



Faculty of Medicine

University of Dhaka

**EFFECTIVENESS OF MULTIMODAL EXERCISE IN CHRONIC
LOW BACK PAIN AMONG SPINAL CORD INJURY PATIENTS**

By

Saddam Hossain

Master of Science in Physiotherapy

Registration no:3435

Roll no: 110

Session: 2012-13



Department of Physiotherapy

Bangladesh Health Professions Institute (BHPI)

May 2022



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We the undersigned certify that we have carefully read and recommended to the Faculty of Medicine, University of Dhaka, for acceptance of this thesis entitled,

“EFFECTIVENESS OF MULTIMODAL EXERCISE IN CHRONIC LOW BACK PAIN AMONG SPINAL CORD INJURT PATIENTS”,

submitted by Saddam Hossain for the partial fulfillment of the requirements for the degree of Master of Science in Physiotherapy.

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Declaration Form

- This work has not previously been accepted in substance for any degree and isn't concurrently submitted in candidature for any degree.
- This dissertation is being submitted in partial fulfillment of the requirements for the degree of M.Sc. in Physiotherapy.
- This dissertation is the result of my own independent work/investigation, except where otherwise stated. Other sources are acknowledged by giving explicit references. A Bibliography is appended.
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List of Abbreviations or Symbols

ASIA	American Spinal Cord Injury Association
BHPI	Bangladesh Health Professions Institute
CRP	Centre for the Rehabilitation of the Paralysed
CTRI	Clinical Trials Registry- India
RCT	Randomized Clinical Trial
SCI	Spinal Cord Injury
SPSS	Statistical Package for Social Sciences
FAC	Functional Ambulatory Category
WHO	World Health Organization

Abstract

Background: Low back pain (LBP) and spinal cord injury (SCI) severely limit daily personal and occupational activities. Only 37% of people with SCI find gainful employment after their injury, and the physical demands of some jobs are a significant barrier to their return to work. Sixty percent of survey respondents with SCI said their limited physical capacity prevented them from returning to work, particularly to the same types of jobs they had before the injury. Traffic accidents, gunshot wounds, knife wounds, falls, and sports injuries are the most common causes of SCI around the world. **Objective:** The main objective of the study is to investigate or discover the effectiveness of multimodal exercise in chronic low back pain patients. **Methodology:** A single group pre-test & post-test quasi experimental design was used to conduct this study. Total 13 samples were selected conveniently from outpatient treatment service of Spinal cord injury Unit, Physiotherapy Department, Centre for the Rehabilitation of the Paralyzed (CRP), Savar, Dhaka. Structured questionnaire was used to assess the socio-demographic and other information of the participants. Total treatment sessions were 4 sessions per week for total 8 weeks. **Outcome measurement tools:** Oxford muscle grade was used to measure the muscle strength of key muscles of lower extremities, 10 meter walk test and 6 minutes' walk test to measure mobility level and functional ambulatory category to basic ambulatory functions. **Analysis of data:** Inferential statistics such as Wilcoxon signed rank test was done using SPSS version 25. **Result:** It was found that muscle strength of the major key muscle had improved significantly ($p < 0.05$) except left ankle planter flexors ($p > 0.05$). As for mobility level and ambulatory function has also significantly improve ($p < 0.05$) after applying multimodal exercise for chronic low back pain. **Conclusion:** In practice, creating a multimodal training program using simple exercises and low-cost exercise equipment is straightforward. Multimodal exercise promotes a sense of enjoyment, saves time, and allows patients to push themselves individually. Furthermore, patients appreciate it since it promotes camaraderie and experience sharing.

Keywords: Multimodal exercise, Chronic low back pain, Spinal Cord Injury.

1.1 Background

Chronic Low Back pain is one of the leading causes of morbidity which occurs due to the rupture of the annulus fibrosus due to various reasons such as lumbar degeneration and chronic strain (Zheng, Wen & Li, 2021). In developed countries, low back pain (LBP) is a common cause of disability and functional loss. While LBP affects about 70% of people at some point in their lives, the annual incidence varies between 25% and 45 percent. The main risk factors are age, gender, lifting heavy objects, and certain occupations (Bardak, Erhan & Gündüz, 2012). SCI patients who are in excruciating pain find it difficult to carry out daily tasks and participate in social activities. According to a recent survey, 77.7% of SCI patients experience moderate or severe pain, with pain interfering with function and health status being significantly higher among those with more severe pain. Furthermore, per SCI patient in the United States, the total annualized cost of pain is \$26,270 (direct cost: \$8,636, indirect cost: \$17,634) (Bi, Lv, Chen, Li & Wang, 2015).

Low back pain (LBP) and spinal cord injury (SCI) severely limit daily personal and occupational activities. Only 37% of people with SCI find gainful employment after their injury, and the physical demands of some jobs are a significant barrier to their return to work. Sixty percent of survey respondents with SCI said their limited physical capacity prevented them from returning to work, particularly to the same types of jobs they had before the injury (Kim & Martin, 2013). Traffic accidents, gunshot wounds, knife wounds, falls, and sports injuries are the most common causes of SCI around the world. The most common sport injury was reported to be diving. Flexion, compression, hyperextension, and flexion-rotation mechanisms are the most common causes of injury. The "primary damage" that these mechanisms cause is referred to as "primary damage." Secondary damage refers to the body's responses in order to overcome primary damage, such as hemorrhage, inflammation, and the release of various chemicals (Chen, Tang, Vogel & DeVivo, 2013).

A prolapsed disc causes sudden and severe lower back pain, as well as pain and other symptoms in the leg when the disc presses on a nerve root (Tidy, 2020). Typically, a

prolapsed lower back disc occurs at the L5-S1 level, which serves an important function for the body. This region, in particular, aids in the transfer of loads from the spine to the pelvis and legs. The L5-S1 spinal motion segment or the lumbosacral joint, which exists in the lower back, is also known as the L5-S1 spinal motion segment or the lumbosacral joint, and it allows for the transition of loads between the lumbar and sacral spines (Dewitt, 2019). Paralysis is the most common symptom in patients with spinal cord injuries, and it has a wide range of effects on their functioning, including bladder problems, respiratory and cardiovascular problems, and sexual function. It influenced social interaction, participation, and communication as well. As a result, people who have suffered a spinal cord injury require not only medical treatment but also full rehabilitation. All other exercises should be avoided during the rehabilitation period. To improve overall function, all other health professionals, particularly physiotherapists, must be involved. Physiotherapists play a critical role in improving the functions of paraplegics with SCI (Harvey, 2016).

People with LBP have a limited range of motion in their hands and arms, whereas people with SCI have a higher curvature in their fingertip and shoulder movement trajectories, as well as a slow hand movement velocity. However, it has been reported that the general shape of velocity profiles and trajectories for hand movements in people with SCI are similar to those found in the general population, leading to the assumption that hand movement kinematics were maintained. The initial and final positions usually constrain hand movements in goal-directed reaches. However, depending on the movement context, the contribution of other joints such as the torso, shoulder, and elbow varies. As a result, it is hypothesized that torso movements, which are directly influenced by SCI or LBP, will show significant adaptation, which will be associated with movement limitations (Kim, Choe, Haig & Martin, 2010). The rehabilitation of SCI patients is primarily focused on functional independence, which varies depending on the severity of the injury. Health professionals try to reduce or prevent complications during the rehabilitation stage. People with SCI have less physical capacity as a result of their injuries. During the rehabilitation stage, physical activity may help them improve their functional status (Nas, Yazmalar, Şah, Aydın & Öneş, 2015).

Due to their pain and functional limitations, people with LBP and SCI may use different movement strategies and muscle recruitment patterns during manual transfer tasks. This includes reduced torso flexion and axial rotation in people with LBP, as well as a unique coordination pattern of torso-hand movements in people with SCIs (Dickerson, Alenabi, Martin & Chaffin, 2018).

Many researchers have discovered the effectiveness of multimodal exercise for chronic lower back pain patients all over the world. This study's goal was to see how multimodal exercise affects chronic lower back pain patients. This was an experimental study that compares the study population's pre- and post-treatment clinical outcomes to determine the efficacy of multimodal exercise in chronic lower back pain patients. The findings of this study would be useful in determining the effectiveness of multimodal exercise in treating lower back pain and other symptoms associated with chronic lower back pain in chronic lower back patients.

1.2 Justification

Bangladesh is a country with over one-third of the population living in and another one-third living just above the poverty level. According to The World Health Organization (2010), Bangladesh has poor prenatal and postpartum care, nutritional deficiencies, high incidence of no- skilled birth attendant utilization and the second-highest maternal mortality and morbidity rates next to sub-Saharan Africa. This study wants to explore the effect of multimodal exercise in chronic lower back patient. This is an experimental study which compares the pre- and post-treatment clinical outcomes of the study population to determine the effectiveness of multimodal exercise in chronic lower back patient. Findings of this study will be helpful to know the effectiveness of multimodal exercise in lower back pain and others associated symptoms of chronic low back pain patients in spinal cord injury unit. Moreover, this study will be helpful to enhance knowledge on the effectiveness of multimodal exercise on chronic lower back patient. This research helps to improve the knowledge of health professionals, as well as to develop the profession. The results of this study may help to guide physiotherapists to give evidence-based treatments to patients with LBP. So, for the development of the physiotherapy profession in musculoskeletal sectors will establish by conducting this type of research work.

1.3 General Objective

To determine the effectiveness of multimodal exercise in person with chronic low back pain.

1.4 Specific objectives

- To determine the socio demographic factors of the respondent.
- To compare the pre- and post-treatment clinical outcomes like oxford muscle grade of major key muscles of lower extremity of the patients.
- To evaluate the mobility and balance outcome before and after applying multi-modal exercises.

1.5 Hypothesis

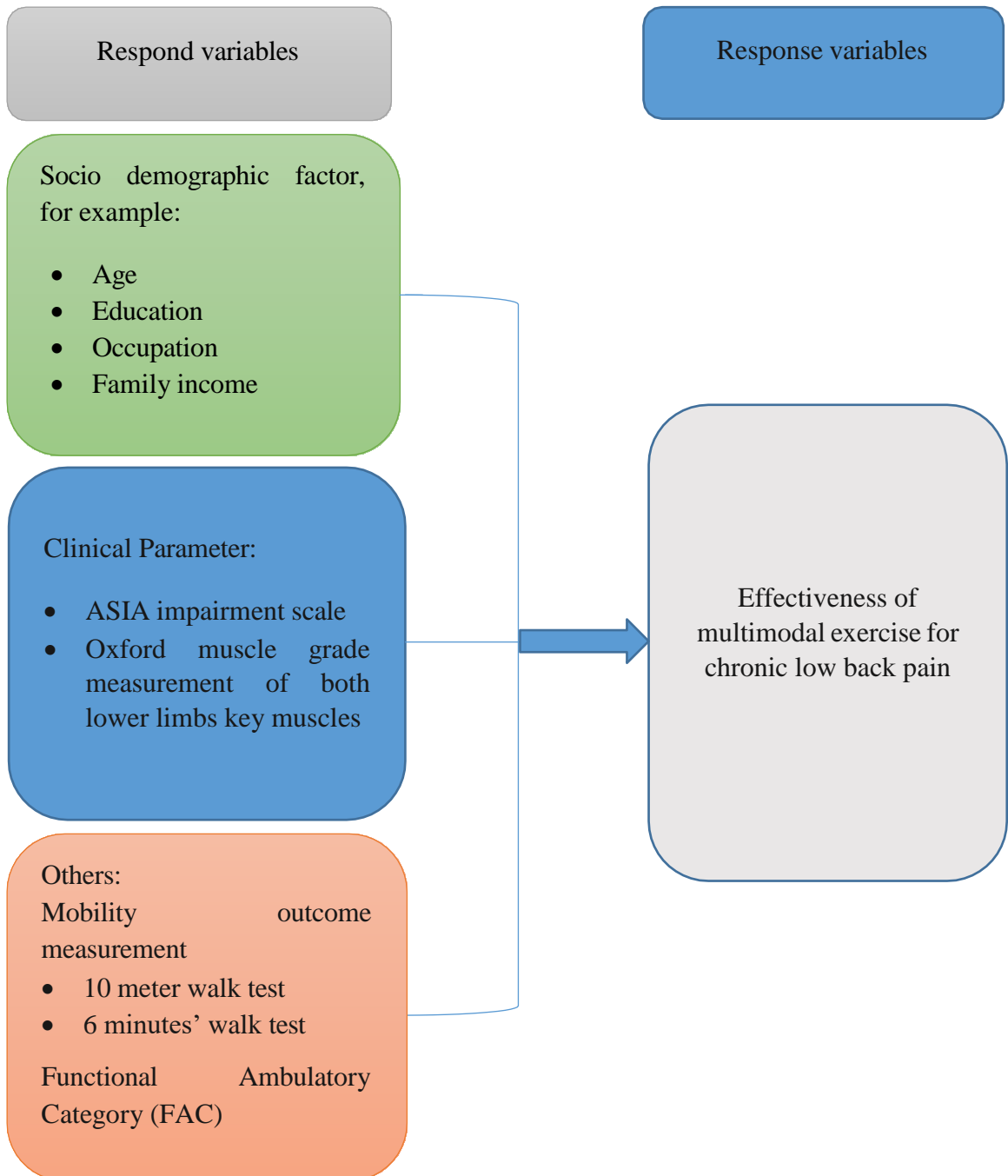
Alternative hypothesis (Ha): Multi-modal exercise was effective for patient with chronic low back pain.

Ha: $\mu_1 - \mu_2 \neq 0$ or $\mu_1 \neq \mu_2$, where the initial and final mean difference the participants was not same.

Null hypothesis (Ho): There was no effect of applying multi-modal exercise on patient with chronic low back pain.

Ho: $\mu_1 - \mu_2 = 0$ or $\mu_1 = \mu_2$, where the initial and final mean difference the participants was same.

1.1 1.6 List of variables



1.6 Operational definitions

Multi-modal exercise: Multimodal exercise such as Muscle Energy Technique, physical modalities, exercise, manual therapy, acupuncture, education, psychological interventions, soft tissue therapies, McKenzie exercise, mobilization, bridging exercise, leg crossing exercise etc. are considered as the effective techniques of lower back pain (Kong, Park, Kweon & Park, 2016).

Incomplete paraplegic SCI: Paraplegia is impairment in motor or sensory function of the lower extremities. According to ASIA impairment scale Incomplete B: Incomplete Sensory, but not motor function is preserved below the neurological level of injury, includes the sacral segments S4-S5. Incomplete C: Incomplete, motor function is preserved below the neurological level of injury, but more than half of the key muscles below the level have a muscle grade less than 3. Incomplete D: Incomplete, motor function is preserved below the neurological level of injury, and at least half of the key muscles below the level have a muscle grade or more. Incomplete E: Normal, motor and sensory functions are normal (Choi, Lee & Kim, 2013).

ASIA impairment scale: The AIS is a standardized examination that includes a motor examination based on myotomes, a sensory examination based on dermatomal, and an anorectal examination. An injury severity or grade and level are assigned based on the findings of these examinations. The sensory examination assesses 28 specific dermatomes bilaterally for light touch (generally a piece of cotton) and pinprick sensations (generally a clean safety pin). For each dermatome and laterality, each examination component is recorded. A grade of 0 indicates that there is no sensation, a 1 indicates that sensation is impaired or altered, and a 2 indicates that sensation is normal. A typical unilateral sensory examination includes 28 dermatomes with 2/2 points for light touch and 2/2 points for pinprick, for a total of 112 points. A sensory examination with a total score of 224 bilaterally is considered fully normal. Technically, the inability to distinguish pinprick sensation from light touch is a 0 score (Roberts, Leonard & Cepela, 2017).

Spinal cord damage has had a tremendous impact on not just personal, family, and social lives. It had a detrimental influence on society since traumatic SCI was more prevalent among all spinal cord injuries. It was estimated that 10 to 83 individuals per million in the globe were impacted (Noonan et al., 2012). Damage to the spinal cord that causes changes in function, either temporarily or permanently, is known as a spinal cord injury (SCI). Traumatic and non-traumatic etiologies are the two types of SCI. Traumatic SCI occurs when the spinal cord is acutely damaged by an external physical impact (for example, a car accident, fall, sports-related injury, or violence), whereas non-traumatic SCI occurs when the primary injury is caused by an acute or chronic disease process, such as a tumor, infection, or degenerative disc disease (Ahuja et al., 2017). SCIs have devastating physical, social, and vocational consequences for patients and their families, and they are characterized by a loss of independence and persistently higher lifelong mortality rates. Furthermore, the direct costs of caring for SCI patients are staggering, ranging from US\$1.1–4.6 million per patient over their lifetime, emphasizing the importance of prevention as the most important intervention we can provide. The development of effective treatments becomes critical for SCI that cannot be prevented (National Spinal Cord Injury Statistical Center, 2014).

The severity of the damage may result in a greater loss of function. The physical capacity of a SCI patient is determined by the severity of the lesion, their age, and their level of activity (Janssen, Dallmeijer, Veeger & van der Woude, 2002). SCI is a life-altering injury that has an impact on daily activities. SCI sufferers' functional independence is dependent on rehabilitation providers (Haisma et al., 2008). There is substantial evidence from earlier research that the severity of the lesion predicts the patient's physical capabilities (Kutty, 2012). Physical activity is essential for SCI recovery. The goal of this therapy is to achieve the highest level of functional capacity and self-sufficiency possible (Dalmeijer & Woude, 2001). The focus of this sort of unique rehabilitation program should be on patient center rehabilitation. Which also includes complete and active participation in the empowerment of persons with SCI, as well as follow-up treatment to improve their functional status and quality of life. (Wolfe, Hsieh, & Mehta, 2010).

The ability of a person's respiratory system, cardiovascular system, and musculoskeletal system to achieve an optimal level of activity, such as power output, oxygen uptake, muscular strength, and respiratory function, is referred to as physical capacity (Haisma et al., 2006). It also focuses on wheelchair skills and ADL training throughout recovery. It aids in the avoidance of problems and the decrease of their severity. Muscle strength and endurance training were also part of the recovery process (Haisma et al., 2008). It is quite difficult to construct or build a conventional and successful aerobic exercise and physical activity program for SCI patients (Zoeller et al., 2005). There is a strong link between a person's quality of life and their recovery process if they have a spinal cord injury. The patient's physical fitness, social, psychological, and general satisfaction with the rehabilitation process and outcome are all factors that influence their quality of life (Kumar & Gupta, 2016).

In the treatment of SCI, a number of factors come into play. Acute therapy begins with the administration of medicinal agents aimed at decreasing the secondary damage cascade, as well as an initial surgical treatment that generally comprises all or a mix of reduction, decompression, and stabilization. An additional component is physical therapy and rehabilitation, which can have a substantial influence on total healing. Finally, late-onset SCI issues such as bowel and bladder dysfunction, discomfort, spasticity, and automatic breathing difficulties play a role (Raslan & Nemecek, 2012). Surgical management of SCI, on the other hand, has become more prevalent in acute medical care. During the rehabilitation stage, psychological distress played an important part in maintaining blood pressure, circulation, breathing, bladder and bowel control, among other things. Physiotherapy played a significant part in the care of SCI patients at this time. Physiotherapists can also help with secondary consequences including musculoskeletal issues. When the patient is medically stable, physiotherapy should begin as soon as feasible. A multidisciplinary approach and a patient-centered approach should be included in the rehabilitation program. The fundamental goal of rehabilitation was to provide the patient a productive life so that they might live a functioning and healthy existence (Harvey, 2016).

Back extension strength, mobility, endurance, and functional impairment can all be improved with exercise. Various activities have been recommended to alleviate chronic LBP, including lumbar stabilization exercise (SE), motor control exercise, core exercise, lumbar flexion exercise, walking exercise (WE), and bracing exercise.

These exercises are designed to help with lumbar stability and core strength (Geneen et al., 2017). In a case-control study by Lee, Kim, Oh, Min & Ryu, (2016) said that lumbar SE aims to improve the muscles' neuromuscular control, strength, and endurance, which are thought to be essential for maintaining dynamic spinal and trunk stability. It is thought to be a safe workout with the added benefit of several phases and cost-effectiveness. Because everyone's lumbar muscle strengths are different, lumbar SE programs should be tailored to each person's needs, using a variety of postures with differing intensities to optimize therapeutic benefit.

Back pain is the most frequent musculoskeletal ailment in Western nations, and it is connected with increased medical cost and job absence. Sixty to eighty percent of individuals will suffer low back pain at some time in their life, and 16 percent of adults in the United Kingdom (UK) visit their general practitioner at least once a year. Back discomfort costs the NHS £1.3 million a day and accounts for 12.5 percent of all work absences in the United Kingdom. However, the best effective treatment for non-specific persistent low back pain is yet unknown (Wu et al., 2020). For patients with CLBP, physical activity (PA) to build aerobic capacity and muscular strength, particularly of the lumbar extensor muscles, is critical in aiding them to accomplish everyday tasks. Different exercises, on the other hand, have been proven to have variable degrees of benefit in relieving lower back pain. Furthermore, too much or too little PA has been linked to low back pain, indicating that PA as a treatment for low back pain is complicated. 85% of back pain cases have no known reason, which is usually discovered after having testing such as X-rays, MRI scans, and blood tests. Understanding the origin of back pain is critical for removing it from the patient's life and preventing the movement from being replicated during therapy. When the reason of back pain is unknown, however, recommending specific therapy can be difficult, thus general exercise is frequently advised instead (Gordon & Bloxham, 2016).

Traumatic spinal cord was a life-threatening trauma that impacted their livelihood and social lives. To enhance their quality of life, an accurate and adequate health system was critical (Conradsson et al., 2018). The life expectancy of spinal cord injury patients has risen steadily in recent years. According to a prior survey, life expectancy has improved by roughly 5 years since the previous day (Wyndaele, & Wyndaele, 2006). SCI was more prevalent in Bangladesh as a low-income third-world nation owing to work-related injuries, and it was more common among young adults. This

tendency is also seen in other nations in the middle and lower middle classes. As a result, their income is reduced, and they, together with their family, are facing serious financial difficulties (Hossain et al., 2019).

Chronic Low Back Pain sufferers may have physical limitations such as a lack of muscular trunk stability and strength, as well as poor static postural control and impaired gait performance. Furthermore, research shows that CLBP patients' motor-cognitive dual task performance (e.g. walking while conducting a cognitive activity) is impaired. This might be due to the fact that pain can impair gait control, as well as executive functioning (Hamacher, Hamacher & Schega, 2014). This is in line with previous findings indicating chronic pain sufferers have worse cognitive performance (e.g. executive skills) (Nadar, Jasem & Manee, 2016). These motor-cognitive deficiencies restrict everyday tasks and may result in an increased risk of falling (IJmker & Lamoth, 2011). However, psychological variables such as worry, sadness, and/or passive coping techniques all have an impact on the development and maintenance of CLBP (Truchon, 2001). Furthermore, these deficiencies reinforce one another: for example, fear of pain causes a reduction in everyday activity (kinesiophobia), which contributes to insufficient muscle stabilization and disability (Vlaeyen & Linton, 2000).

Multidisciplinary techniques are recommended to treat the various deficits of CLBP. When compared to standard treatment, they have demonstrated to be more successful in reducing pain and impairment. In this regard, professionals from many professions use a mix of conservative (e.g. pharmaceutical, physical, and psychological) therapies (Kamper et al., 2015). Researchers developed a unique multimodal exercise intervention (MultiMove) for CLBP patients to build on this comprehensive therapy strategy and to increase its effectiveness. Through a combination of three training components, MultiMove addresses the stated poor physical (e.g. dynamic postural control, trunk stability), cognitive (e.g. executive skills), and psychological (e.g. kinesiophobia) dimensions of CLBP (Schega et al., 2021).

Strength and flexibility training are the foundation of MultiMove, since they have been demonstrated to be the most effective exercise therapies for CLBP patients thus far (Searle, Spink, Ho & Chuter, 2015). The second component of MultiMove is a motor-cognitive training based on the Life Kinetik concept to treat CLBP patients'

poor dual task performance and executive functions. This type of training has already been demonstrated to reduce gait variability and fear of falling in healthy older persons (Theill, Schumacher, Adelsberger, Martin & Jäncke, 2013). Because it has been proven that balance/stabilization training is beneficial for CLBP sufferers (Searle, Spink, Ho & Chuter, 2015), a dynamic balancing training with dance-therapeutic components is the third component. Furthermore, dancing may be used as a therapeutic tool. Inherently, exercises need a mix of skills. of motor and cognitive skills (for example, the ability to recall) and do many partial motions at the same time) and are also linked to social engagement (Dhami, Moreno & DeSouza, 2015).

This social connection, when combined with the benefits of motor-cognitive training, may aid in the treatment of kinesiophobia. Dance therapies have been demonstrated to be effective in this regard. increase functional mobility, sensorimotor, and cognitive abilities Adults and the elderly's endurance performance. Dance therapies may also help to reduce gait variability and enhance gait speed (Fong Yan et al., 2017). Furthermore, dancing has been shown to be better than traditional training methods (which mostly include repetitive physical exercises) in terms of training-induced brain plasticity in elderly persons (Rehfeld et al., 2018). Dance-therapeutic treatments have previously been successfully used in the field of neurological rehabilitation as a result of these various advantages. As a result, tailoring the strategy to the demands of CLBP patients appears to be a viable option (Ho et al., 2020).

Multimodal is predicted to increase physical and physiological functions (e.g., Timed Upand-Go (TUG) performance, gait variability, haemodynamic response in the prefrontal cortex [PFC]) as well as cognitive performance (aspects of executive functions) by combining these three components. With such modifications, it's expected that pain would be reduced and quality of life will improve.

3.1 Study design

This study had done through using Experimental study design. The study was a quantitative exploration of one-group pretest-posttest Quasi-experimental study. Multimodal exercise combined with conventional physiotherapy applied to the participants. This methodology was chosen to meet the study aim as an effective way to collect data. The researcher wanted to determine the effectiveness of multimodal exercise for incomplete paraplegic SCI patients during rehabilitation. A pre-test (before intervention) and post-test (after intervention) was administered with each subject to compare the clinical parameters like measuring oxford muscle grade of both lower limbs and the mobility outcome like performing 10 meter walk test and 6 minutes' walk test.

3.2 Study Area

The study was conducted at Spinal Cord Injury unit, CRP, Savar.

3.3 Study population

A population refers to the entire group of people or items that meet the criteria set by the researcher. The populations of this study was the incomplete paraplegic Spinal Cord Injury patients at the CRP, Savar.

3.4 Study Duration

The study duration of this study was from August 2021 to February 2022.

3.5 Sample Size

13 participants with incomplete paraplegic SCI patients were recruited from indoor SCI unit, Centre for the Rehabilitation of the Paralysed (CRP), Savar, Dhaka.

3.6 Sampling Scheme

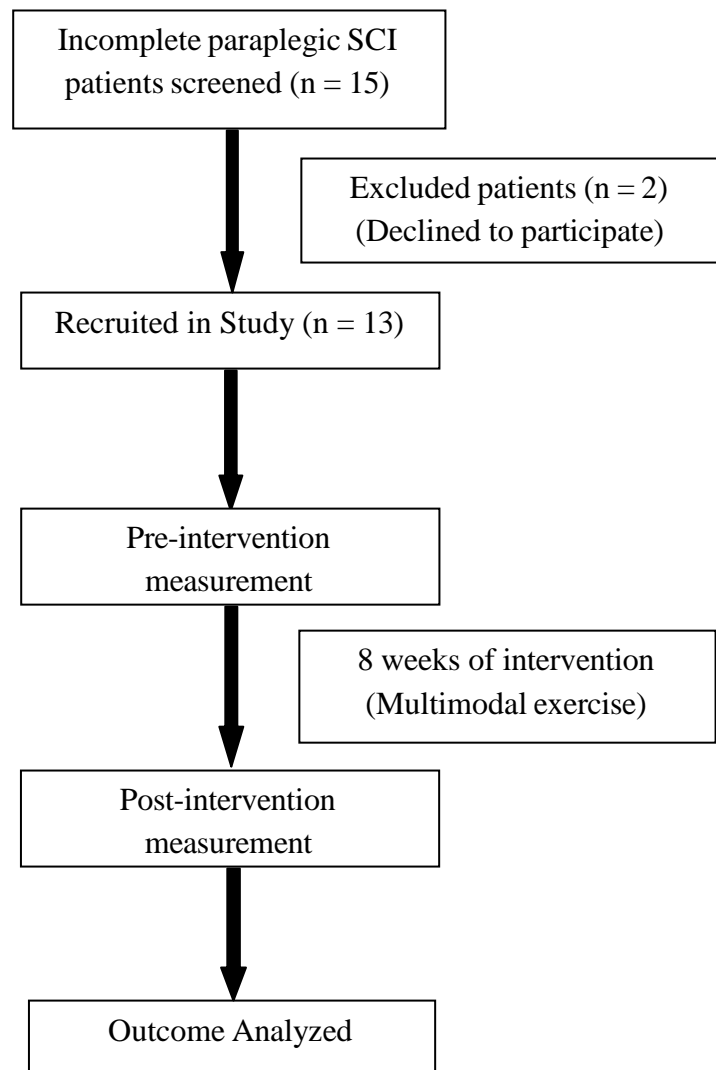


Figure 1: CONSORT flowchart of the study

CONSORT flowchart for a one-group pretest-posttest Quasi-experimental study design where a treatment program including multimodal exercise on walking capacity and functionality for Incomplete Paraplegic Spinal Cord Injury patients.

3.7 Inclusion Criteria

- Paraplegic Spinal Cord injury patients with chronic low back pain. (T7-L5) (Kennedy, 1987).
- Male & Female both paraplegic patients were included (McColl, Charlifue, Glass, Lawson & Savic, 2004).
- Incomplete C & D patients according to ASIA (Choi, Kim & Kim, 2013).

3.8 Exclusion Criteria

- Oxford Muscle Grade those are less than 3.
- Complete Spinal Cord Injury Patient.
- Any experience with chronic inflammatory pain (e.g., rheumatoid arthritis, ankylosing spondylitis, etc.).
- Individuals who have refused to participate in the study.

3.9 Method of data collection

Face to face interviews are the most effective way to get full cooperation of the participant in a survey. According to the participants' understanding level, sometimes the questions were described in the native language so that the patients can understand the questions perfectly and answer accurately.

3.10 Data collection tools



In that time some other necessary materials were used like pen, pencil, and white paper and clip board. Data collector took permission from each volunteer participant by using a written consent form in Bengali & English. The Data was collected by qualified Physiotherapists who are working at indoor SCI unit. Two different assessors were assigned.


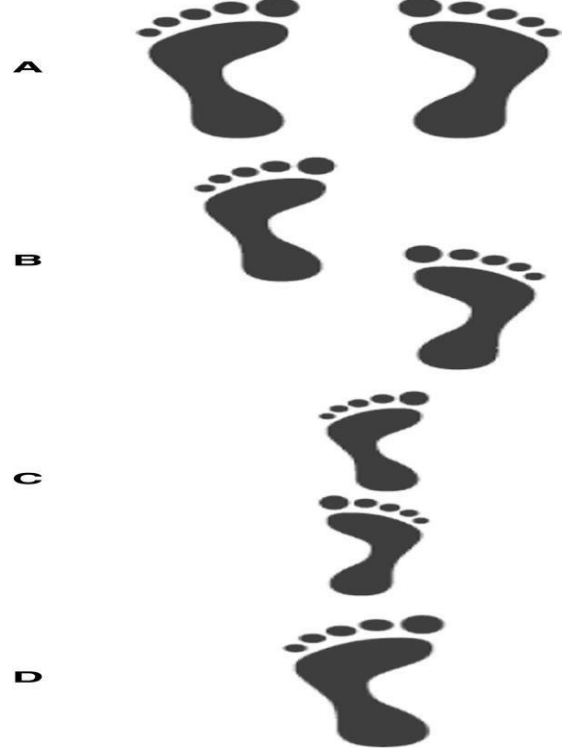
3.11 Measurement tools


Oxford muscle grade scale was used for measuring the muscle power of the both lower extremity key muscles, mobility & balance outcome of SCI patients was measured by 10 meter and 6 minutes' walk test and ambulatory functions was measured by basic motor ability questionnaire.

3.12 Treatment regime

All the physiotherapy treatments were performed at Spinal cord injury unit, CRP, Savar, 4 sessions per week in total 8 weeks. Each Session consists of 40 minutes. Two qualified physiotherapists were involved for this multimodal exercise program for SCI unit.

Code	Intervention	Figure
S1	<p>Warm up and aerobic exercise (20 min)</p> <p>Intensity: 50%–60% MHR</p> <ul style="list-style-type: none"> • Stationary bicycle/pedalier • Walking as fast as possible on a circuit with obstacles ramps, stairs, and irregular ground • Gait training in parallel and different surfaces 	
S2	<p>Task-oriented activities (8 series of repetitions) to strengthen muscular groups that participate in different tasks performed in rapid series to improve aerobic capacity:</p> <p>Intensity: 50%–60% MHR</p>	

	<ul style="list-style-type: none"> • Steps: Short bouts of stair climbing to train the task of climbing stairs • Sit-to-stand: To train the task of sitting down and getting up from a chair • Balance on tiptoe: To train the propulsion phase of gait. (plantar flexors) 	
<p>S3</p>	<p>Balance and tonic postural activities (15 min)</p> <p>Balance in standing position and postural tonic activities (on the floor and on unstable ground planes)</p> <ul style="list-style-type: none"> • Bipodal step forward • Unipodal step forward • Bipodal step backward • Unipodal step backward • Bipodal lateralizations on u.s. 	

S4	<ul style="list-style-type: none"> • Stretching exercises (5 mins) 	
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3.13 Quality control and confirmation

Investigator applied to The Clinical Trials Registry- India (CTRI) for clinical trial registration to maintain quality control and this trial has been registered. The registration number for this trial is CTRI/2021/11/038010.

3.14 Ethical issues

A research proposal had submitted to the local ethical review committee of Bangladesh Health Professions Institute (BHPI) for being approval. The ethical consideration was making sure by an informed consent letter to the participant.

3.15 Informed consent

The investigator used a consent form both in English and Bengali to take the participant's consent and contained the consent of the participant that he/she was participating in the study and giving permission to the investigator to start the data collection sessions.

In order to ensure that the research have some values, the meaning of collected data has to be presented in ways that other research workers can understand. In other words, the researcher has to make sense of the results. As the result came from an experiment in this research, data analysis was done with statistical analysis.

Statistical analysis was performed by using descriptive statistics for socio-demographic data and inferential statistics for individual differences of muscle power by Oxford muscle grade measurement and mobility outcome measurement by 10 meter walk test and 6 minutes' walk test and also ambulatory function by basic motor abilities questionnaire through Statistical Package for the Social Science (SPSS) version 25.

Baseline characteristics

The baseline characteristics of the participants showed that mean age (years) of the single group was 39.23 and average the monthly income of the family was 19923.08 BDT. Gender distribution among the participants showed that 11 (84.6%) participants were male and 2 (15.4%) were female. In terms of education, 2 (15.4%) participants had no formal education, 7 (53.8%) had primary education, 3 (23.1%) had passed the HSC and 1 (7.7%) participant had gained bachelor or above degree. According to descriptive statistics 7 (53.8%) were service holder, 3 (23.1%) were businessmen or worked in crowd, 1 (7.7%) were house wife and 2 (15.4%) were unemployed. About marital status, 3 (23.1%) of the participants were unmarried and 10 (76.9%) of the participants were married. As per ASIA impairment scale, 7 (53.8%) of them were incomplete C and 6 (42.2%) of them were incomplete D.

Table 2: Baseline Characteristics of the participants

Variable(s)	Descriptive statistics
Age (Mean)	39.23
Gender (n %)	Male = 11 (84.6), Female = 2 (15.4)
Education (n %)	No formal education = 2 (15.4), Primary education = 7 (53.8), HSC = 3 (23.1), Bachelor or above = 1 (7.7)
Marital status (n %)	Unmarried = 3 (23.1), Married = 10 (76.9)
Present occupation (n %)	Service = 7 (53.8), Business or work in crowd = 3 (23.1), Housewife = 1 (7.7), Not engaged in any occupation = 2 (15.4)
ASIA Impairment Scale (n %)	Incomplete C = 7 (53.8), Incomplete D = 6 (46.2)
Monthly income of the family (Mean)	19923.08 BDT

Demographic statistics

Gender distribution of the participants:

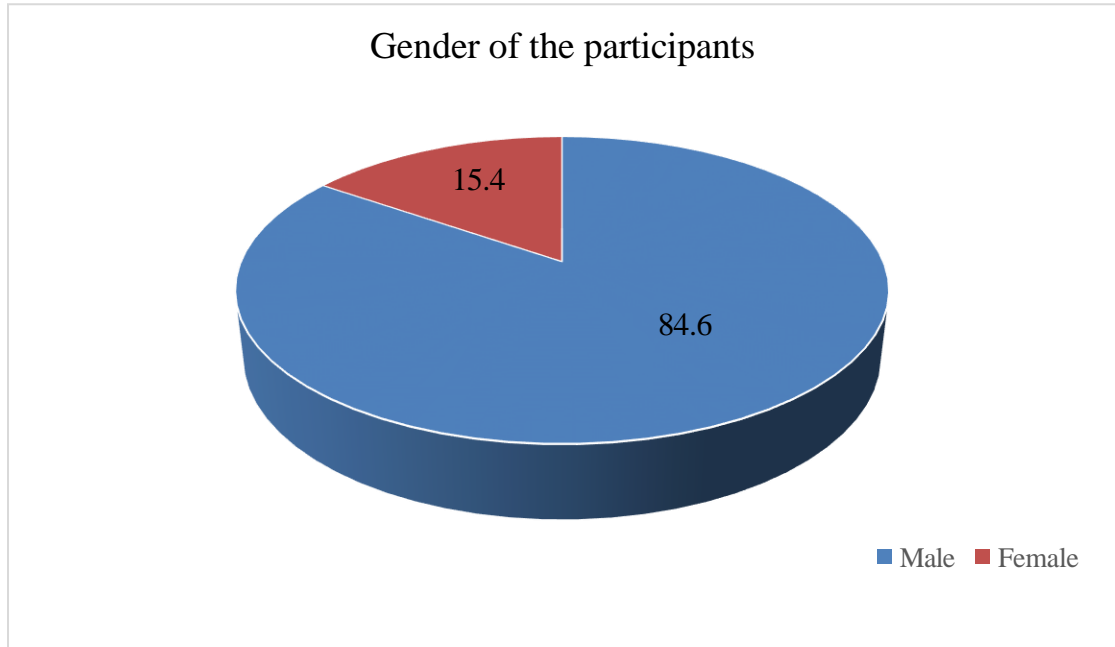


Figure 2: Gender of the Participants

Figure 1 showed that among the 13 participants, 11 (84.6%) participants were male and 2 (15.4%) were female.

Educational distribution of the participants:

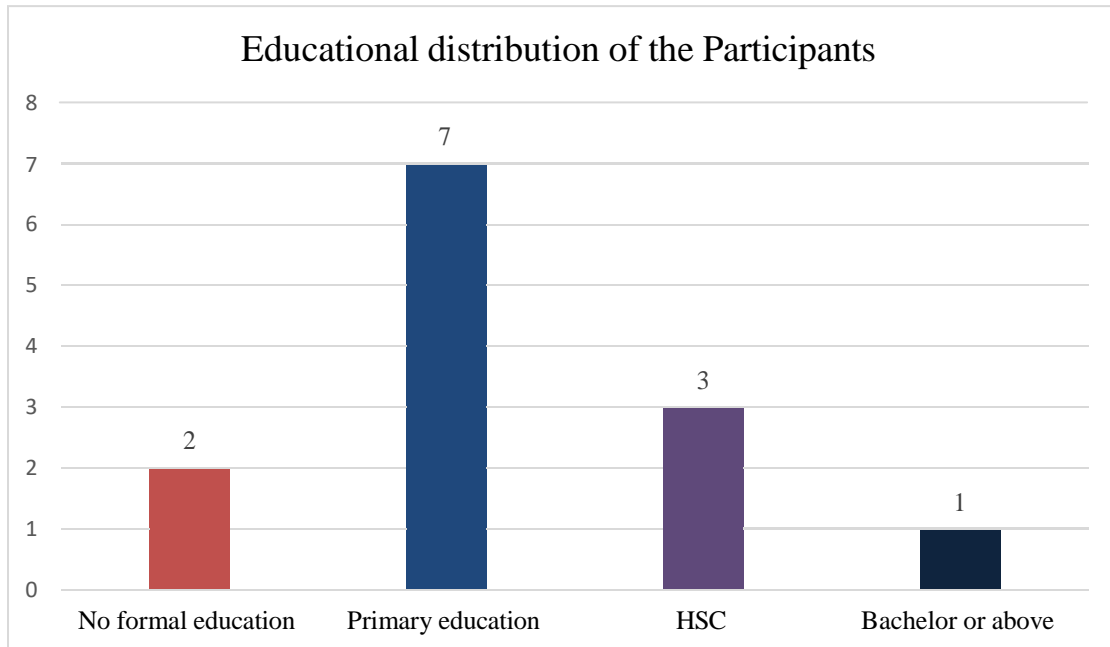


Figure 3: Educational distribution of the Participants

Figure 2 showed that among the 13 participants, 2 (15.4%) participants had no formal education, 7 (53.8%) had primary education, 3 (23.1%) had passed the HSC and 1 (7.7%) participant had gained bachelor or above degree.

Occupational distribution of the participants:

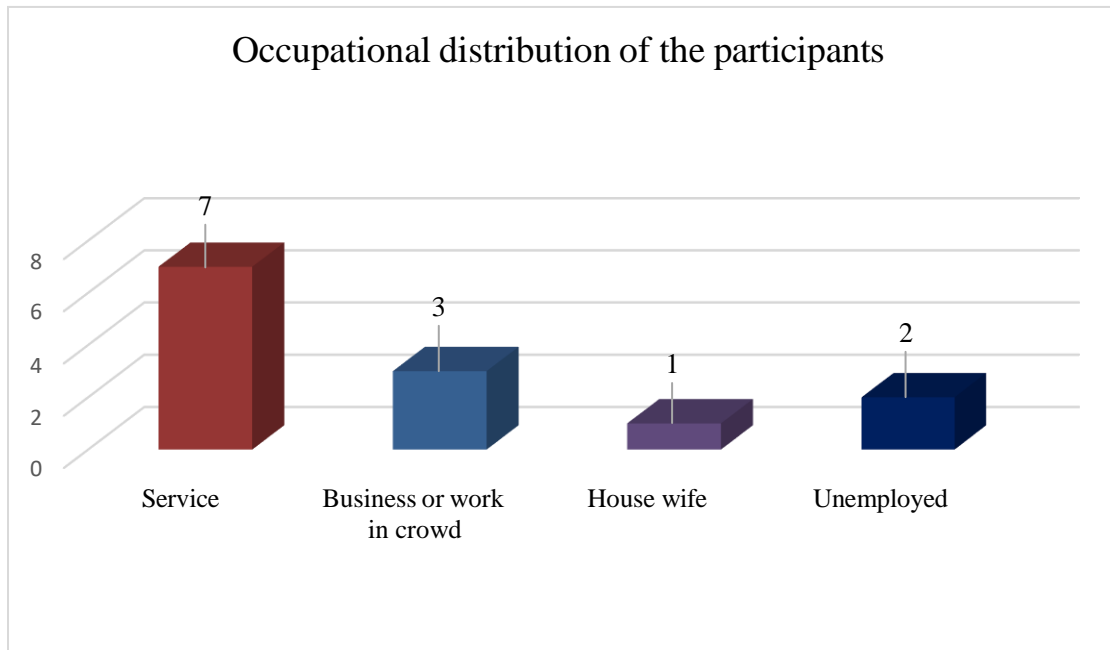


Figure -4: Occupational distribution of the participants

Figure 3 showed that among the 13 participants, 7 (53.8%) were service holder, 3 (23.1%) were businessmen or worked in crowd, 1 (7.7%) were house wife and 2 (15.4%) were unemployed.

Inferential statistics

Parametric test was used to do analyzed interval/ ratio data and non-parametric test used to analyzed the nominal/ordinal data. Also normality of data was checked (Table - 2). Normality of data was tested by Kolmogorov-Smirnov test. As the value of Kolmogorov-Smirnov test is less than .05, which indicate that the data distribution is not normal. The Kolmogorov-Smirnov test was used to determine normal distribution of the SPADI data. The results of this test indicated that the data for SPADI was not normally distributed and hence non-parametric statistics were used for the analysis of data. As this study was a quantitative exploration of one-group pretest-posttest Quasi-experimental study, the within group analysis of lower extremity key muscles through Oxford muscle grade measurement, improvement of mobility by 10 meter walk test and 6 minutes' walk test and ambulatory function by basic motor abilities questionnaire of the participants was done by Wilcoxon signed rank test.

Table 3: Normality test of data

	Kolmogorov-Smirnov		
	Statistic	df	Sig.
Right hip flexor (After)	.431	13	.000
Left hip flexor (After)	.532	13	.000
Right knee extensors (After)	.352	13	.000
Left knee extensors (After)	.470	13	.000
Right ankle dorsiflexors (After)	.327	13	.000
Left ankle dorsiflexors (After)	.283	13	.005
Right long toe extensors (After)	.283	13	.005
Left long toe extensors (After)	.240	13	.039
Right ankle planter flexors (After)	.240	13	.039
Left ankle planter flexors (After)	.295	13	.003
Number of steps (After)	.202	13	.014
Time in seconds (After)	.228	13	.006
Total distance (After)	.203	13	.018
Basic motor abilities (After)	.532	13	.000

Wilcoxon sign-ranked test is used when two groups of matched subjects, one group represent one condition and the other group represent other condition; to see if there is significant deference within the groups.

The formula of Wilcoxon sign-ranked test:

$$Z = \frac{W_s - \frac{n(n+1)}{4}}{\sqrt{\frac{n(n+1)(2n+1)}{24}}}$$

Here,

n = number of pairs where differences is not 0

W_s = smallest of absolute values of the sum

“The statistical approach to determining sample size was the power calculation. Statistical power is a measure of how likely the study was to produce a statistically significant result for a difference between groups of a given magnitude” (Hicks, 2009).

Table 4: Researcher has calculated all the Z value and have presented in the following tables (Wilcoxon Signed rank test) for within the group measurement.

Oxford muscle grade measurement	Participants of the group (n = 13)			
	Right		Left	
	Z	p	Z	P
Hip flexor (L2)	3.317	0.001**	3.317	0.001**
Knee extensors (L3)	3.162	0.002**	3.162	0.002**
Ankle dorsiflexors (L4)	3.000	0.003**	2.828	0.005**
Long toe extensors (L5)	2.828	0.005**	2.828	0.005**
Ankle planter flexors (S1)	2.236	0.025**	1.414	0.157

(* $p < .05$, ** $p < .01$; level of significance)

Hip flexors (L2)

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for $n = 13$ Wilcoxon table gives a z score (3.317) which is greater than critical value of 1.96 and a p value (.001) which is less than 0.05 for right hip flexors and a z score (3.317) which is greater than critical value of 1.96 & a p value (.001)

which is less than 0.05 for left hip flexors. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

Knee extensors (L3)

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for $n = 13$ Wilcoxon table gives a z score (3.162) which is greater than critical value of 1.96 and a p value (.003) which is less than 0.05 for right knee extensors and a z score (3.162) which is greater than critical value of 1.96 & a p value (.002) which is less than 0.05 for left knee extensors. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

Ankle dorsiflexors (L4)

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for $n = 13$ Wilcoxon table gives a z score (3.000) which is greater than critical value of 1.96 and a p value (.002) which is less than 0.05 for right ankle dorsiflexors and a z score (2.828) which is greater than critical value of 1.96 & a p value (.005) which is less than 0.05 for left ankle dorsiflexors. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

Long toe extensors (L5)

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for $n = 13$ Wilcoxon table gives a z score (2.828) which is greater than critical value of 1.96 and a p value (.005) which is less than 0.05 for right long toe extensors and a z score (2.828) which is greater than critical value of 1.96 & a p value (.005) which is less than 0.05 for left long toe extensors. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

Ankle planter flexors (S1)

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for $n = 13$ Wilcoxon table gives a z score (2.236) which is greater than

critical value of 1.96 and a p value (0.025) which is less than 0.05 for right ankle planter flexors. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain on right ankle planter flexors. On the other hand, Wilcoxon table gives a z score (1.414) which is less than critical value of 1.96 & a p value (.157) which is greater than 0.05 for left ankle planter flexors. So, the null hypothesis is accepted and alternative hypothesis is rejected at 5% level of significance which means there was no effect of applying multi-modal exercise on patient with chronic low back pain on left ankle planter flexors.

Table 5: Researcher has calculated all the Z value and have presented in the following tables (Wilcoxon Signed rank test) for within the group measurement.

Mobility Outcome measurement	Participants of the group (n = 13)		
		Z	P
10 meter walk test	Number of steps	3.187	0.001**
	Time	3.180	0.001**
6 minutes' walk test	Total distance	3.189	0.001**

(* p < .05, ** p < .01; level of significance)

10 meter walk test

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for n = 13 Wilcoxon table gives a z score (3.187) which is greater than critical value of 1.96 and a p value (.001) which is less than 0.05 for number of steps and a z score (3.180) which is greater than critical value of 1.96 & a p value (.001) which is less than 0.05 for time of the 10 meter walk test. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

6 minutes' walk test

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for n = 13 Wilcoxon table gives a z score (3.189) which is greater than critical value of 1.96 and a p value (.001) which is less than 0.05 for total distance in 6 minutes' walk test. So, the null hypothesis is rejected and alternative hypothesis is

accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

Table 6: Researcher has calculated all the Z value and have presented in the following tables (Wilcoxon Signed rank test) for within the group measurement.

Functional Ambulatory Category (FAC)	Participants of the group (n = 13)	
	Z	P
Basic Motor Abilities	3.317	0.001**

(* $p < .05$, ** $p < .01$; level of significance)

Basic Motor Abilities

By examining the final test statistics through Wilcoxon signed - ranked test, it was discovered that for $n = 13$ Wilcoxon table gives a z score (3.317) which is greater than critical value of 1.96 and a p value (.001) which is less than 0.05 for basic motor abilities. So, the null hypothesis is rejected and alternative hypothesis is accepted at 5% level of significance which means multi-modal exercise was effective for patient with chronic low back pain.

The purpose of this study was to determine the effect of Multimodal exercises in patients with paraplegia spinal cord injury. Total 13 participants were taken in this study. In this one-group quasi-experimental study 13 paraplegic participants with SCI were assigned with convenient sampling technique. Among these 13 participants, they were assigned to a single group. There was no experimental group or control group. This group attended in the SCI indoor department of physiotherapy, CRP, Savar from which this study aimed to determine the effect of Multimodal exercises for paraplegic SCI patients. The outcome was measured by using structured questionnaire. In this study, Oxford muscle grade measurement was used to measure the muscle power of the lower limb key muscles, mobility of the participants was measured by 10 meter walk test and 6 minutes' walk test and finally ambulatory function of the participants was measured by basic motor questionnaire. Age, gender, marital status, occupational status, educational status, ASIA impairment scale were taken into the consideration as demographic variables.

The present study found almost similar characteristics on baseline in age, gender, living area, marital status, educational status, occupational status and monthly family income. 13 paraplegic spinal cord injury patients were included as sample of this study, among them 11 (84.6%) were male and about 2 (15.4%) were female. Anderson and Kilduff (2009) found that male was 63% and female was 37% among 231 participants following SCI. So, it seems that male participants are more permeable than female participants in spinal cord injury. Male genders were found to be more prone to have SCI than female (National Spinal Cord Injury Statistical Center, 2014). The reason may majority of women were remained in home in Bangladesh and are not subjected to violent form of work to which men are more exposed. Out of the participants mean age were 39.23. Similarly, Bombardier et al. (2008) also found age range from (25-40 years) in their study. Both results claim that active younger is more vulnerable with the incidence of spinal cord injury. In this study out of 13 participants, service holders were 7 (53.8%), business or work in crowd were 3 (23.1%), housewife was 1 (7.7%), unemployed were 2 (15.4%) higher due to traumatic spinal cord injury. Tzanos et al. (2016) stated that in Greece, the

Spinal cord injury is mostly occurred who were found poorly engaged with occupation and the same picture had emerged from the present study in case of occupation. In this study, the participants' average monthly income was 19923.08 BDT. It manifested that most of spinal cord injured patient came from middle or lower income family. It is nearly similar with Singh et al. (2003) within 483 participant's 217 participants' family income less than Rs.5000 per month. This type of population is less concern with safety measure and more vulnerable to injury.

Multimodal is the first research to address the numerous deficits of CLBP by integrating motor-cognitive, dance-therapeutic, as well as strength and flexibility training. First and foremost, it is anticipated that the combination of these three components would encourage participants to move their spine often, therefore alleviating their anxiety of movement. In addition, the group setting will allow the opportunity to get mutual support and encouragement from peers while participating in physical activities. Furthermore, the interweaving effects of the three training components demonstrate the hypothesised benefit of Multi- Move for CLBP patients. The fundamental component, which includes specialized strengthening and flexibility exercises, focuses on the entire lumbar spine, especially the lumbar multifidus and transversus abdominus muscles, which have been shown to exacerbate pain in CLPB patients.

The increased lumbar stability might help to slow down the deterioration of the vertebrae and joint structures, laying the groundwork for the functional abilities needed in everyday tasks, as well as the motor-cognitive and dance-therapeutic components of Multimodal. Furthermore, the majority of everyday motions are accompanied by a secondary duty (e.g. walking and talking). This element will be addressed during motor-cognitive training, in which patients will be presented with new tasks on a regular basis that need cognitive and physical interaction. This talent, which was developed in a fun atmosphere, might be very useful in improving patients' dual task performance. The following dance-therapeutic intervention, which targets trunk range of motion and combines cognitive challenges, emphasizes the aforementioned components.

In case of clinical parameters like ASIA impairment scale, out of the 13 paraplegic SCI patients, incomplete C were 7 (53.8%) and incomplete D were 6 (46.2%) participants. As for the muscle strength of the lower limb major key muscles measured by Oxford muscle grade measurement, all major key muscles of lower limb have shown significant improvement ($p < 0.05$) in terms of muscle strength except left planter extensors ($p < 0.05$). This is mainly stated that as for requirements of lower limb muscle strength, incomplete C & D participants is more suitable to assess and meet the criteria of this study. Noonan et al. (2012) also found in his study that 65.8% of the 324 participants of his study was incomplete C and 34.2% of them was incomplete D. He also found significant improvement ($p < 0.05$) in all the major key muscles of the lower limb through applying multimodal exercise for the paraplegic spinal cord injury patients. So it was concluded that there is a significant effectiveness of the Multimodal exercise in case of measurement of muscle strength of lower limb key muscles.

In this study, mobility functions of the participants had assessed through 10 meter walk test and 6 minutes' walk test where the p value less than 0.05 in both number of steps and total time needed in terms of the 10 meter walk test and total distance covered by the patient in terms of 6 minutes' walk test. Over the course of the trial, the group's time to walk 10 meters improved more. This enhanced their walking pace, allowing them to complete the 10-meter pathway in less time. So the test for the mobility outcome level is significant and concluded that there is a significant effectiveness of the Multimodal exercise in case of measurement of mobility outcome level. One study showed that the multimodal exercise was used for the functional changes in spinal cord lesion patients. Including this exercise with multidisciplinary team also played a vital role for measuring daily performance for SCI patients (Catz, Itzkovich, Agranov, Ring & Tamir, 1997).

An article by Lord and Rochester (2005) described that subjects in the circuit training group improved more than those in the control group in the 6-minute walk distance test. This indicates that towards the end of the research, the participant's endurance and walking ability have improved. The six-minute walk test measures physical capacity and walking function at a submaximal level and is used to assess walking endurance. The total distance walked rose dramatically from the fourth to the eighth

week, and was about 52.1 percent to 65.5 percent of the expected values of healthy patients.

In terms of Functional Ambulatory Category (FAC) in this study, there was a significant improvement ($p < 0.05$) after applying the multimodal exercise to the paraplegic SCI patients. The FAC is a six-point (from 0-5) hierarchical rating system that indicates how much help someone needs to walk. This scale makes it simple to categorize people based on their walking abilities, with the highest score indicating someone who can walk freely and without help (Kollen, Kwakkel & Lindeman, 2006).

The findings of this study show that multimodal exercise is more effective in increasing ambulatory function. Some rehabilitation doctors believe that this approach is too strenuous for neurologically disabled people, and hence it is not a viable option or treatment option. Previous research has shown that using multimodal exercise program on walk capacity and functionality can help stroke survivors improve their quality of life (Pellicer, Lusa, Casanovas & Ferrer, 2017).

In practice, creating a multimodal training program using simple exercises and low-cost exercise equipment is straightforward. Multimodal exercise promotes a sense of enjoyment, saves time, and allows patients to push themselves individually. Furthermore, patients appreciate it since it promotes camaraderie and experience sharing.

There were some situational limitations and barriers while considering the results of the study in different aspects. Those are as follows:

- The investigator only questioned a limited number of subjects (13 in total) that was difficult to generalize the result.
- This study was only conducted among incomplete paraplegia SCI patient at CRP. So the data cannot be generalized to the practice of documentation by all physiotherapists in Bangladesh. It will be more effective if we used it experiment on other category patients of SCI and compare.
- It is only the research ever in this Multimodal exercise in Bangladesh, so local resources about documentation were not available for comparison.
- Time and resources were limited that have a great deal of impact of the study.

7.1 Conclusion

Spinal Cord injury is known as an illness or an injury which causes paralysis that results in the partial or total loss of use of all four limbs. The current study was a one-group pre-test and post-test design quasi-experimental which was used in this study to examine the effectiveness of Multimodal exercises for chronic low back pain for paraplegic SCI patients during rehabilitation. This study found statistically significant improvement in case of muscle strength of the lower limb major key muscles which measured by Oxford muscle grade measurement. In case of mobility outcome & functional ambulatory status this study also was found significant improvement among the participants.

7.2 Recommendations

The researcher proposed the various recommendations to certain authorities and personnel. A double blinded randomized clinical trial is recommended in future with large sample size. Government need to plan awareness program in different area of our country for preventing the SCI and its complications with the risk. Specialized those were involved in the management and treatment team should refer to Physiotherapists for improvement for the client's conditions. CRP providing massive services to the SCI patients and need to create more post for Physiotherapy to provide collaborative services. Continued and regular study in this area should play an essential part in improving quality of life of the SCI patient. Recommendation for other researcher for further research in this field to increasing the number of sample.

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ANNEXURE 1: IRB from BHPI



বাংলাদেশ হেল্থ প্রফেশন্স ইনস্টিটিউট (বিএইচপিআই) Bangladesh Health Professions Institute (BHPI)

(The Academic Institute of CRP)

Ref: CRP-BHPI/IRB/10/2021/503

Date: 03/10/2021

Saddam Hossain
Part II M.Sc. in Physiotherapy
Session: 2019-2020, Student ID: 111190067
BHPI, CRP, Savar, Dhaka- 1343, Bangladesh

Subject: Approval of the thesis proposal “Effectiveness of multimodal exercise in chronic low back pain” by ethics committee.

Dear Saddam Hossain,
Congratulations.

The Institutional Review Board (IRB) of BHPI has reviewed and discussed your application to conduct the above-mentioned dissertation, with yourself, as the principal investigator and Professor Md. Fazlul Karim Patwary as thesis supervisor. The Following documents have been reviewed and approved:

Sr. No.	Name of the Documents
1	Dissertation Proposal
2	Questionnaire (English and Bengali version)
3	Information sheet & consent form

The purpose of the study is to find out the effectiveness of multimodal exercise in chronic low back pain. The study involves use of an Oswestry Low back disability questionnaire and numerical pain rating scale (NPRS). That may take 20 to 30 minutes to fill in the questionnaire and there is no likelihood of any harm to the participants. The members of the Ethics committee have approved the study to be conducted in the presented form at the meeting held at 09:15 AM on March 30, 2021 at BHPI [27th IRB Meeting (extended)].

The institutional Ethics committee expects to be informed about the progress of the study, any changes occurring in the course of the study, any revision in the protocol and patient information or informed consent and ask to be provided a copy of the final report. This Ethics committee is working accordance to Nuremberg Code 1947, World Medical Association Declaration of Helsinki, 1964 - 2013 and other applicable regulation.

Best regards,

Muhammad Millat Hossain
Assistant Professor, Dept. of Rehabilitation Science
Member Secretary, Institutional Review Board (IRB)
BHPI, CRP, Savar, Dhaka-1343, Bangladesh

ANNEXURE 2: Data Collection Permission

The Chairman,
Institutional Review Board (IRB)
Bangladesh Health Professions Institute (BHPI),CRP
Savar, Dhaka-1343. Bangladesh.
Subject: Application for review and ethical approval.

Dear Sir,

With due respect, I am Saddam Hossain, student of Part II of M.Sc. in Physiotherapy program at Bangladesh Health professions institute (BHPI),an academic institute of Centre for the Rehabilitation of the Paralyzed (CRP) under the faculty of medicine, University of Dhaka. As per the course curriculum, I have to conduct a thesis entitled "Effectiveness of multimodal exercise in chronic low back pain". This is an experimental study, under the most honorable supervisor Professor Md. Fazlul karim patwary. The purpose of the study is to determine the effectiveness of multimodal exercise in chronic low back pain in inpatient unit.

The study involves use of an Oswestry low back disability questionnaire and the numerical pain rating scale (NPRS) and it may take 20 to 30 minutes to fill in the questionnaire. There is no likelihood of any harm to the participants and / or participation in the study may benefit the participants or other stakeholders. Related information will be collected from the patient's guide books. Data collectors will receive informed consent from all participants and the collected data will be kept confidential.

Therefore, I look forward to having your kind approval for the thesis proposal and to start data collection. I can also assure you that I will maintain all the requirements of the study.

Sincerely,



Saddam Hossain

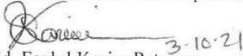
Part-(II) M.Sc. in Physiotherapy

Session: 2019-2020

Bangladesh Health Professions Institute

(An academic Institution of CRP)

Recommendation from the thesis supervisor



Professor Md. Fazlul Karim Patwary
Jahangirnagar University

Thesis presentation date: 30 March 2021

Forwarded
E. Rahman

Course coordinator: M.Sc. in Physiotherapy

ANNEXURE 3: CTRI Trial Registration



Clinical Trial Details (PDF Generation Date :- Fri, 12 Nov 2021 14:20:43 GMT)

CTRI Number	CTRI/2021/11/038010 [Registered on: 12/11/2021] - Trial Registered Retrospectively	
Last Modified On	10/11/2021	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Physiotherapy (Not Including YOGA)	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	Effects of Multimodal exercise in chronic low back pain	
Scientific Title of Study	Effectiveness of Multimodal exercise in chronic low back pain	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Saddam Hossain
	Designation	Clinical Physiotherapist
	Affiliation	Bangladesh Health Professions Institute
	Address	BHPI, CRP-Savar, Dhaka, Bangladesh 1343 Other
	Phone	
	Fax	
	Email	shossainrasel@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Prof Md Fazlul Karim Patwary
	Designation	Professor
	Affiliation	Institute of Information Technology
	Address	Jahangirnagar University, Savar, Dhaka, Bangladesh. 1342 Other
	Phone	
	Fax	
	Email	patwary@juniv.edu
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Ehsanur Rahman
	Designation	Associate Professor & MPT Co-ordinator
	Affiliation	Bangladesh Health Professions Institute
	Address	BHPI, CRP-Savar, Dhaka, Bangladesh 1343 Other
	Phone	
	Fax	
	Email	ehsanurrahman.bhpi@gmail.com

ANNEXURE 4: Consent form

Assalamu-Alaikum / Adab,

My name is Md. Saddam Hossain, student of M.Sc. in physiotherapy at Bangladesh Health Professions Institute (BHPI), CRP. I am conducting a study for partial fulfillment of Masters of Science in Physiotherapy degree, titled, “Effectiveness of Multi-modal exercise in Chronic low back pain patients.”

Through this research, I will see the efficacy of specific stabilization exercises along with existing physiotherapy for the case of postpartum low back pain. For this regard, I would need to collect data from the postpartum women having low back pain. Considering the area of research, you have met the inclusion criteria and I would like to invite you as a participant of my study. If you participate in this study, I will evaluate for a particular intervention (Effectiveness of Multi-modal exercise in Chronic low back pain patients.) for low back pain. The interventions that would be given are safe and will not cause any harm.

I want to meet with you a few couple of sessions during your as usual therapy. Your participation will be voluntary. You have the right to withdraw consent and discontinue participation at any time. If you have any query about the study or your right as a participant, you may contact with, Md. Saddam Hossain researcher or Professor Fazlul Haque Patwary, Institute of Information Technology, Jahangirnagar University, Savar, Dhaka.

Do you have any questions before I start?

So may I have your consent to proceed with the interview? Yes/No.....

I have read and understand the contents of the form.

I agree to participate in the research without any force.

Signature of the participant

Signature of the interviewer

ANNEXURE 5: Questionnaire (English)

(Please fill the questionnaire with a black ball point and give tick and fill up the blank part of each question which is best suited to answer)

Part I: Personal information

ID: _____ Date: _____ Mobile No: _____
Name: _____ Address: _____

Part I: Socio-demographics

Q	Question	Variables/ Instruction	Answer
1	Age in Years (Write)		
2	Education	1) No formal education 2) Primary education 3) SSC 4) HSC 5) Bachelor or above	
3	Marital Status	1) Unmarried 2) Married 3) Divorcee 4) Widow	
4	Present Occupation:	1) Service 2) Business or work in crowd 3) Housewife 4) Retired 5) Not engaged in any occupation	
5	Average monthly income of the family (Write)		

Part II: Clinical parameters

Oxford muscle grade measurement				
Lower extremity keys muscles	Lower extremity right		Lower extremity left	
	Before	After	Before	After
Hip flexors (L2)				
Knee extensors (L3)				
Ankle dorsiflexors (L4)				
Long toe extensors (L5)				
Ankle planter flexors (S1)				

ASIA IMPAIRMENT SCALE (AIS):

Part III: Mobility and Balance Outcome measures

10 meter walk test	Number of steps	Before treatment	After Treatmen t
	Time		
6 minutes' walk test	Number of rest		
	1st Rest (Distance)		
	Total distance		

Part IV: Functional Ambulatory Category (FAC)

Basic Motor Abilities (Before treatment)	
Nonfunctional ambulation	0
Ambulator Dependent for Physical Assistance Level II	1
Ambulator Dependent for Physical Assistance Level I	2
Ambulator Dependent for Supervision	3
Ambulator Independent Level Surfaces only	4
Ambulator Independent	5

Basic Motor Abilities (After treatment)	
Nonfunctional ambulation	0
Ambulator Dependent for Physical Assistance Level II	1
Ambulator Dependent for Physical Assistance Level I	2
Ambulator Dependent for Supervision	3
Ambulator Independent Level Surfaces only	4
Ambulator Independent	5