EFFECTIVENESS OF MANUAL THERAPY COMBINED WITH INCLINED BOARD STANDING ON QUALITY OF LIFE IN PATIENTS WITH NON-SPECIFIC MECHANICAL LOW BACK PAIN –A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

To determine the effectiveness of manual therapy combined with inclined board standing on quality of life in patients with non-specific mechanical low back pain. Single-center, parallel group, observer-blind randomized controlled trial. Outcomes were assessed at baseline, 2 weeks post-intervention, and after a 2-month follow-up. Treatment Group 1 received manual therapy combined with inclined board standing. Treatment Group 2 engaged in inclined board standing alone. Primary outcomes were measured using the Numeric Pain Rating Scale (NPRS) for pain intensity and the SF-12 Physical Component Summary (PCS) for quality of life.

The study included equal groups with a majority of female participants (68.2%) and those aged 18-29 years. ANOVA results of treatment groups showed significant improvements in PCS scores across stages with the combined therapy group demonstrating greater enhancements. The trial demonstrated that manual therapy combined with inclined board standing is more effective for reducing pain and improving quality of life.

Trial Registration: ClinicalTrials.gov NCT05780593 (registered 13th March 2023)

What is already known on this topic: Low back pain (LBP) is a common condition with significant health and economic impacts, traditionally managed with physical therapy, medications, and surgery. However, these treatments often have limited long-term effectiveness.

What this study adds: Despite the widespread use of therapeutic exercises for low back pain (LBP), no previous study has evaluated the efficacy of inclined board standing (IBS). This study fills this gap, providing strong evidence that IBS significantly improves pain,

functional capacity, and quality of life in LBP patients, and is a valuable addition to rehabilitation programs, enhancing physical function and reducing disability more effectively than manual therapy alone.

How this study might affect research, practice or policy: This study provides compelling evidence for the inclusion of inclined board standing (IBS) in rehabilitation protocols for low back pain (LBP). By demonstrating the significant benefits of IBS, this research encourages further studies to explore its long-term effects and optimal implementation. Incorporating IBS into treatment plans to enhance patient outcome by clinicians in clinical settings. Additionally, policy makers could use these findings to update clinical guidelines, promoting evidence-based practices that improve functional capacity and reduce disability in LBP patients.

INTRODUCTION

Individuals of all ages and backgrounds experience low back pain (LBP), a common musculoskeletal condition with significant socioeconomic implications worldwide (1). Its care is complicated and difficult because to its complex etiology, which frequently incorporates biomechanical, psychological, and lifestyle aspects (2). Of all the treatment approaches, manual therapy and exercise interventions have received significant interest due to their potential effectiveness in reducing the symptoms of low back pain (LBP) and enhancing the quality of life (QOL) of patients (3, 4). Low back pain was of two types such as mechanical (non-specific) and non mechanical (specific) (5). Back pain originating from the spine, intervertebral disks, or surrounding soft tissues is referred to as mechanical low back pain due to alter mechanics of the body. This encompasses spinal compression fractures, lumbar spondylosis, spondylolisthesis, spondylolysis, disk herniation, and acute or chronic traumatic injury (6). Chronic mechanical low back pain is frequently a result of overuse or repetitive damage, and it frequently develops as a secondary injury at work (7, 8). Globally, there were 568.4 million cases of low back pain in 2019, and the age-standardized point prevalence estimate was 6972.5 cases per 100,000 people. From 1990 to 2019, there was a little decline of -0.164% in this value (9). A variety of manual therapy procedures, including mobilization, soft tissue mobilization, and spinal manipulation (10), are used with the goal of improving musculoskeletal function and reducing pain (5). Numerous studies have demonstrated its effectiveness in addressing LBP, with data indicating to improvements in pain, disability, and quality of life (5, 6). In addition to manual therapy, exercise-based therapies have become essential treatments for lower back pain (LBP). These interventions emphasize postural training, strengthening, and flexibility to improve functional capacity and reduce pain-related limitation (1, 11). In order to support conventional manual therapy and exercise programs for the management of low back pain, there has been an increasing amount of interest in investigating new strategies in recent years (12). An example of one such method is inclined board standing, which is standing on an inclined board that has been carefully created to provide regulated spinal alignment and calf stretch (9). Suggested advantages of inclined board standing include decompressing spinal structures, enhancing circulation, and enabling neuromuscular re-education (13).

Although inclined board standing and manual therapy are considered effective therapies for the management of lower back pain, there is an absence of comparison studies to determine how successful each is in enhancing quality of life. Comprehending the relative effectiveness of various therapies is essential for improving patient care pathways and guiding evidence-based treatment decisions. Therefore, the purpose of this study is to conduct a thorough comparative analysis in order to determine the impact of manual therapy and inclined board standing therapies on the improvement of QOL in patients with LBP. Incline board standing is innovative treatment in the growing field of therapies for the management of the low back pain.

METHODOLOGY

Sample Size: A total of 44 participants suffering from low back pain were recruited for this study at Physical Department of Agile Institute of Rehabilitation Sciences Bahawalpur after the approval from the IRC letter from the Agile Institute of Rehabilitation Sciences, Bahawalpur with the reference No: AIRS/IRC/PT-01

Study Design: A randomized controlled trial design with parallel group allocation was used in this study. Using computer-generated randomization, participants who met the inclusion criteria were randomized at random to either Treatment Group A or Treatment Group B.

Inclusion Criteria

1. Individuals aged 18 to 65 years.
2. Diagnosed with chronic mechanical lower back pain lasting for at least 3 months and NPRS grading was >3.
3. Willingness to follow the intervention procedure and take part in the study for 3 months

Exclusion Criteria

1. Presence of specific spinal morbidities such as vertebral fracture, spinal tumor, infection, or inflammatory disorder such as osteomylitis, pot's disease etc.
2. Spinal surgery within the previous 6 months.
3. Past medical history of major neurological disorders or other systemic illnesses that impact the musculoskeletal system.
4. Pregnancy or intending to get pregnancy during the study period.
5. Concurrent enrollment in clinical trials or other rehabilitation programs for the treatment of low back pain.

Independent Variables

1. Manual Therapy Intervention
2. Passive Stretching of Hip Abductors
3. Inclined Board Standing

Dependent Variables

1. Quality of Life (QOL) improvement measured by physical component summary of SF-12 Questionnaire
2. Pain intensity (mild, moderate and severe) measured by numeric pain rating scale

Data Collection Procedure: Baseline data was carried out to gather the participant's demographics and baseline measures of pain intensity and quality of life. Over the course of two weeks, individuals received the allocated treatments after completing their baseline evaluations. Using the NPRS (pain intensity such as mild, moderate and severe) and SF-12 (physical component summary measure the patient's Quality of life), post-intervention assessment were carried out as soon as the intervention period ended to measure changes in pain intensity and quality of life.

Treatment Group 1 (n = 22 participants): A licensed physical therapist adopted established methods to give manual therapy intervention and passive stretching of the hip abductors to participants assigned to Treatment Group 1.

Treatment Group 2 (n = 22 participants) Participants allocated to Treatment Group B received inclined board standing exercise supervised by qualified physical therapist for 01 minute / 3 times a day over a period of 2 weeks.

Treatment Group 1 (Manual Therapy Intervention)

Participants receive a session of manual therapy focused on spinal mobilization techniques, which include passive accessory joint movements and gentle oscillatory movements aimed at improving spinal segmental mobility and reduce the pain. Along with the manual therapy passive stretching of the hip abductors muscles, holding for the 20-30 seconds.

2-Month Follow-Up (Treatment Group 1) Participants in Treatment Group A undergo a follow-up session consisting of manual therapy techniques targeting any residual areas of dysfunction or discomfort. Passive stretching exercises for hip lateral rotators are also reviewed and reinforced, with emphasis on participant adherence to the home exercise program.

Treatment Group 2 (Inclined Board Standing Intervention)

Participants in Treatment Group 2 engaged in inclined board standing sessions for 01 minute each, three times per week, for a total of 06 sessions over the 2 weeks intervention period. During each session, participants stand on a specially designed inclined board at a 45 degree of angle in which forefeet are placed on the inclined surface and heels on the ground with a gradually increasing inclination angle. Participants are instructed to maintain a relaxed upright posture while standing on the inclined board for 01 minute.

2-Month Follow-Up (Treatment Group 2) Participants in Treatment Group 2 do not receive any additional interventions during the follow-up period. However, they are encouraged to continue with regular physical activity and exercise as tolerated.

Data Analysis: Descriptive statistics were used to summarize demographic characteristics and baseline measurements. Comparisons between treatment group-A and treatment group-B were analyzed using appropriate inferential statistics such as independent t-tests or Mann-Whitney U tests for continuous variables. Changes in QOL, pain intensity were analyzed using repeated measures analysis of variance (ANOVA). Statistical significance was set at $p < 0.05$. Data analysis was performed using statistical packages of social sciences (SPSS).

RESULTS

The CONSORT 2010 Flow Diagram outlines the progression of participants through a randomized controlled trial. Initially, 50 individuals were assessed for eligibility, with 6 excluded: 3 did not meet inclusion criteria, 2 declined to participate, and 1 was excluded for other reasons. This left 44 participants who were then randomized into two groups of 22 each. Both groups received the allocated intervention, with no participants failing to receive the intervention for any given reasons. During the follow-up phase, no participants were

lost, and none discontinued the intervention in either group. Finally, all 22 participants in each group were analyzed, with no exclusions from the analysis. This diagram ensures clear and transparent reporting of participant flow through the study, adhering to the CONSORT 2010 guidelines as mentioned in figure 1.

4.1: Frequency of the Demographic Variables

The analysis reveals several key insights regarding the distribution of respondents across different categories. In terms of groups, an equal distribution is observed between Group 1 and Group 2, with both comprising 50% of the total sample size as presented in Table 1. Regarding age demographics, the majority of respondents fall within the 18-29 years category, accounting for 27.7% of the sample, followed by 30-41 years (20.5%), 42-53 years (18.2%), and 54-65 years (13.6%). Gender distribution shows a higher representation of females, constituting 68.2% of the sample, while males make up 31.8%. Additionally, the mean age of the respondents is calculated to be 1.96. These findings provide a comprehensive understanding of the demographic composition of the sample, aiding in further analyses and interpretations within the scope of the study.

4.2: Analysis of variation for NPRS during three stages (Pre, post and follow-up) of intervention in two groups (G1 and G2)

The analysis of variance (ANOVA) revealed significant effects for both the variable (pain and the Quality of life) "Stages" ($F = 134.814$, $p < .0001$) and the variable "Groups" ($F = 22.25$, $p < .0001$) on the dependent variable. For "Stages," the F-value of 134.814 with 2 and 129 degrees of freedom indicates a highly significant effect. Similarly, for "Groups," the F-value of 22.25 with 1 and 130 degrees of freedom also indicates a highly significant effect. These results suggest that both "Stages" and "Groups" have a substantial impact on the dependent variable, with p-values well below the conventional significance threshold of .05 as in table number 2.

4.3: Analysis of variation for physical component summary (PCS) during three stages (Pre, post and follow-up) of intervention in two groups (G1 and G2)

First, the effect of the intervention stages was determined to have a mean square (MS) of 3541.151 and a sum of squares (SS) of 7082.303 with two degrees of freedom (df). The exceptionally significant effect of intervention stages on PCS scores is indicated by the F-value of 63.829 ($p <.0001$). Furthermore, the PCS scores' 50% variation may be associated to the stages of the intervention, according to the Eta Squared value of 0.5. With considerable improvements shown from pre- to post-intervention and continued benefits at follow-up, this data implies that the timing of the intervention has a major impact on PCS scores.

Second, with respect to the impact of treatment groups, groups had an MS of 2222.2 and an SS of 2222 with 1 df. The F-value of 24 showed that treatment groups had a highly significant impact on PCS scores ($p <.0001$). With an Eta Squared value of 0.16, treatment groups may be responsible for 16% of the variation in PCS scores. This result implies that the two treatment groups' PCS scores

differ significantly from one another, with one group showing better results than the other as represented in table number 3.

Figure 5.1: The diagram provides a clear representation of participant progress through the trial, from initial assessment and allocation to follow-up and final analysis, ensuring adherence to the CONSORT 2010 guidelines.

Figure 5.2: The figure demonstrates that the intervention had a significant impact on reducing NPRS scores, though there is a slight increase at follow-up

- The left box plot compares two groups: G1 and G2. G1 shows higher NPRS scores with a median around 8 and an interquartile range (IQR) from approximately 6 to 10. G2 shows lower NPRS scores with a median around 4 and an IQR from approximately 3 to 6. The comparison indicates a statistically significant difference with $p \leq 0.001$ as shown in above figure 2.
- The right box plot compares the NPRS scores at three stages: pre-intervention, post-intervention, and follow-up. Pre-intervention scores are the highest with a median around 8 and an IQR from approximately 6 to 10. Post-intervention scores are lower with a median around 4 and an IQR from approximately 2 to 5. Follow-up scores show an increase with a median around 6 and an IQR from approximately 4 to 8. The comparison indicates statistically significant differences at $p \leq 0.001$.

Figure 5.3: The figure shows two box plots comparing the Physical Component Summary (PCS) scores of two groups (G1 and G2) and the PCS scores across different stages of intervention (pre, post, and follow-up).

The left box plot indicates that Group 1 (G1) has significantly higher PCS scores than Group 2 (G2), with a p-value of less than or equal to 0.001. The right box plot displays a significant increase in PCS scores from pre-intervention to post-intervention and follow-up, with all comparisons showing a p-value of less than or equal to 0.001as shown in figure 3.

Figure 5.4: The figure presents a simple linear regression analysis of the Physical Component Summary (PCS) as influenced by the Numeric Pain Rating Scale (NPRS) across three stages of intervention: follow-up, post-intervention, and pre-intervention.

- The first panel (pre-intervention stage) shows a negative correlation with an R^2 of 0.253. The regression equation is PCS = 51.96 - 3.44 * NPRS, with an RMSE of 3.84. This relationship is also significant (F(1,42) = 14.23, P-value = 0.0005).
- The second panel (post-intervention stage) also shows a negative correlation, though weaker than the follow-up stage (R^2 = 0.310). The regression equation is PCS = 47.76 - 2.82 * NPRS, with an RMSE of 5.50. The relationship remains significant (F(1,42) = 18.84, P-value < 0.0001).
- The third panel (follow-up stage) shows a strong negative correlation between PCS and NPRS (R^2 = 0.786). The regression equation

is PCS = 56.49 - 4.63 * NPRS, with a Root Mean Square Error (RMSE) of 4.78. The analysis indicates a significant relationship ($F(1,42) = 154.47$, P-value < 0.0001) as shown in figure 4.

Each panel contains scatter plots with blue dots representing group G1 and red dots representing group G2. A regression line with a shaded confidence interval band is superimposed on the scatter plots, illustrating the linear relationship between PCS and NPRS at each intervention stage.

DISCUSSION

This randomized clinical trial, carried out within the Physical department of the Agile Rehabilitation Complex in Bahawalpur, Pakistan, has revealed the efficacy of two treatments in pain reduction and quality of life improvement, namely manual therapy and inclined board standing. The results of the ANOVA test show that the patients in the treatment group A (receiving manual therapy and passive stretching of hip lateral rotators) had a more significant reduction in pain and enhancement in the quality of life compared with the patients in the control group (inclined board standing). Although both of these groups demonstrated improvement over time, the results draw attention to the superiority of manual therapy over the other group in producing outstanding outcomes. ANOVA analysis of the data revealed a statistically significant effect of treatment group A (manual therapy) on the dependent variables with a calculated value of 22.25 and p-value<0.0001. This inequality is an indication that the combined approach of manual therapy and inclined bed resting is significant in pain relief and enhancement of normal physiological functions. Patients in both groups showed progress throughout the treatment period. The findings of ANOVA demonstrated significant effects at the end of the intervention. "Stages" had a highly significant effect on the dependent variable, implying that the interventions had an influence on the outcomes measured, for instance, pain and quality of life. This is an indicator that the intervention was effective in creating the desired results since because different stages showed great development of the measured variables. A meta analysis and a systematic review were conducted by Hidalgo B et al (2014)to synthesize the data from randomized controlled trials assessing the efficacy of manual therapy interventions (manual therapy means spinal manipulation, mobilization, and soft tissue therapy) for the treatment of chronic low back pain (14). The study found that manual therapy resulted in a significant reduction in pain intensity and improvements in outcome measures compared with different control methods. Subgroup analyses also showed that certain types of manual therapy techniques, such as spinal manipulation, were more efficient in alleviating pain. In sum, this research substantiated the effectiveness of manual therapy as part of the intervention for treating chronic low back pain with the help of conclusive evidence provided (14). Another clinical randomized controlled trial assessed and compared the effects of manual therapy, including spinal manipulation and mobilization, with those exercise therapy including stretching and strengthening exercises in subacute

low back pain. The treatment modalities have demonstrated that both manual therapy and exercise therapy (15) resulted in a reduction in pain intensity and functional disability. However at the end of the study, those who received manual therapy had greater pain intensity and disability scores changes than those who received exercise therapy. This work has shown that manual therapy as an early intervention can provide pain relief for low subacute back pain patients (16). An update on systematic evaluations assessing the effectiveness of exercise and manual treatment for varying phases of nonspecific low back pain was presented by Hidalgo and their colleagues (14). Their results confirm manual therapy's efficacy as an intervention for low back pain by demonstrating its considerable influence at different phases of the health condition (14). The significance of incorporating sub-classification techniques in randomized controlled trials (RCTs) assessing manual treatment and exercise therapy for non-specific persistent low back pain was highlighted by Fersum et al. (2010). This highlights the effectiveness of manual therapy in meeting the demands of certain patients and shows that customized treatments based on patient characteristics or subgroups might improve treatment outcomes (17).

CONCLUSION

The randomized control trial on manual therapy and inclined board standing showed that these interventions were effective treatments for pain reduction and quality of life improvement in low back pain patients. The ANOVA test showed that combined manual therapy and inclined board standing patients experienced a greater reduction in pain and enhanced quality of life compared with those receiving inclined board standing alone. The study also found that manual therapy had a statistically significant effect on dependent variables, indicating its efficacy in pain relief and restoration of normal physiological functions.

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