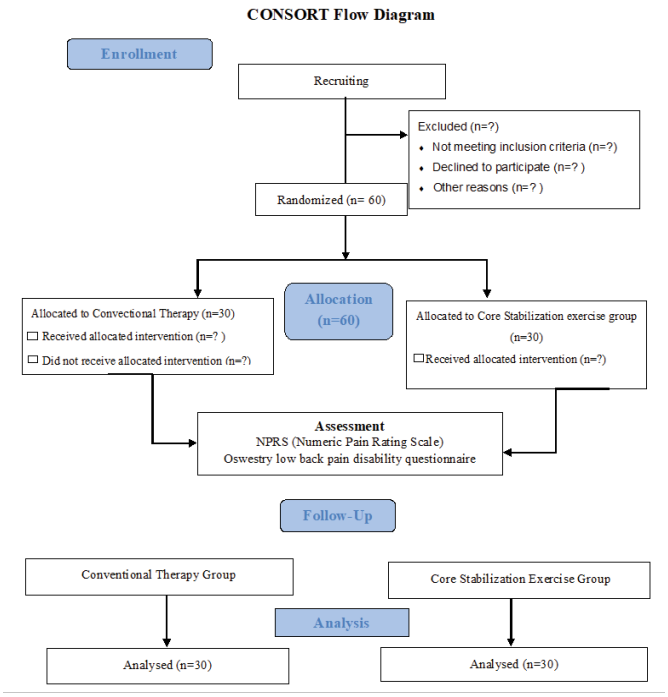

Figure 1: Consort flow diagram.

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Outcome measurement

Functional disability (Oswestry low back pain disability questionnaire): The self-completed questionnaire asks 10 questions about ten different topics: pain intensity, lifting, ability to take care of oneself, walking, sitting, sexual function, standing, social life, sleep quality, and ability to travel. Six sentences detailing several possible events in the patient's life related to the topic follow each topic area. The patient then evaluates the statement that most accurately describes their circumstance. The first statement in each question receives a score of zero, signifying the least amount of handicap, and the last statement receives a score of five, signifying the most severe disability. To get the index, the answers to all questions are added together, then multiplied by two (range 0 to 100) [39].

Pain: The NPRS (Numeric Pain Rating Scale) is a segmented numerical version of the Visual Analog Scale (VAS), in which the respondent chooses an integer value between 0 and 10 that best describes the degree of their pain. Horizontal bars or lines are the most typical format. The 11-point numerical scale runs from 0 (which represents the least amount of pain, such as "no pain") to 10 (which represent the most extreme amount of pain, such as "pain as bad as you can conceive" or "worst pain imaginable") [40].

Proprioception: utilizing a Dualer IQ Digital Inclinometer and the active angle repetition test, one can assess one's trunk proprioception while standing. The first lumbar vertebra is where one end of the inclinometer is placed, and the sacrum is where the other end is placed. Test was conducted standing up. The participants were instructed to flex their trunks until they reached the goal sagittal plane angle of 30°, hold it for three seconds, and then return to an upright position. We asked the participants to correctly identify the perceived target angle three times after they had each felt the target angle three times in total. The difference between the target angle the individuals perceived and the angle they later discovered was averaged [41].

Intervention:

Conventional: Graduate physiotherapist will be involved in the treatment of patients. It will include McKenzie directional preference, Maitland and Mulligan technique and electro physical modalities.

Core stability exercise: The "cat" and "camel" stretches as well as a brief aerobic exercise might be included in the warm-up. Recognizing the neutral spine position, which is said to be the posture of power and balance for the best athletic performance in many sports, is the first step in a core stability training program [26]. Learning to activate the muscles of the abdominal wall is the first step in core stability training. It may take more time and practice for those who struggle with voluntary motor pathway activation, suffer from persistent low back pain, or exhibit fear-avoidance behavior to learn to recruit muscles alone or in conjunction with motor patterns [27,28]. A crucial first step is to cue people to hollow their abdomens, which may activate the transversus abdominis, as well as to brace their abdomens, which activate several muscles, including the transversus abdominis, external obliques, and internal obliques. According to one study, hollowing and bracing the abdomen before doing abdominal curls helped to activate the transversus abdominis and internal obliques during the abdominal curling exercise [29,30]. Training should be advanced once these activation techniques are mastered and the transversus abdominis is "awakened." The "major 3" exercises as outlined by McGill can then be incorporated by the beginner. These include the "bird dog" stance, the side bridge (also known as a side plank), and the curl-up. At this point, the prone plank and bridging can also be incorporated [28]. Pelvic bridging works very well to stimulate the lumbar paraspinals [31]. Supine, hook-lying, or quadruped positions are used for the first workouts. It should be emphasized that the spine should not be flattened or tilted but should instead maintain a neutral position. Additionally stressed is regular, rhythmic diaphragmatic breathing. After demonstrating strong control with the static core exercises, the person can move on to exercises including a physio ball. It should be noted that non-weight-bearing core exercises, such those done on a physio ball, could not result in better athletic performance [32]. Therefore, patients should move on to more practical activities in the sitting, standing, and walking positions as soon as possible. Focus should be given on improving balance and coordination while executing a variety of movement patterns in the three cardinal planes of

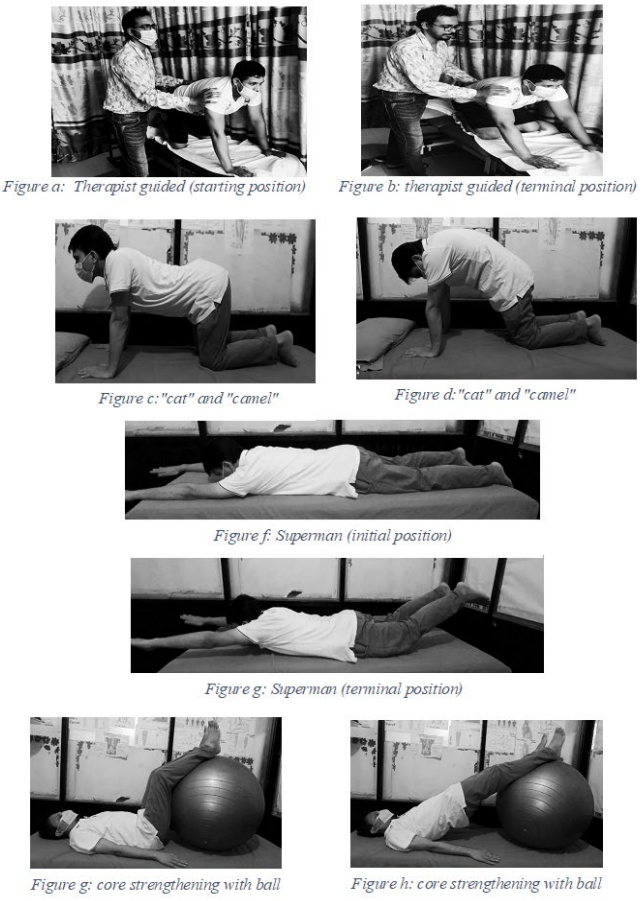

Figure a: Therapist guided (starting position)

Figure b: therapist guided (terminal position)

Figure c: "cat" and "camel"

Figure d: "cat" and "camel"

Figure f: Superman (initial position)

Figure g: Superman (terminal position)

Figure g: core strengthening with ball

Figure h: core strengthening with ball

Figure 2: Core stabilization exercise.

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Table 1: Sprit statement for RCT protocol.

Time point	Enrolment	Allocation	Post-allocation		
	0	T_0	T_1	T_2	T_3
Enrolment					
Eligibility screen	X				
Informed consent		X			
Demographic Questionnaire		X			
Allocation		X	X		
Intervention					
Core stability exercise			X		
Patient education			X		
Assesment of proprioception		X			X
NPRS		X		X	X
ROM		X		X	X
Oswestry low back pain disability questionnaire		X		X	X

movement sagittal, frontal, and transverse—as one advance through the early stages of a core strengthening program. Exercises ought to be done while standing and should imitate functional motions. Acceleration, deceleration, and dynamic stability are frequently needed during functional training. Reflexive control and postural regulation should be practiced in a sophisticated core stabilizing program [25].

Core strength training guidelines (FITT)

Frequency: 4 times a week. **Intensity:** Since all exercises will mostly done using subjects own body weight, one should focus on higher repetitions of 10 or more. Isometric contractions should be maintained for duration of time. (Ex. 15-20 seconds).

Time: 20-25 minute

Type: Body weighted exercises. During each exercise patient should contract abdominal muscles as if patents were expecting to get hit in the stomach. Also, important to remember proper breathing techniques inhaling and exhaling on opposite movements.

The SPIRIT scheme diagram of the study schedule and management; "(Table 1)" NPRS, Numeric Pain Rating Scale; ROM, Rang of Motion; -T_1: pre-study, Screening/Consent T_0: Baseline Randomization T_2: Study, 2 weeks after intervention T_3:4-weeks post assessment.

Data analysis

Statistical analysis of data will be performed in Statistical Package for Social Science (SPSS), version 25.0. Statistical analysis will be performed according to nature of data. Normal distribution of the data will be test by kolmogorov smirnov test. In case of normal distribution parametric test will be performed.

Ethical consideration

Helsinki guidelines 2008 will be followed during the study periods. Initially a consent form will be given to each participant. This form explains the title, objective, confidentiality & anonymity of the research project. The participant will be also informed that, they are free to withdraw at any time. The researcher will keep the information in a secured place [33]. It will be explained to all the participants that their personal identity will be kept confidential, their name & address would not be written, except for social number or a pseudonym. Only principal investigator had the access of that information. Finally, the study will be reviewed and approved by the authorities.

Discussion

There is plenty of proof that people with persistent LBP and sacroiliac pain don't properly activate their core muscles and have weak cores [34-38]. Additionally, there is proof that people with chronic LBP have greater fatigability, a smaller cross section, and fatty infiltration of the paraspinal muscles [39]. These patients also appear to have less ability to adapt for unforeseen trunk disturbance and more problems with balance. Additionally, back pain sufferers appear to over-activate superficial global muscles, but deep spinal muscle control and activation are compromised. Therefore, core stability exercises offer a solid theoretical foundation for the treatment of spinal diseases as well as the prevention of various musculoskeletal conditions. Studies on LBP account for most of the level 1 evidence for stabilization exercises, which is mixed. Five randomized trials have, to our knowledge, supported stabilizing exercises for LBP [35]. However, several of these studies have methodological issues, among them are a dearth of real controls, a high attrition rate, and statistical irregularities [36]. The superiority of stabilizing exercises is also disputed by two other randomized trials [37]. Both studies' control groups featured generalized strengthening elements in addition to other characteristics [33]. Stabilization is useful for spinal problems, but it may not be better to other therapeutic exercise regimens, according to systematic reviews that have been conducted [38,40].

Results

This study will provide the effects of core stability exercise therapy with conventional Proprioception physiotherapy compared to the conventional alone on pain proprioception and disability for chronic low back pain patient.

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Author contributions

Md. Waliul Islam: Critical intellectual input, read and approval of the final submission, study concept and design, methodology, writing manuscript draft, study supervision.

Md. Tanzir-Uz-Zaman: Critical intellectual input, read and approval of the final submission, study concept and design, methodology, revision for critically intellectual content.

Md. Golam Kibria: Critical intellectual input, read and approval of the final sub- mission, study concept and design, methodology.

Abdullah Ibn Abul Fazal: Critical intellectual input, read and approval of the final sub- mission, study concept and design, methodology.

Md. Jubair Hassan: Critical intellectual input, read and approval of the final sub- mission, study concept and design, methodology.

Md. Mostafijur Rahman: Critical intellectual input, read and approval of the final sub- mission, study concept and design, methodology.

Saddam Hossain: Critical intellectual input, read and approval of the final submission, writing manuscript draft.

Md. Kutub Uddin: Critical intellectual input, read and approval of the final sub- mission, revision for critically intellectual content.

Mohammad Ainur Nishad Rhajib and Md Zakir Hossain: Critical intellectual input, read and approval of the final sub- mission, revision for critically intellectual content.

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First Author:

ORCiD https://orcid.org/0000-0003-1062-5349.

Corresponding Author:

ORCiD https://orcid.org/0000-0002-1952-9436

Declaration of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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