Original Article

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Efficacy of a Health Education and Self-Awareness Booklet with Specific Therapeutic Exercises versus Vitamin D3 Supplementation for Managing Chronic Low Back Pain: An Assessor-Blinded, Multicentre Randomised Clinical Trial

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Abstract:

Objective: Maintaining optimal vitamin D3 levels may play a key role in managing chronic low back pain (CLBP) and enhancing functional outcomes. This study aimed to compare the effects of health education and self-awareness booklets versus vitamin D3 supplementation combined with therapeutic exercises on pain intensity, vitamin D levels, and functional disability in individuals with CLBP.

Material and Methods: This randomized clinical trial was conducted at two physiotherapy rehabilitation centers in Dhaka, Bangladesh, involving 84 participants with chronic low back pain (CLBP), randomly allocated into two equal groups.

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Group A received specific therapeutic exercises and a health education/self-awareness booklet, while Group B received vitamin D3 supplementation alongside the same exercises over a three-month period. Primary outcomes included pain intensity (assessed via the Brief Pain Inventory) and serum vitamin D3 levels. Functional disability, measured using the Roland-Morris Disability Questionnaire (RMDQ), served as the secondary outcome. Assessments were conducted at baseline and post-intervention, with a per-protocol analysis applied.

Results: Both groups demonstrated significant improvements in pain intensity and functional disability following the intervention (p-value<0.001). However, Group B showed significantly greater reductions in disability scores (p-value<0.001), which corresponded with a marked increase in serum vitamin D3 levels (p-value<0.001).

Conclusion: Both interventions were effective in reducing pain and disability in individuals with CLBP. However, the addition of vitamin D3 supplementation led to significantly greater improvements, highlighting its potential role in enhancing the efficacy of conservative CLBP management.

Keywords: chronic low back pain, health education booklet, therapeutic exercise, vitamin D3 supplementation

Introduction

Vitamin D3 is essential for maintaining musculoskeletal health, particularly in supporting bone integrity and skeletal muscle function in the lower back region[1]. It is predominantly synthesized through sunlight exposure, with its active form, 1,25-dihydroxyvitamin D3 (calcitriol), exerting effects via vitamin D3 receptors (VDRs) in various tissues[2]. These receptors influence cell growth, differentiation, and neuromuscular function. Deficiency in vitamin D3 can impair muscle performance and contribute to chronic pain through mechanisms such as oxidative stress, mitochondrial dysfunction, and central neuronal hypersensitivity[3].

Vitamin D deficiency—commonly defined as serum 25-hydroxyvitamin D3 levels below 20 ng/mL (50 nmol/L)—is a widespread public health concern, even in sun-rich countries[4]. Prevalence estimates range from 37–42% in temperate zones (e.g., the US and Europe) to 22–33% in tropical regions like Thailand and Singapore[5]. Contributing factors include limited sun exposure, inadequate dietary intake, obesity, darker skin pigmentation, and comorbid conditions such as diabetes mellitus[6].

Chronic low back pain (CLBP) is a highly prevalent condition with multifactorial origins and complex management needs. Current best practices recommend a multidisciplinary approach combining physical, educational, and, when appropriate, biochemical interventions[7]. Therapeutic exercises are central to CLBP management, addressing core strength, flexibility, and neuromotor control. Exercises such as planks, bridges, and stretches reduce mechanical strain, improve movement patterns, and help alleviate pain and prevent recurrence[8].

Complementing physical interventions, health education and self-awareness booklets provide patients with essential knowledge and tools to actively manage their condition[9]. These materials dispel misconceptions about low back pain, encouraging patients to adopt beneficial behaviours such as staying active and avoiding prolonged bed rest[10]. By fostering self-management and coping strategies, health education empowers individuals to take control of their recovery, leading to improved outcomes and reduced reliance on healthcare services[11]. Vitamin D supplementation offers another critical component, addressing biochemical

deficits that exacerbate musculoskeletal dysfunction and chronic pain[12]. Vitamin D deficiency, a widespread issue even in sun-rich regions, contributes to oxidative stress, mitochondrial dysfunction, and central neuronal hypersensitivity, all of which can worsen pain and hinder physical rehabilitation[13]. By optimizing vitamin D levels, supplementation enhances muscle function and reduces the neurological factors associated with chronic pain, creating a supportive biochemical environment for recovery[12].

CLBP remains a significant public health challenge, with limited evidence comparing multidisciplinary interventions targeting both educational and biochemical factors. While therapeutic exercises are widely recognized for their efficacy, the combined impact of health education and vitamin D3 supplementation on pain intensity, functional disability, and biochemical outcomes is not well understood. This study hypothesizes that in conjunction with therapeutic exercises, health education and self-awareness booklets will show comparable or superior effects on managing CLBP compared to vitamin D3 supplementation with exercises. The primary aim of this study was to evaluate the effectiveness of these interventions in improving pain intensity, serum vitamin D3 levels, and functional disability.

Material and Methods

Study design and settings

This randomised clinical trial employed an assessor-blinded, multi-centre, two-arm parallel research design from January 2023 to April 2023 in the Centre for the Rehabilitation of the Paralysed (CRP) and the Saic College of Medical Science and Technology (SCMST), Dhaka, Bangladesh. The Centre for the Rehabilitation of the Paralysed (CRP) is a not-for-profit organization offering comprehensive rehabilitation services, including physiotherapy, occupational therapy, and vocational training. It specializes in spinal cord injury management but is also renowned for its quality services for chronic low back pain patients and serves a large patient population, with approximately 129,471 patients treated annually. In contrast, the Saic College of Medical Science and Technology (SCMST) is a private, for-profit institution focusing on medical education and clinical training in physiotherapy, occupational therapy, and diagnostic sciences. While SCMST primarily functions as an academic centre, it provides healthcare services through affiliated hospitals and clinics, contributing to the clinical skill development of healthcare professionals in Bangladesh[14,15].

Participant recruitment and diagnosis of CLBP

Individuals with CLBP were recruited for this study between January and April 2023 from the Outpatient Service Unit, Department of Physiotherapy, CRP, and SCMST in Dhaka, Bangladesh. Eligible participants had experienced CLBP for over 3 months, classified as central pain according to ICD-10-CM Code M54.5 criteria[13], were 18 years or older, residing in or near Dhaka city, and employed in office, industrial, or corporate settings involving static postures or desk jobs requiring at least 6 hours of sitting daily[9]. Exclusion criteria encompassed the presence of comorbidities, such as rheumatoid arthritis, ankylosing spondylitis, osteomalacia, or spinal tuberculosis, as well as any history of osteoporotic fractures[12]; post-menopausal women or females over the age of 50 were excluded, along with individuals reporting recent intake of calcium or vitamin D3 supplements, regular engagement in resistance training, or high-impact weight-bearing activities within the past 6 months; additionally, patients presenting dural signs, a positive straight-leg raise test, or bowel and bladder incontinence were not included in the study.

In this study, CLBP was diagnosed based on pain persisting for more than 3 months, following a systematic clinical protocol. This included a detailed patient history assessing pain duration, intensity, location, associated symptoms (e.g., numbness or radiculopathy), and psychosocial factors such as stress or depression.

A physical examination was conducted to evaluate musculoskeletal and neurological involvement, including tests such as the straight leg raise[16,17]. Diagnostic imaging (e.g., X-ray or MRI) was used selectively in cases presenting with red flags or when symptoms persisted despite initial conservative management, in line with the American College of Physicians' guidelines recommending clinical evaluation over routine imaging[18,19].

Randomization and blinding

Eligible participants were referred to the musculoskeletal units of the Department of Physiotherapy, CRP, and SCMST for further screening with a concealed random allocation after the screening process. Before commencing the intervention, there was a separate cubicle for the blinded assessors to complete the informed consent and baseline assessment of both Group A and B participants. After the end of the treatment protocol, each participant re-entered the same room for outcome evaluation. A computerised random allocation technique using Microsoft Excel 2013 was used to assign the participants to the groups.

Sample size calculation

The sample size was calculated using statistical power analysis, facilitated by the PASS 2005 software (NCSS, Kaysville, UT, USA). To detect a statistically significant difference with a power of 90% and a two-sided alpha level of 0.05, a minimum of 38 participants per group was needed. To account for a potential 20% dropout rate, the sample size was increased to 42 participants per group (total n=84), preserving the study's intended statistical power. The power calculation was based on expected changes in the primary outcome measure and pain intensity, as observed in prior studies of chronic musculoskeletal conditions[20,21].

Intervention

Group A interventions

Group A participants received a study-specific therapeutic exercise program set by the trial investigators with a health education and self-awareness booklet.

- **Health education and self-awareness booklet:** A booklet consisting of different health education and self-awareness tips like avoiding long-term static sitting and standing; taking naturally vitamin D3-containing foods like milk, cereal, orange juice, yogurt, mushrooms, margarine, hard-boiled eggs, sea fish like tuna, salmon, etc.; 60 minutes of sun exposure from 11 am to 2 pm daily, 7–8 hours of sleep per night, avoid stress, avoid, smoking, and maintain a healthy body weight[22].

- **Specific therapeutic exercise program:** The specific therapeutic exercise protocol consists of the McKenzie's Mechanical Diagnosis and Therapy (MDT) Method, including directional preference, sustained positioning, flexion, or the extension principle (most often need extension principle) with a set of 10 repetitions[23]; stretching exercises of the erector spine muscle, hamstring, and triceps surae; lumbar stabilization exercises; weight-bearing aerobics exercise includes jogging, jogging with stair climbing, and 30 minutes of brisk walking and heating modalities (i.e., Infra Red Radiation)[24].

Group B interventions

Group B participants also received the same specific therapeutic exercise program intended for Group A, but also with 40,000 IU vitamin D3 supplement capsules[25] prescribed by a registered physician, to be taken once a week for 8 weeks.

Both groups followed a structured therapeutic exercise protocol, with each session lasting up to 45 minutes, conducted 3 times per week over a period of 8 weeks.

Outcome Measurements

Brief Pain Inventory (BPI)

The Brief Pain Inventory (BPI) is a fifteen-item tool designed to assess pain severity and its impact on daily functioning. It evaluates how pain interferes with relationships, emotional well-being, quality of life, and physical activities such as sleep, general activity, and walking. The inventory also includes pain diagrams and queries about medication use, including analgesics. Higher scores indicate greater pain severity and interference[16,26]. The BPI demonstrates excellent internal consistency (Cronbach's alpha=0.91), strong interrater reliability (ICC=0.84–0.90), and robust test-retest reliability with kappa values exceeding 0.70[17,27].

Measurement of vitamin D levels

Following the pre-treatment assessment, blood samples were obtained from all participants at the clinic's laboratory. Serum levels of 25-hydroxyvitamin D2 and D3 were analysed using the Elecsys Vitamin D Total II assay (Roche Diagnostics)[28], a method closely correlated with the reference standard of liquid chromatography–tandem mass spectrometry. Vitamin D levels were subsequently classified into 3 categories: inadequate (<20 ng/mL), insufficient (20–29.9 ng/mL), and sufficient (>30 ng/mL)[29,30].

Ronald Morris Disability Questionnaire (RMDQ)

The Roland-Morris Questionnaire (RMQ) is a 24-item, patient-reported tool designed to assess pain-related functional impairment caused by lower back pain (LBP)[31]. Each item is scored as 0 if left blank or 1 if selected, resulting in a total score ranging from 0 to 24, where higher scores indicate greater impairment. The questionnaire demonstrates absolute reliability (SEM: 1.7–2.0 points) and strong test-retest reliability, with intra-class correlation coefficients ranging from 0.79 to 0.88[32].

Data analysis

Statistical analyses were conducted using IBM SPSS Version 25. Data normality was assessed via the Kolmogorov-Smirnov test, which indicated non-normal distribution (p-value<0.05). Accordingly, descriptive statistics were reported as medians and interquartile ranges (IQR) for sociodemographic variables. Parametric tests were applied to interval or ratio data, while non-parametric tests were used for nominal or ordinal data. Baseline differences in continuous variables between groups were analyzed using the Mann-Whitney U test. Categorical and ordinal variables were assessed using Fisher's exact test and Pearson's Chi-square test, respectively. Between-group comparisons of pain intensity, serum vitamin D3 levels, and functional disability were performed using the Mann-Whitney U test, while within-group changes were evaluated using the Wilcoxon signed-rank test. Statistical significance was set at p-value<0.05.

Ethical issues and informed consent

The study received approval from the CRP Ethical Review Committee (ERC) of the Centre for the Rehabilitation of the Paralysed (CRP), Savar, Dhaka-1343 (CRP-R&E-0401-0412), and the Saic College of Medical Science and Technology (SCMST), Mirpur-14, Dhaka-1216 (SCMST/IRB/25-11/12-002), Bangladesh. Written informed consent was obtained from all participants and their legal guardians. All procedures adhered to the relevant guidelines and regulations, including the principles outlined in the Declaration of Helsinki.

Results

A total of 101 individuals with chronic low back pain (CLBP) were screened, with 17 excluded due to not meeting the inclusion criteria or unwillingness to participate. Consequently, 84 eligible patients were enrolled in the trial, with no dropouts during the intervention. The Consolidated Standards of Reporting Trials (CONSORT) was followed to conduct this study and is supplied as Figure 1.

Demographic and clinical characteristics

The demographics and clinical characteristics of the participants are summarized in Table 1. The average age was 37.50 years (IQR: 27 to 55). Of the total participants, 23 (27.4%) were female, while 61 (72.6%) were male. Nearly half (n=40; 47.6%) resided in rural areas, with 42 (50.0%) having secondary or higher education. A substantial proportion (41; 48.8%) had no formal employment. Regarding clinical parameters, only 7 (8.3%) engaged in daily exercise, while 17 (20.2%) had at least 2 hours of sun exposure daily. A minimal number (n=6; 7.1%) reported a habit of daily milk consumption. These characteristics did not show any statistically significant differences between the groups (p-value>0.05).

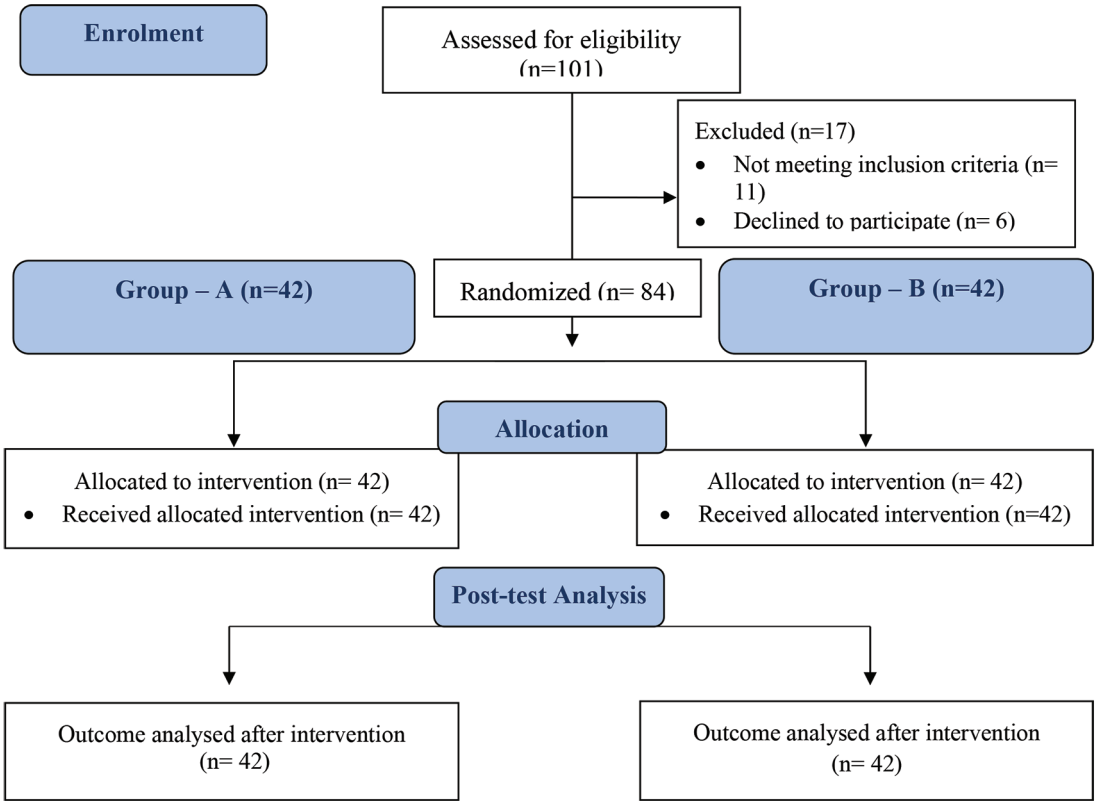

Figure 1 Consolidated standards of reporting trials (CONSORT) of the study

Table 1 Demographic and clinical characteristics of the participants

Variables	Group A (n=42)	Group B (n=42)	p-value
Demographic characteristics			
Age in years [median (IQR)][a]	43 (29.50 to 55)	38 (25 to 56.25)	0.91*
Sex [% (n)][b]			
Male	73.8 (31)	71.4 (30)	0.33
Female	26.2 (11)	28.6 (12)	
Education [% (n)][c]			
Primary education	40.5 (17)	26.2 (11)	0.41
Completed SSC & HSC	42.9 (18)	57.1 (24)	
Bachelor and above degree	16.7 (7)	16.7 (7)	
Living area [% (n)][c]			
Urban	31.0 (13)	28.6 (12)	0.09
Rural	50.0 (21)	45.2 (19)	
Semi-urban	19.0 (8)	26.2 (11)	
Occupation [% (n)][c]			
No formal job/Unemployed	59.5 (25)	38.1 (16)	0.72
Student	14.3 (6)	40.5 (17)	
Service holder	26.2 (11)	21.4 (9)	
Clinical characteristics			
Exercise habit [% (n)][b]			
Yes	7.1 (3)	9.5 (4)	0.51
No	92.9 (39)	90.5 (38)	
Sun exposure [% (n)][b]			
Less than 2 hours/daily	19.0 (8)	21.4 (9)	0.56
More than 2 hours/daily	81.0 (34)	78.6 (33)	
Milk consumption [% (n)][b]			
Yes	11.9 (5)	2.4 (1)	0.75
No	88.1 (37)	97.6 (41)	
Chronic illness [% (n)][c]			
Diabetic Mellitus	40.5 (17)	26.2 (11)	0.46
Hypertension	42.9 (18)	57.1 (24)	
Heart disease	16.7 (7)	16.7 (7)	
Body mass index [median (IQR)][a]	23.9 (20.6 to 26.7)	24.4 (19.9 to 27.2)	0.64
Brief Pain Inventory (BPI) [median (IQR)][a]			
Pain severity score	5.3 (4.8 to 5.5)	5.3 (4.8 to 5.8)	0.84
Affective score	5.4 (4.6 to 6)	5.4 (4.3 to 6)	0.76
Activity score	5.7 (4.7 to 6)	5.2 (5 to 5.7)	0.31
Vitamin D3 Level (ng/mL) [median (IQR)][a]	17.4 (15.8 to 19.4)	17.0 (15.8 to 19.2)	0.67
Ronald Morris Disability Questionnaire (RMDQ) [median (IQR)][a]	8 (5 to 12)	8.5 (5.8 to 12.3)	0.95

*baseline compatible, [a]Mann-Whitney U test, [b]Fisher exact test, [c]Pearson Chi-square test, IQR=inter quartile range, SSC=secondary school certificate, HSC=higher secondary certificate

Brief Pain Inventory

Table 2 compares pain and activity outcomes for two groups (A and B) before and after treatment, measuring Pain Severity, Affective, and Activity Scores. Each group's baseline and post-treatment median scores (with IQR) are presented, alongside within-group (p-value=0.01) and between-group (p-value=0.01) change scores. Both groups showed significant improvements (p-value<0.01) post-treatment, but Group B consistently achieved lower median scores, indicating a greater treatment efficacy, with statistically significant differences favoring Group B across all measures (p-value<0.01).

Vitamin D3 level measurement

Figure 2 compares vitamin D3 levels (in ng/mL) for Group A (blue) and Group B (purple) at baseline and after the intervention. At baseline, Group A had a level of 17.4 ng/mL, and Group B was slightly lower at 17 ng/mL. After the intervention, Group A's level increased to 31.5 ng/mL, while Group B's level increased more significantly to 39.1 ng/mL. The chart visually highlights that both groups experienced an increase in vitamin D3 levels post-intervention, with Group B showing a significantly greater improvement (p-value<0.01).

Ronald Morris Disability Questionnaire (RMDQ)

Table 3 compares outcomes on the Ronald Morris Disability Questionnaire (RMDQ) for two groups (A and B) before and after treatment. At baseline, both groups had similar medians (Group A: 8, Group B: 8.5). Post-treatment, Group A's median dropped to 4.5 and Group B's to 3, with significant within-group improvements (p-value=0.03 for Group A, p-value=0.01 for Group B). The between-group change was significant (p-value<0.01), indicating that Group B showed a greater reduction in disability scores.

Discussion

This study compared two multidisciplinary interventions for CLBP: therapeutic exercises combined with either health education (Group A) or vitamin D3 supplementation (Group B). Both groups showed significant improvements in pain intensity, serum vitamin D levels, and functional disability. However, Group B exhibited greater reductions in pain severity, affective and activity interference, and disability scores, alongside a more substantial increase in serum vitamin D3 (39.1 ng/mL).

Table 2 Baseline and after-treatment status of pain by Brief Pain Inventory Domains

Outcome group	Baseline	After treatment	Within group change scores		Between group change scores	
	Median (IQR)	Median (IQR)	Z	p	Z	p
Pain severity score						
Group A	5.3 (4.8 to 5.5)	4.2 (3.3 to 5.2)	5.544	0.001*	6.052	0.0001*
Group B	5.3 (4.8 to 5.8)	2.5 (1.4 to 3.7)	5.047	0.001*		
Pain affective score						
Group A	5.4 (4.6 to 6)	4.9 (3.3 to 5.9)	5.489	0.001*	6.518	0.0001*
Group B	5.4 (4.3 to 6)	3.4 (2.4 to 4.3)	5.358	0.001*		
Activity score						
Group A	5.7 (4.7 to 6)	4.5 (3.1 to 5.7)	5.542	0.001*	4.990	0.0001*
Group B	5.2 (5 to 6.7)	2.1 (2.1 to 4.9)	5.256	0.001*		

*significant at 95% confidence level, within-group analysis: wilcoxon rank test, between-group analysis: Mann-Whitney U test, IQR=inter quartile range

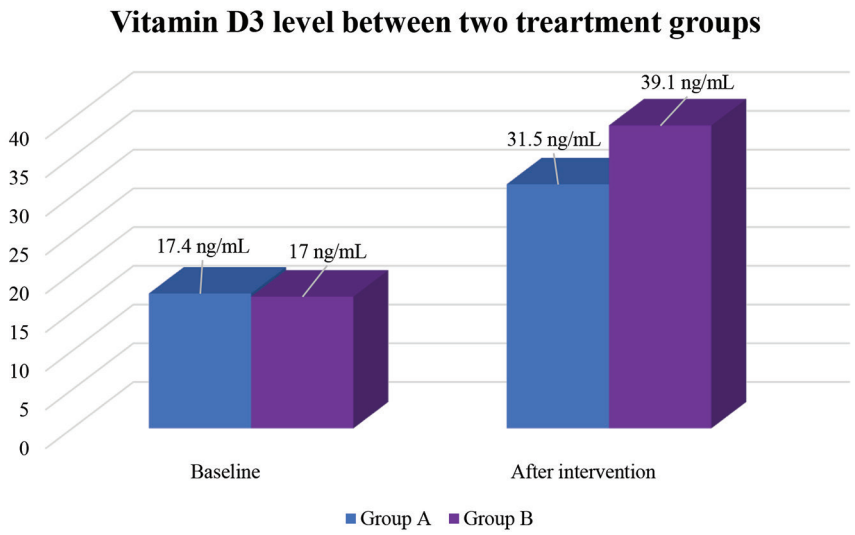

Figure 2 Differences in vitamin D3 levels across both groups

Table 3 Baseline and after-treatment status of back pain induced disability by Ronald Morris Disability Questionnaire (RMDQ)

Outcome group	Baseline	After treatment	Within group change scores		Between group change scores	
	Median (IQR)	Median (IQR)	Z	p	Z	p
Ronald Morris Disability Questionnaire (RMDQ)						
Group A	8 (5 to 12)	4.5 (3.8 to 7)	2.820	0.03*	7.648	0.01*
Group B	8.5 (5.8 to 12.3)	3 (2 to 4)	5.519	0.01*		

*significant at 95% confidence level, within-group analysis: wilcoxon rank test, between-group analysis: Mann-Whitney U test, IQR=inter quartile range

This study found that both intervention groups, therapeutic exercises combined with health education (Group A) and with vitamin D3 supplementation (Group B), achieved statistically significant reductions in pain severity, affective interference, and activity limitation scores. Notably, Group B consistently demonstrated greater improvements, with lower post-treatment median pain scores and significant between-group differences favoring vitamin D3 supplementation (p-value<0.01). These results align with findings from a 2016 meta-analysis by Wu et al.[33], which reported a modest but statistically significant reduction in pain scores among individuals receiving vitamin D3 supplementation compared to placebo (mean difference −0.57, 95% CI: −1.00 to −0.15, p-value=0.01), suggesting that correcting vitamin D3 deficiency may enhance pain relief in chronic musculoskeletal conditions.

The increase in vitamin D3 levels in this study contrasts with some existing literature. Ghai et al.[34] found no significant association between vitamin D deficiency and chronic pain in certain cohorts, suggesting that the observed benefits might be intervention-specific or population-dependent. The post-intervention levels exceeding the 30 ng/mL threshold recommended for optimal musculoskeletal health by Hernigou et al.[35] align with the systematic review and meta-analysis by de Souza et al.[36], which demonstrated improved functional outcomes with vitamin D supplementation in elderly populations. The differential response between Group A and Group B could indicate that the intervention's efficacy is amplified by achieving or surpassing this threshold, particularly in Group B, where the 39.1 ng/mL level suggests a robust metabolic or therapeutic response.

Comparatively, the RMDQ reductions observed align with prior research validating its sensitivity to change in chronic low back pain populations. Sung and Wu[37] established a minimal detectable change of 2.5-5 points, which is consistent with the drops from 8 to 4.5 in Group A and 8.5 to 3 in Group B, indicating clinically meaningful improvements. The greater reduction in Group B's scores suggests a stronger therapeutic effect, potentially tied to the higher vitamin D3 levels, a hypothesis supported by Alonso-Pérez et al.[12], who reported a correlation between elevated vitamin D status and reduced musculoskeletal pain.

Conclusion

This study shows significant improvements in pain and disability across both groups, with greater reductions in the group achieving higher vitamin D levels. The results underscore the treatment's effectiveness and suggest that optimizing vitamin D may enhance therapeutic outcomes. These findings align with existing evidence supporting vitamin D's role in pain management. Future research should employ randomized, standardized trials with broader metrics to validate and generalize these results.

Trial registration

Clinical Trials Registry India (CTRI/2022/11/047074).

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Conflict of interest

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