Department of Nutrition & Food Technology
Faculty of Applied Science & Technology
Jashore University of Science & Technology, Jashore- 7408, Bangladesh

Ph. D. Proposal Approval Letter

Dated: 7th June 2022

This is to certify that Muhammad Shahidul Islam, Assistant Professor of the Department of Physiotherapy at SAIC College of Medical Science and Technology (SCMST), SAUC Tower, M-1/6, Mirpur-14, Dhaka-1216 is a Ph. D. student at the Department of Nutrition and Food Technology, Jashore University of Science and Technology, Jashore-7408, Bangladesh. He is conducting his Ph. D. thesis titled **"Therapeutic Exercise, Educational booklet and Vitamin D3 Supplement for the Management of Chronic Mechanical Low Back Pain"** under the supervision of **Dr. Md. Ashrafuzzaman Zahid, *Ph. D.***, Associate Professor, Department of Nutrition and Food Technology, Jashore University of Science and Technology, Jashore-7408, Bangladesh. He is co-supervised by **Professor Dr. Md. Sohrab Hossain, *Ph. D.***, Professor, Department of Physiotherapy, Bangladesh Health Professions Institute (BHPI), CRP, Savar, Dhaka-1343, Bangladesh.

He is applying for ethical approval and trial registration for the trial titled **"Effect of Therapeutic Exercise, Educational booklet and Vitamin D3 Supplement for the Management of Chronic Mechanical Low Back Pain".**

The Approved proposal and Case Report Form (CRF) is attached herewith.

Sincerely

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Dr. Md. Ashrafuzzaman Zahid, *Ph. D.*
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology, Jashore-7408, Bangladesh.
ashraf@just.edu.bd

Department of Nutrition & Food Technology
Faculty of Applied Science & Technology
Jashore University of Science & Technology, Jashore- 7408, Bangladesh

Title: Effect of Therapeutic Exercise, Educational booklet and Vitamin D3 Supplement for the Management of Chronic Mechanical Low Back Pain.

Researcher
Muhammad Shahidul Islam
Ph. D. Student
Department of Nutrition & Food Technology
Jashore University of Science & Technology

Supervisors

1) Dr. Md. Ashrafuzzaman Zahid, Ph. D.,
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology, Jashore-7408, Bangladesh.

2) Professor Dr. Md. Sohrab Hossain, Ph. D.
Professor
Department of Physiotherapy
Bangladesh Health Professions Institute (BHPI), CRP, Savar, Dhaka-1343, Bangladesh.

Background:

Low back pain (LBP) is identified worldwide as a leading contributor of Years Lived with Disability (YLDs) (Robert et al., 2014). It is considered as a common reason of disability in developed countries and also in developing countries (Hoy et al., 2012). About 55–80% people suffer from LBP in their lifetime, and worldwide yearly cost of Chronic LBP is estimated at thousands billion dollars. Causes of low back pain comprise of -osteoarthritis (OA) of facet joint, soft tissue injury e.g., sprain, degeneration of intervertebral disc, instability, impingement of nerve, infection, and tumor. Mostly, facet joints OA, is thought to be the cause of low back pain in 15–45% as it is the load-bearing joints of the posterior spine (Pan et al., 2020).

Deficiency of Vitamin-D has been connected with chronic type of musculoskeletal (MsK) pain like as LBP. At Indian subcontinent the rate of vitamin-D deficiency is found in about 50% to 90% persons, and it is ascribed to low dietary consumption along with skin color and lifestyle changing in spite of the accessibility of sufficient sunlight. Study on the effect of vitamin-D supplementation in symptom improvement of chronic type of pain like LBP is conflicting (Al-

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Saeed, Mohammed, Azizieh, & Gupta, 2013; Ghai et al., 2017). Besides 50% of patients who went for their chronic LBP in the hospital are found suffering from lack of nutrition (Correia, et al, .2014).

Poor nutritional status is positively linked with the presence of chronic LBP. Bangladesh is a developing country with a massive population though we have very limited resources and opportunities to get proper medical care due to insufficiently skilled professionals and expensive services. Moreover, the awareness among the mass about LBP is not quite clear which made it tough to prevent the occurrence of these issues. Physiotherapy intervention has a great role to prevent LBP and restore the functions maximizing the ability to perform daily life. Early identification or evaluation of nutritional conditions are important in handling risks and improving the prognosis of chronic LBP individuls (Georges, et al.,2019).

Justification:

Pain felt at back is one of the greatest musculoskeletal complications in the average people. It is also one major cause of morbidity and disability. Besides long time suffering gradually affects the individual physical and psychological status. Multiple factors are associated with LBP. Studies nutritional status may have an impact on LBP status. Poor nutritional status may impact our general health status. Protein, minerals, vitamins are major nutrients, among them, Vitamin D is directly related to our bony health which benefits the body by absorbing calcium (Ca) and phosphorus (P) from the diet we take. So, early assessment and monitoring of nutritional status and management of LBP may help to reduce the deterioration of physical function and psychological status of the individuals.

Although there are many treatment options available, due to high cost and ineffectiveness all treatments are not accessible and acceptable to all. Therapeutic exercises are evidence-based, the accepted treatment for all. And vitamin D3 supplement is a cost-effective treatment and easy means to fill up the deficiency of vitamins in the body. Studies found therapeutic exercise and vitamin D3 supplements has a beneficial effect on chronic LBP patients.

Very little research has been done before about chronic type of back pain and the factors responsible for this, but in Bangladesh no RCT study conducted to compare the effect of nutritional supplement, educational booklet and therapeutic exercise treating the chronic back pain. Researchers want to find out the information regarding this area. Also thinking about

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

nutritional status is important for Bangladesh. The findings of this study concentrate on the national and universal stage to help future researchers and health ministry's whereas they may outspread their collaboration to bring easiness in the lives of assessment of physical function and psychological status among the patients with chronic type of low back pain in Bangladesh.

General objective:

The main objective of the study is to find out the efficacy of therapeutic Exercise, educational booklet and Vitamin D3 Supplement for the management of chronic mechanical Low Back Pain.

Specific Objectives of this project-

To accomplish the aim of the project the study will conduct in 3 phases with the following specific objectives,

1. To know about the physical function and psychological status of the chronic mechanical LBP (MLBP) patient.
2. To explore the effect of providing educational booklets and Vitamin D3 supplements on the physical function and psychological status of chronic MLBP patients.
3. To evaluate the effect of providing educational booklets, therapeutic exercise and Vitamin D3 supplements on the physical function and psychological status of chronic MLBP patients.

Literature Review:

Pain, stiffness, or muscle spasm feel usually between the margin of the lower rib and the creases of buttock, with or without pain radiation along the passage of the sciatic nerve is defined as a low back pain. It's a common musculoskeletal condition, which arises in all including, from developing countries to developed countries, from children to the elderly population, and almost everyone during their period of life with acute episode or chronic condition (Chen et al., 2021). LBP (CLBP) is connected with numerous biopsychosocial aspects which may have effect on bone health. A relationship between ill bone health and back pain is well known in conditions like as osteoporosis, osteoarthritis (OA), and inflammatory arthritis. In these situations, the link between back pain and health of bone can be facilitated by fracture in vertebrae, abnormal spinal curvature, inflammatory changes, degeneration of joint intervertebral disc degeneration (Briggs, Straker, Burnett, & Wark, 2012).

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Analysis of different research proposed that decreased vitamin D level is linked with pain at back, this associations was observed strongly in women aged more than 60 years. Although Vitamin D helps in the metabolism of bone calcium, the connection between vitamin D and back pain severity is still debated (Hao-Wei Xu, Shu-Bao Zhang, Yu-Yang Yi, & Hao Chen, 2021). Another study stated that vitamin D has the potential to decrease pain and inflammation by modifying sensory neuron excitability and with an anti- and proinflammatory cytokines. Besides, vitamin D levels is linked to increases in muscle strength, which can explain rationale for how vitamin D supplementation might be helpful to improve pain and function in persons suffering from LBP. The Institute of Medicine recommends daily dosage for vitamin D3 is 10 µg for both adults and children (20 µgs for <70 years old), with a tolerable maximum intake level is 100 µgs, whereas the Endocrine Practice Guidelines Committee recommends daily dosage of vitamin-D3 is 37.5–50 µg per day for the persons who are vulnerable of vitamin D deficiency (less than 20 ng/mL), with a tolerable maximum intake level at 200 µgs per day (Zadro et al., 2018).

Physical exercise is thinks as an efficient way of excite osteogenesis (i.e. increasing bone density in osteoporotic patients). Studies recommends that weight-bearing aerobic exercises like walking, stair climbing, jogging, and Tai Chi; Strength and resistance exercises with loading (with weights) or without (swimming, cycling) are effective for improving bony health of the specific limbs. To use the weight-bearing exercises as an effective means, exercises should reach the mechanical intensity suitable to regulate an significant ground reaction force. Some other studies suggested multicomponent exercises like aerobics, progressive resistance exercises etc and whole-body vibration (Benedetti, Furlini, Zati, & Letizia Mauro, 2018).

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Conceptual framework of the study:

The independent variables are the leaflet, therapeutic exercise, and vitamin -D3 supplement and the dependent variables are physical function and psychological status.

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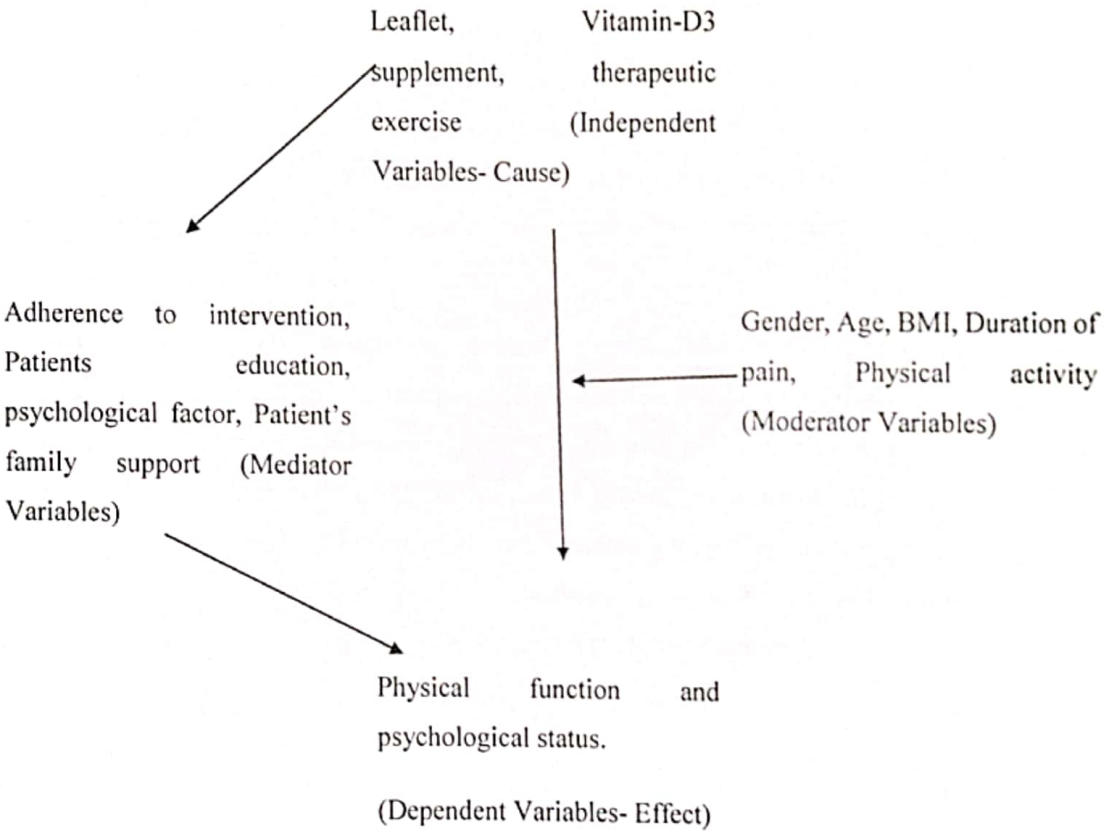

Methodology:

Phase I study: Cross-sectional study.

Phase-II: Randomised Control Trial (RCT).

Phase-III: Parallel group RCT design.

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

Research outlines:

Phase I: The phase I study will be conducted to find out the "Physical function and psychological status of the patients with chronic mechanical low back pain". A cross-Sectional study design will be used to complete the study. The study duration will be 4 months.

Phase II: The phase II study title will be selected as "Efficacy of the educational booklet and Vitamin D3 supplement for the management of chronic mechanical LBP". To achieve the objective a randomized control trial study will be conducted at Dhaka, Savar and Manikganj District of Bangladesh. There will be intervention groups that will receive nutritional supplements including vitamin D3 tablets and advice to improve nutritional status of the body, and a control group will receive only educational booklets. The outcome will find out the mean standard deviation with 95% CI.

Phase III: Phase III study title will be chosen as "Efficacy of educational booklet, therapeutic exercise and Vitamin D3 supplement on physical function and psychological status for the management of chronic mechanical LBP". To achieve the objective a parallel-group randomized control trial study will be conducted at Dhaka, Savar and Manikganj District of Bangladesh. There will be 2 interventions and 1 control group. The control group will get advice by an educational booklet and one experimental group will get only Vitamin D3 and another one will get a Vitamin D3 supplement with therapeutic exercise. The outcome will find out the mean standard deviation with 95% CI.

Study Population and area:

Chronic Mechanical LBP sufferer seeking treatment at different hospitals of Dhaka, Savar and Manikganj District of Bangladesh including Centre for the Rehabilitation of the Paralysed (CRP).

Study period

The study will be conducted from July 2022- to October 2024.

Sample size

The sample number will be obtained by Epi info software for a cross-sectional study.

For cross-sectional study Calculated Sample size 246 by assuming the expected frequency is 80% and according to Census report, 2011 population of Manikgonj District is 1392867, confidence limit is 5%.

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

For the RCT study, the sample size will be calculated as the estimation of sampling as a scientific way and will be selected as the standard number of the sample as a calculation guide for the RCT study.

Sampling technique

The researcher will use a hospital-based randomization process to determine the sample population. Also, the computer-generated concealed allocation will be used for group allocation.

Inclusion criteria

A participant will be eligible to participate if -

1. Mechanical low back pain: chronic pain felt in the lumbar/sacral regions and may be linked with musculo-ligamentous sprains and strains, disk displacement, and other conditions with persist for more than 3 months. **(ICD-10-CM-Code M54.5).**
2. Age ranges from 18 years and above
3. Both male and female patients.
4. Those who will be motivated and given consent to include in the study.

Exclusion criteria:

Participants will be excluded for the following causes-

1. Presence of any kind of comorbidities that can affect BMD like RA, Ankylosing Spondylitis, Osteomalacia, TB spine, etc., and any history of osteoporotic fracture.
2. Post-menopausal women. Because menopause is marked as a common contributing factor for bone degeneration in midlife women. Usually, female lost 50% of their trabecular bone and 30% of cortical bone during their lifetime, about ½ of which is lost during the first 10 year of menopause (Finkelstein et al., 2008).
3. Use of calcium, vitamin D3 supplement, resistance training, and high impact weight-bearing activities regularly within the past 6 months.
4. Currently smoking or persons having a history of smoking in the last ten years.
5. Mechanical low back pain patients related with bowel and bladder incontinence.
6. Patients who were receiving medications that can affect BMD e.g. estrogen, progesterone, etc.
7. History of psychiatric disorders or under psychological treatment.)

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

8. Unwilling to participate.

Outcome measurements tools:

- Demographic, lifestyle, and anthropometric information-

  Will be collected by a written questionnaire prepared by researchers.

- Serum calcium and vitamin-D level-

  By following standard protocol samples will be collected by expert persons and the researcher will collect the information from laboratory test reports.

- Physical function-

  Following things will measure to know about the physical condition of the participants,

  - Low back pain related information- will be measured by **Visual analog scale.**
  - Nutritional status - by **Mini nutritional assessment scale.**
  - Impact of back pain of functional activities- **Oswestry low back pain disability index questionnaire (ODI).**
  - Risk of a worse result persistent disabling back pain- by **STarT back screening tool.**

- Psychological status-

  Fear avoidance beliefs questionnaire (FABQ)

BMI:

To measure the body mass index, weight (in kg) will divide by height (in meter) squared (m2). Results will categorize according to criteria by the World Health Organisation (WHO): normal weight, BMI -less than 24.9 kg/m2; overweight, 25 to 29.9 kg/m2; obesity, BMI more than 30 kg/m2.Bodyweight will be measured by a digital weight machine and height will be measured by using a Measurement tape.

Vitamin D Level:

Patients are categorized based on vitamin D levels, like - deficient (less than 20 ng/mL); insufficient (20 to 30 ng/mL); sufficient (more than 30 to 100 ng/mL).

Serum Calcium:

A normal S. Calcium level is 8 to 10 mg/dL. Level may be varied in laboratories.

VAS:

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

The visual analog scale (VAS) is a common tool to quantify pain intensity. Patient are requested to mark or indicate their perceived pain intensity along a 100 mm horizontal line, and this marking is then meausre from the left side. It is rated at the left end as '0 mm' (no pain) and at the right end as '100mm' (very severe pain). Reliability study shows p- values range from .60 to .78, strong correlation with VAS for pain was also noticed in the study (Boonstra, Preuper, Reneman, Posthumus, & Stewart, 2008).

Mini nutritional assessment Scale:

It is 18 items validated screening tool was primarily established to measure the nutritional status of older adults and mainly for research study. The tool evaluates different (4) aspects: anthropometric assessment (BMI, weight reduction; general assessment; short dietary assessment, and subjective assessment). After the summation, scores are categorized as Mini Nutritional Assessment-Long Form, persons can be divided into 3 groups using threshold values of less than 17 as "malnourished," 17 to 23.5 as "at risk of malnutrition," and ≥24 as "normal nutritional status," with a highest total score of 30 points (Holvot et al., 2020; Kiesswetter et al., 2014). The accuracy of the full MNA-16 is more than 90% (with 95% CI, 87.50%–95%). To identify the malnourished and those at risk, MNA-16 is 90.40% sensitive and 86.9% specific (Woldekidan, Haile, Shikur, & Gebreyesus, 2021).

Oswestry lumbar spine disability index:

The ODI scale assesses how the severity and symptoms of LBP affect the functional activities of the individuals. This scale consists of ten items including pain, personal care, lifting, walking, sitting, standing, sleeping, sex (if applicable), social, and travel. These items consist of 6 items, with a score from 0 to 5. 0 indicates the minimum disability, and 5 indicates the highest disability (Rehab measure, 2013). The test shows excellent test-retest reliability (ICC=0.95%,CI=95%) and excellent internal consistency for overall ODI score (0.83) (Gottle, Garratt, Krogstad, & Stuge, 2012).

STarT back Screening tools:

This tool used to identify persons with low back pain (LBP) those are vulnerable of a poor prognosis of persistent pain leads to disabling condition and by this means facilitates to the proper treatment options (Haglund, Bremander, & Bergman, 20 19). This tool is comprises of 9 items including referred lower limb pain, comorbid pain, two items for disability,

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

bohersomeness, catastrophizing, fear, anxiety, and depression. Answers of the questions are marked as agreeing (1) or disagree (0), except the question about bothersomeness "Overall, how bothersome has your back been the last two weeks?" this question is answered by using 5-point Likert scale and response as a- 0=not at all, slightly, moderately, 1=very much 1 and extremely (bothersome). The total score ranges 0- 9, where 9 means the worst prognosis. The last 5 items are concise into a psychosocial subscale where 5 means the highest score, indicating maximum risk for development of chronic back pain. LMP patients score totally from 0–3 are categorized as low risk (e.g. self-management strategies), and those scoring a minimum of 4 points on total score of which a maximum of three items from the psychosocial risk factors are categorized as medium risk (suitable for physiotherapy management) and those scoring from 4/5 on the psychosocial subscale are categorized as high risk of poor prognosis concerning persistent disability (appropriate for psychologically informed interventions). For this scale, reliability of total score and psychosocial subscore found 0.90 (0.82, 0.94) and 0.82 (0.70, 0.90) respectively (Robinson, & Dagfinrud, 2017).

Fear Avoidance Beliefs Questionnaire:

It measures the degree that fear of pain impacts a person 's avoidance of physical activity (measured by the FABQ-PA subscale score) or work (measured by the FABQ-W). The FABQ comprises of 16 items, divided into two subscales -1. fear-avoidance beliefs for work (FABQ-Work) with 11 items and 2. fear avoidance beliefs for physical activity (FABQ-PA) with 5 items. The score of the items is measured by using 7-point Likert scale categorized from strongly disagree to strongly agree. Each subscale score is used independently- In the FABQ-Work (range 0 to 42) 7 from 11 items are added to a sum score (6, 7, 9-12,15), and in the FABQ-PA (range 0 to 24) 4 of the 5 items (2 to 5) (Grotle, Brox, & Vøllestad, 2006). It is a subjective questionnaire, focusing exactly on way how a patient with low back pain fears avoidance beliefs towards physical activity and work affect persons' back pain, ultimately leads to disability. Test-retest reliability for this scale is excellent (r=0.84-0.91) (Rehab Measure, 2014).

Intervention:

1) **Leaflet**

By leaflet important guidelines will provide for MLBP patients with low vitamin D and S. Calcium level, to help with knowing appropriate diet and healthy lifestyle to increase

Dr. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

nutritional status as well as overall improvement of Physical and Psychological condition of the body.

2) Therapeutic exercise

Exercises will focus on both the back pain and nutritional status of the participants. Each session will continue for 25-30 minutes.

3) Vitamin D3 along with advice

In this study, one group will receive a vitamin-D3 supplement, which will be provided by a research fund. A chart of capsule-taking dates and time will be maintained to avoid any kind of misconduct. Besides, in this group participants will receive some nutritional advice to lead a healthy life.

Code		Interventions
L		**Leaflet:** ✓ Take naturally Vitamin D3 containing food like- Milk, Cereal, Orange juice, Yogurt, Cereal, mushroom, margarine, hard-boil eggs, Sea fish like Tuna, Salmon, etc (Zaman et al., 2017). ✓ 30- 35 minutes sun exposure 11 am to 2 pm (Augustine, Madhavan, & Kulkarni, 2018; Harinarayan, Holick, Prasad, Vani, & Himabindu, 2013). ✓ 7–8-hour sleep (Gao et al., 2018). ✓ Avoid stress, smoking and maintain healthy body weight (Dean and Soderlund, 2015). ✓ Avoid alcohol consumption. ✓ Do regular physical activity.
	TH.1	**Therapeutic Exercise:** Postural advice- Maintain erect posture in sitting and standing, Avoid long sitting or standing, Avoid forward bending (Kim, Cho, Park, & Yang, 2015).

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

TH	TH.2	McKenzie's directional preference includes - sustained positioning, flexion, or extension principle (most often need extension principle). Exercise will be completed in a set of 10 repetitions (Dunsford et al., 2011).
	TH.3	Stretching Exercises- stretching of erector spine muscle, hamstring, and triceps surae (França, Burke, Caffaro, Ramos, & Marques, 2012).
	TH.4	Lumbar stabilization exercises (Yoon, Lee, & Kim, 2013).
	TH.5	Weight-bearing aerobics exercise includes jogging, jogging with stair climbing, and 30 minutes of brisk walking. (Benedetti et al., 2018).
	TH.6	Heating modalities- IRR
S + A		**Vitamin D3 Supplement + Advice:** • Vitamin supplement dosage will be prescribed by the physician. • Take Vitamin D and calcium rich food like- milk, hard-boiled egg , sea fish, fruits, sea fish to improve your bony health. • Avoid uric acid containing food like- red meat, cauliflower, peas etc. • Avoid Alcohol and smoking. • Avoid sedentary life.

Progression for therapeutic exercise (TH):

Along with leaflet **(L)** and Vitamin D3 supplement along with advice **(S+A)** exercise will be prescribed for 4weeks.

TH. 5 will be performed by patients at home.

DR. M. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

	Week 1	Week 2	Week 3	Week 4
Frequency	3 days in a week	3 days in a week	3 days in a week	3 days in a week
Types	TH.1+TH.2+TH.3 (ES) + TH.6	TH.1+TH.2+TH.3 (ES, HS,) +TH.4+ TH.6	TH.1+TH.2+TH.3 (ES,HS,TS)+TH.4 + TH.6	TH.1+TH.2+TH.3 (ES,HS,TS)+TH.4 + TH.6
Intensity	TH.2= 10repX 1set TH.3(ES)=10repX1 set (with 5-10 sec hold) TH.6= 10 minutes	TH.2= 10repX 1set TH.3 (ES,HS)=10repX1s et (with 5-10 sec hold) TH.5 = 10repX 1set TH.6= 10 minutes	TH.2= 10repX 1set TH.3=10repX1set (with 5-10 sec hold) TH.5 = 10repX 2 set TH.6= 10 minutes	TH.2=10repX 1 set TH.3=10repX1set (with 5-10 sec hold) TH.5 = 10repX 3 set TH.6= 10 minutes
Time	1 time in a day	1 time in a day	1 time in a day	1 time in a day

Expected outcome:

As per the researcher's best knowledge the study is being conducted for the first time in Bangladesh. So, it is difficult to assume which group will perform better in between-group analysis. Complying with evidence, it is expected that all groups will improve from baseline, but experimental groups will improve more.

Data analysis

Data will be analyzed by SPSS 22 version and Microsoft Excel 13. The statistical test will select according to the nature of the Data.

Data audit

An external auditor will examine the data and all the data will be kept at a data repository.

Ethical Consideration:

- The researcher will take the WHO clinical trial registration for the study.

Dr. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

- The investigator will take ethical permission from the ERC of the Centre for the Rehabilitation of the Paralysed (CRP), IRB of the Faculty of Biological Science at Jashore University of Science and Technology and the Institute of Physiotherapy Rehabilitation and Research (IPRR) of Bangladesh Physiotherapy Association (BPA).
- The research will be Followed by the World Health Organisation (WHO)& Bangladesh Medical Research Council (BMRC) guidelines.
- Confidentiality will strictly be maintained.
- Informed consent will be ensured from each participant.
- Participants will be informed that they have the right to proceed or withdraw from the study at any time of the respondents.

Funding

The investigator will arrange his fund to do this study.

1) Researcher will bear all the cost of pathological tests
2) Researcher will manage funds for Vitamin D3 Supplementation
3) Researcher will bear the data collection cost and treatment cost if applicable.
4) Moreover researcher can apply for grants with the concern of the department during the doctoral study.

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

Timeline (Gantt chart) for study outline

Phase I-Phase III (Timeline from April, 2022 to October, 2023)

	April-May, 22	June-July, 22	Aug-Sept, 22	October-Nov, 22	August-Sept, 22	Oct-Nov,22	Dec, 22-Jan, 23	Feb-March, 23	April-May, 23	June-July,23	August-Oct, 23
Planning											
Develop questionnaire											
Proposal writing											
Ethical review											
Trial registration											
Questionnaire validity											
Piloting study											
Data Collection											
Data analysis											

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Final draft											
Publication											

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

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DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

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Dr. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

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DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

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DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Department of Nutrition & Food Technology
Faculty of Applied Science & Technology
Jashore University of Science & Technology, Jashore- 7408, Bangladesh

Case Report Form (CRF)

Respondent ID…….

This questionnaire is developed to measure the effect of therapeutic exercise, and vitamin D3 supplement for the management of MLBP patients. Please provide the appropriate answers.

Patient Name: Date:

Address: Mobile:

Section 01: Patient's Socio-demographic Information

Question	Patient Response	Code
1.What is your age?	……. Years	
2.Sex	• Female • Male	01 02
3. Marital status	• Married • Unmarried	01 02
4. Yearly income of family	……. Tk	

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

4. What is your educational level?	• No formal education • Primary • Secondary • Higher-secondary • Graduate • Post-graduation	**01** **02** **03** **04** **05** **06**
5. What is your Occupation?	• Housewife • Farmer • Shopkeeper • Service holder • Business • Day-labor • Student • Unemployed • Others	**01** **02** **03** **04** **05** **06** **07** **08** **09**

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Section 02: Lifestyle and health related information

Questions	Patients' response	Code
6. Do you have a regular exercise habit?	• Yes • No	01 02
7. Do you have Diabetes Mellitus?	• Yes • No	01 02
8. Do you have Hypertension?	• Yes • No	01 02
9. Do you have kidney disease?	• Yes • No	01 02
10. Do you have a sun-exposure habit?	• Yes • No	01 02
11. Do you have a milk consumption (≥7 cups/week) habit?	• Yes • No	01 02

Section 03: Anthropometric measurement

12. Weight	..... kg
13. Height	..... cm
14. BMI	..... kg/ m^2

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Section 04: Laboratory test results

Write the obtained value from investigation report

Test	Value
Vitamin D	..... ng/ML
S. Calcium	.....mg/DL

Section 05: Physical function

Low back pain related information

Pain severity (question 16) will be measured by VAS scale which is leveled as a '0= No pain and 10= severe pain). Please indicate the patient's perceived pain intensity in the line below.

Questions	Patients Response
15. How many days have you been suffering from back pain?	..... months
16. Severity of back pain.	0 10

Nutritional status

Nutritional status will be measured by Mini nutritional assessment questionnaire. Please put a tick mark on the appropriate answer.

Questions	Patients' response
1. Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?	0 = severe loss of appetite 1 = moderate loss of appetite 2 = no loss of appetite

Dr. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

2. Weight loss during the last months?	0 = weight loss greater than 3 kg 1 = do not know 2 = weight loss between 1 and 3 kg. 3 = no weight loss
3. Mobility	0 = bed or chair bound 1 = able to get out of bed/chair but does not go out 2 = goes out
4. Has suffered psychological stress from acute disease in the past 3 months.	0 = yes 2 = no
5. Neuropsychological problems	0 = severe dementia or depression 1 = mild dementia 2 = no psychological problems
6. Body Mass Index (BMI) (weight in kg)/(height in m)	0 = BMI less than 19 1 = BMI 19 to less than 21 2 = BMI 21 to less than 23 3 = BMI 23 or greater
Total	

Screening score (subtotal max. 14 points) - Put tick mark on the box

12-14 points: Normal nutritional status ☐

8-11 points: At risk of malnutrition ☐

0-7 points: Malnourished ☐

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

For a more in-depth assessment, continue with Next questions-

Questions	Patients' response
7. Lives independently (not in nursing home or hospital)	1 = yes 0 = no
8. Takes more than 3 prescription drugs per day	0 = yes 1 = no
9. Pressure sores or skin ulcers	0 = yes 1 = no
10. How many full meals does the patient eat daily?	0 = 1 meal 1 = 2 meals 2 = 3 meals
11. Selected consumption markers for protein intake ❖ At least one serving of dairy products (milk, cheese, yoghurt) per day ❖ Two or more servings of legumes or eggs per week ❖ Meat, fish or poultry every day 0.0 = if 0 or 1 yes 0.5 = if 2 yes 1.0 = if 3 yes	Yes..... No..... Yes..... No..... Yes..... No..... .....
12. Consume two or more servings of fruit or vegetables per day?	0 = no 1 = yes

Dr. Md. Ashrafuzzaman Zahid
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

13. How much fluid (water, juice, coffee, tea, milk...) is consumed per day?	0.0 = less than 3 cups 0.5 = 3 to 5 cups 1.0 = more than 5 cups
14.Mode of feeding	0 = unable to eat without assistance 1 = self-fed with some difficulty 2 = self-fed without any problem
15. In comparison with other people of the same age, how does the patient consider his / her health status?	0.0 = not as good 0.5 = does not know 1.0 = as good 2.0 = better
16. Self-view of nutritional status	0 = views self as being malnourished 1 = is uncertain of nutritional state 2 = views self as having no nutritional problem
17. Self-view of nutritional status	0 = views self as being malnourished 1 = is uncertain of nutritional state 2 = views self as having no nutritional problem
18. In comparison with other people of the same age, how does the patient consider his / her health status?	0.0 = not as good 0.5 = does not know 1.0 = as good 2.0 = better
19. Mid-arm circumference (MAC) in cm	0.0 = MAC less than 21 0.5 = MAC 21 to 22 1.0 = MAC greater than 22
20. Calf circumference (CC) in cm	0 = CC less than 31

Dr. Md. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

	1 = CC 31 or greater
Total	

Assessment (max. 16 points): .....

Screening score: .....

Total Assessment (max. 30 points): .....

Malnutrition Indicator Score: Put tick marks on the box

24 to 30 points □ Normal nutritional status

17 to 23.5 points □ At risk of malnutrition

Less than 17 points □ Malnourished

Oswestry Low Back Pain Disability Questionnaire

This questionnaire has been designed to give us information as to how your back pain has affected the patient's ability to manage in everyday life. Please answer every section and mark in each section only the one box that applies to patients.

(If two or more statements in any one section seem related to patients, please just mark the box that most closely describes the patient's problem)

1. **Pain Intensity**
   0= I can tolerate the pain I have without having to use pain killers.
   1= The pain is bad but I manage without taking pain killers.
   2= Medicine gives complete relief from pain.
   3= Medicine gives moderate relief from pain.
   4= Medicine gives very little relief from pain.
   5= Medicine has no effect on the pain and I do not use them.

2. **Personal Care**
   0= I can look after myself normally without causing extra pain.
   1= I can look after myself normally but it causes extra pain.
   2= It is painful to look after myself and I am slow and careful.
   3= I need some help but manage most of my personal care.
   4= I need help every day in most aspects of self-care.

DR. MD. ASHRAFUZZAMAN KHAN
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

5= I do not get dressed, wash with difficulty and stay in bed.

3. **Lifting**

0= I can lift heavy weights without extra pain.

1= I can lift heavy weights but it gives extra pain.

2= Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned for example on a table.

3= Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.

4= I can lift only very light weights.

5= I cannot lift or carry anything at all.

4. **Walking**

0= Pain does not prevent me walking any distance

1= Pain prevents me walking more than 1 mile

2= Pain prevents me walking more than 0.5 miles

3= Pain prevents me walking more than 0.25 miles

4= I can only walk using a stick or crutches

5= I am in bed most of the time and have to crawl to the toilet.

5. **Sitting**

0= I can sit in any chair as long as I like

1= I can only sit in my favorite chair as long as I like

2= Pain prevents me sitting more than 1 hour

3= Pain prevents me from sitting more than 0.5 hours

4= Pain prevents me from sitting more than 10 minutes

5=Pain prevents me from sitting at all

6. **Standing**

0= I can stand as long as I want without extra pain.

1= I can stand as long as I want but it gives me extra pain.

2= Pain prevents me from standing for more than 1 hour

3= Pain prevents me from standing for more than 30 minutes

4= Pain prevents me from standing for more than 10 minutes

DR. MD. ASHRAFUZZAMAN KHAN
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

5=Pain prevents me from standing at all

7. Sleeping

0= Pain does not prevent me from sleeping well.

1= I can sleep well only by using tablets.

2= Even when I take tablets I have less than 6 hours sleep.

3= Even when I take tablets I have less than 4 hours sleep.

4= Even when I take tablets I have less than 2 hours of sleep.

5= Pain prevents me from sleeping at all.

8. Sex Life

0= My sex life is normal and causes no extra pain.

1= My sex life is normal but causes some extra pain.

2= My sex life is nearly normal but is very painful.

3= My sex life is severely restricted by pain.

4= My sex life is nearly absent because of pain.

5= Pain prevents any sex life at all.

9. Social Life

0= My social life is normal and gives me no extra pain.

1= My social life is normal but increases the degree of pain.

2= Pain has no significant effect on my social life apart from limiting energetic interests such as dancing.

3= Pain has restricted my social life and I do not go out as often.

4= Pain has restricted my social life to my home.

5= I have no social life because of pain.

10. Travelling

0= I can travel anywhere without extra pain.

1= I can travel anywhere but it gives me extra pain.

2= Pain is bad but I manage journeys over 2 hours.

3= Pain restricts me to journeys of less than 1 hour.

4= Pain restricts me to short necessary journeys under 30 minutes.

5= Pain prevents me from travelling except to the doctor or hospital.

Dr. Md. Ashrafuzzaman Zahid
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408.

Total:

STarT back screening tool

To measure the prognosis of LBP this tool will be used. This will categorize the patient's problem as low (score 0-3), medium (score 4-9), high (if the score of the last 5 questions found 4 or 5).

Thinking about the last 2 weeks tick your response to the following questions:

Questions	Response	Score
1. My back pain has spread down my leg(s) at some time in the last 2 weeks.	• Disagree • Agree	0 1
2. I have had pain in the shoulder or neck at some time in the last 2 weeks.	• Disagree • Agree	0 1
3. I have only walked short distances because of my back pain.	• Disagree • Agree	0 1
4. In the last 2 weeks, I have dressed more slowly than usual because of back pain.	• Disagree • Agree	0 1
5. It's not really safe for a person with a condition like mine to be physically active.	• Disagree • Agree	0 1
6. Worrying thoughts have been going through my mind a lot of the time.	• Disagree • Agree	0 1
7. I feel that my back pain is terrible and it's never going to get any better.	• Disagree • Agree	0 1
8. In general I have not enjoyed all the things I used to enjoy.	• Disagree • Agree	0 1

Dr. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

9. Overall, how bothersome has your back pain been in the last 2 weeks?	• Not at all • Slightly • Moderately • Very much • Extremely	0 0 0 1 1

Total score (Q.1-Q.9) .....

Sub score (Q.5-Q.9) .....

Section-6: Psychological status

Fear Avoidance Beliefs questionnaire (FABQ) is used to measure psychological status. Scale consists of two parts. One part is related to physical activity and another part is related to work.

Physical Activity (PA) related:

Here are some of the things other patients have told us about their pain. For each statement, please mark the number from 0-6 to indicate how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

	Completely disagree			**Unsure**			**Completely agree**
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6

Dr. Md. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

Total Score: .....

Work related:

The following statements are about how your normal work affects or would affect your back. Please mark the exact point.

	Completely disagree			Unsure			Completely agree
6.My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
7.My work aggravated my pain.	0	1	2	3	4	5	6
8.I have a claim for compensation for my pain.	0	1	2	3	4	5	6
9.My work is too heavy for me.	0	1	2	3	4	5	6
10.My work makes or would make my pain worse	0	1	2	3	4	5	6
11.My work might harm my back	0	1	2	3	4	5	6
12.I should not do my regular work with my present pain	0	1	2	3	4	5	6
13.I cannot do my normal work with	0	1	2	3	4	5	6

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408

my present pain							
14. I cannot do my normal work till my pain is treated	0	1	2	3	4	5	6
15.I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6
16.I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6

Total Score: .....

DR. MD. ASHRAFUZZAMAN ZAHID
Associate Professor
Department of Nutrition and Food Technology
Jashore University of Science and Technology
Jashore-7408