Effectiveness of strengthening exercise plus activities of daily living instructions in reducing pain in patients with lumbar disc herniation: a randomized controlled trial [version 1; peer review: awaiting peer review]

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Abstract

Background: Lumbar disc herniation (LDH) is one of the most common causes of chronic low back pain (CLBP) with sciatica. The exercise intervention was found effective in improving CLBP, although a paucity of research evaluated the effectiveness of exercise intervention to alleviate CLBP due to LDH. This study aimed to evaluate the effectiveness of the combination of back and hip strengthening exercises and activities of daily living instructions (ADLIs) to improve CLBP with sciatica due to LDH.

Method: This assessor-blinded randomized clinical trial was conducted on 70 patients with CLBP with sciatica due to LDH. The patients were randomly allocated either in the intervention group (IG) or control group (CG). Patients in IG received both back and hip strengthening exercises five days a week for six weeks. Patients in CG received pharmacological therapy for three weeks, followed by hot moist compression for another three weeks. Patients of both groups followed the ADLIs at the time of the intervention and at least three months after the intervention. Back pain intensity and perceived pain due to sciatica were measured by the Visual Analogue Scale and range of hip flexion during the Straight Leg Raising Test, respectively, at three weeks and six weeks of intervention, and three months after the intervention.

Results: Back pain and sciatica improved significantly (p < 0.05) in both groups at the end of the intervention and follow-up, while the IG showed significantly better improvements (p < 0.05) at the end of the intervention. However, only ADLIs were not adequate to sustain the improvements after the intervention.
Conclusion: The combination of back and hip strengthening exercises and ADLIs improves CLBP with sciatica due to LDH. Nevertheless, it is required to instruct patients to follow ADLIs and perform strengthening exercises regularly to maintain the improvements.

Trial registration: ClinicalTrials.gov, NCT05021718.

Keywords
Back pain, Daily living instructions, Lumbar disc herniation, Sciatica, Strengthening exercise.
Introduction

Low back pain (LBP) is the pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds with or without leg pain. Around 70-80% of people experience LBP at least once during their lifetime, while 18% of the people suffer from LBP at any given time. LBP prevalence is also high in middle and low-income countries, including Bangladesh. Nearly 97% of patients have LBP due to mechanical factors, while 2% are due to visceral disease and 1% non-mechanical reasons. Intervertebral disc herniation is the most common cause of LBP in adults, and that accounts for 4% of mechanical LBP. Intervertebral disc herniation is defined as a focal displacement of disc material beyond the limits of the intervertebral disc space. The lower lumbar spine (L4/5 and L5/S1 level) is the most common site of disc herniation. In addition, about 60% of patients with LBP presented with radiating leg pain, which is also known as sciatica. Nerve root compression by the herniated lumbar intervertebral disc (LDH) is considered the most common cause of sciatica, although there are many possible causes.

Most of the patients recover spontaneously within two to four weeks from the acute phase of LBP without receiving any treatment. However, about 10 – 20% of patients develop chronic low back pain (CLBP) that may lead to significant disability. Exercise is regarded as the first-line treatment of CLBP. Different types of exercise, including strengthening exercise, flexibility training, aerobic exercise, resistance training, and stretching exercise, effectively gain short-term and long-term improvements in patients with CLBP.

Strengthening exercise is frequently included in the exercise program as it enhances the lumbar extensor muscle strength of LBP patients. Research showed that strengthening exercise was more effective than aerobic exercise and other exercises to improve CLBP. In addition, strengthening exercise is also safe for the elderly, and it helps regain muscle strength. Ishak et al. showed in their systemic review that strengthening exercise effectively alleviates pain and prevents disability in the elderly with CLBP. However, a paucity of research evaluated the effectiveness of strengthening exercise to improve pain in patients with CLBP due to LDH. In addition, activities-of-daily-living instruction (ADLI) is a useful tool that enables patients with LBP to perform daily tasks efficiently without increasing direct demand on injured areas. It helps to enhance spinal stability and limit LBP and, consequently, intensifies the recovery.

This study aimed to evaluate the effectiveness of combined back and hip strengthening exercises and ADLIs to improve pain intensity in patients with CLBP due to LDH. In addition, we also investigated whether only ADLIs were sufficient to sustain improvements after the intervention. To our best knowledge, it is the first research that assessed the effectiveness of combined strengthening exercises and ADLIs to improve CLBP due to LDH. We hypothesized that this combined therapy would alleviate pain significantly after the end of the intervention, and only ADLIs would be adequate to maintain the progress at follow-up.

Methods

Participant selection

The sample size was determined as 34 in each group using OpenEpi version 3.1, assuming 7.74% as the estimated prevalence rate at a 95% confidence level with 9% precision. Outpatients with CLBP caused by one or more lumbar discs herniation attending the Department of Physical Medicine & Rehabilitation, Chittagong Medical College Hospital, were recruited for the study. The recruitment was done from July 2018 to February 2019. Initially, the patients were clinically re-examined by a physical medicine consultant of Chittagong Medical College Hospital, and then the diagnosis was confirmed by magnetic resonance imaging (MRI).

Patients aged 18 – 59 years and with a history of pain for the last three months, or more were included in the study. Patients with pregnancy, cauda equina syndrome and other pathological conditions of the spine were excluded. Details of inclusion and exclusion criteria are presented in Table 1. All participants received detailed information about the research project. Informed consent, both in written and oral form, was obtained from each subject to participate in the study. Demographic characteristics of the participants, including age, weight, and height, were recorded at the hospital before the commencement of the intervention.

Trial design

This parallel-group randomized controlled trial was reported following the Consolidated Standards for Reporting Trials (CONSORT) guidelines. The CONSORT diagram is shown in Figure 1. No changes were made to methods after trial commencement.

All eligible patients were randomly allocated to either the intervention group (IG) or control group (CG). Randomization was done by lottery method using the unique identification number of the participants. An independent person who was not part of the research was involved in randomization. Both researchers and assessors were unaware of randomization.
### Table 1. Inclusion and exclusion criteria of the patients. LDH: Lumbar disc herniation; MRI: magnetic resonance imaging.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age: 18-59 years</td>
<td>• Painful spinal deformity</td>
</tr>
<tr>
<td>• Clinically diagnosed LDH that was confirmed by MRI.</td>
<td>• Cauda equina syndrome</td>
</tr>
<tr>
<td>• Duration of the pain: ≥3 months</td>
<td>• Progressive neurological signs and/or muscle-wasting</td>
</tr>
<tr>
<td></td>
<td>• History of spinal surgery, spine fracture, scoliosis, tuberculosis, and tumors.</td>
</tr>
<tr>
<td></td>
<td>• Treated with epidural injections.</td>
</tr>
<tr>
<td></td>
<td>• Pregnancy</td>
</tr>
</tbody>
</table>

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**Figure 1. The CONSORT diagram.**

- **Screening of patients by history and clinical evaluation**
  - Eligibility assessment (n = 80)
  - Confirmation of eligibility and lumbar disc herniation by MRI
    - Patients excluded (n = 8) after assessing MRI
      - Disc herniation other than lumbar region (n = 3)
      - Presence of spinal tumor (n = 5)
  - Eligible participants (n = 72)
  - Declined to participate (n = 2)

- **Randomization into two groups (n = 70)**
  - Experimental group (n = 35)
    - Received back and hip strengthening exercises + ADLIs – 6 weeks
  - Control group (n = 35)
    - Received Naproxen (500 mg) and Baclofen (10 mg) tablet twice a day for three weeks + ADLIs – 3 weeks
    - Received hot moist compression + ADLIs – Next 3 weeks.

- **Outcomes were evaluated at 3 weeks of the intervention and at the end of the intervention (at 6th week)**
  - Patients of both groups were asked to follow the ADLIs at least for 3 months after the intervention

- **Follow-up: Outcomes were evaluated after 3 months of the intervention**
Table 2. Summary of the interventions and activities of daily living instructions (ADLIs).

<table>
<thead>
<tr>
<th>Back and hip strengthening exercises received by IG</th>
<th>Therapy received by the CG</th>
<th>Activities of daily living instructions (ADLIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>1st week:</strong> Pelvic tilt exercise: The patients were instructed to lie on the back with the knees bent and feet flat on the floor. Then they were asked to tighten the buttocks and abdomen so that they tip up slightly. Afterward, they are asked to press the lower back to the floor and hold for six seconds while breathing evenly.</td>
<td>• <strong>Week 1 to week 3:</strong> Naproxen (500 mg) and Baclofen (10 mg) tablet twice a day for three weeks.</td>
<td>Both groups received the following ADLIs at the time of the intervention and for at least three months after the intervention. ✓ Avoid forward bending. ✓ Avoid heavy weightlifting. ✓ Avoid prolonged standing. ✓ Avoid prolonged sitting. ✓ Use a plain, firm bed. ✓ Lie down in a supine position.</td>
</tr>
<tr>
<td>• <strong>2nd and 3rd week:</strong> Back strengthening exercise: In the prone position, the patients were instructed to lift their upper body off the ground while keeping their legs on the floor. They were asked to hold the position for about three to four seconds. Hip strengthening exercise: In the prone position, the patients were trained to perform alternate hip extension.</td>
<td>• <strong>Week 4 to week 6:</strong> Hot moist compression for the next three weeks, five days a week, once a day for a total of 15 sessions.</td>
<td></td>
</tr>
<tr>
<td>• <strong>4th and 5th week:</strong> The patients were instructed to raise their head and shoulders and extend their hips in the prone position. They were asked to maintain the position for five to six seconds.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• <strong>6th week:</strong> In the prone kneeling position, the patients were instructed to lift the opposite arm and leg simultaneously until the body is in a straight line and to hold the position for four to five seconds. Then they were asked to do the same movement on the other side.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IG = Intervention group, CG = Control group.
**Intervention**

Patients in IG received different back and hip strengthening exercises for six weeks, five days a week, once a day, for a total of 30 sessions. Under the supervision of the researchers, a trained physiotherapist instructed the patients at the hospital. The exercises were initiated from a basic level and were gradually progressed. The intensity of exercises, including the cycle and repetition of exercise, was controlled depending on the individual subject's exercise tolerance and pain thresholds. The details of back and hip strengthening exercises are presented in Table 2.

The patients in CG received pharmacological therapy and hot moist compression as suggested in previous studies. They were treated with Naproxen (500 mg) and Baclofen (10 mg) tablet twice a day for three weeks, followed by hot moist compression for the next three weeks, five days a week, once a day for a total of 15 sessions. Patients were asked to take drugs regularly at home, while hot moist compression was given by a physiotherapist at the hospital. In addition, the patients in both groups were instructed to follow the activities in daily living instructions (ADLIs) during the intervention and at least three months after the intervention. Details of ADLIs are demonstrated in Table 2.

**Outcome measures**

Evaluation of the intensity of back pain of the patients was the primary outcome of the intervention. In addition, the patient's perceived pain due to sciatica was also assessed as the secondary outcome. The severity of perceived back pain was evaluated using a Visual Analogue Scale (VAS). VAS is regarded as valid and reliable for rating back pain. Patients were asked to rate their perceived pain on a 0-to-10-point scale, where 0 indicated no pain at all and 10 indicated the most severe imaginable pain.

In addition, the straight leg raising test (SLRT) was performed for clinical assessment and to evaluate the progression of sciatica. SLRT is an important clinical test for assessing sciatica or the lumbar root irritation caused by disc herniation. The SLRT has high sensitivity but low specificity to diagnose LDH. The SLRT was performed with the patients lying in the supine position without any pillow under their heads. Then the examiner gently lifted the patient's leg by the posterior ankle while keeping the knee fully extended position. The examiner stopped raising the leg when the patient felt pain, or the maximum flexion was obtained. Then the range of hip flexion (RHF) without pain was measured by a hand-held goniometer. The test was done for both affected and unaffected legs.

Outcomes were evaluated at baseline, at three weeks, and at six weeks of the intervention. Patients were followed up after three months of the intervention. All measurements were performed at the hospital by an independent assessor who was unaware of group allocation and intervention.

**Statistical analysis**

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS Inc, Chicago, IL), version 26. Descriptive statistics were generated, and results were presented as mean ± SD. Continuous variables were non-normally distributed. Hence, differences between the groups at baseline, at three months, post-intervention, and at follow-up were analyzed by the Mann-Whitney U test. Differences in outcomes at different time points in the same group were analyzed with Wilcoxon's signed-rank test. A p-value less than 0.05 was considered statistically significant.

**Ethical approval and registration**

The research protocol was approved by the ethics committee of Chittagong Medical College (Approval number: CMC/PG/2018/226) and was registered at ClinicalTrials.gov (Identifier: NCT05021718). The original protocol was strictly maintained.

**Results**

**Baseline evaluation**

A total of 72 participants met all the inclusion criteria and were confirmed to have LDH by MRI images. However, two participants declined to participate in the study before the start of the intervention. Hence, 70 subjects were finally included in the study who were equally allocated to either in IG or CG. The mean age of the participants in IG was 42.37 ± 10.32 years and in CG was 38.94 ± 8.33 years. At the same time, the mean BMI of participants in IG and CG was 26.14 ± 4.49 kg/m² and 24.58 ± 4.15 kg/m², respectively. Table 3 shows the baseline demographic and clinical characteristics of the patients. Baseline assessment of demographic and clinical characteristics of patients did not show any significant differences (p > 0.05) between the two groups.

**Back pain intensity**

The within-group analysis demonstrated that back pain intensity decreased significantly in both groups at all time points compared to baseline.
From baseline to three weeks of intervention, back pain intensity reduced by 59.17% (7.20 ± 0.90 to 2.94 ± 1.11, p < 0.05) in IG, and 59.07% (7.11 ± 0.80 to 2.91 ± 0.82, p < 0.05) in CG. However, no significant differences (p = 0.951) between groups were observed.

From baseline to the end of the intervention, back pain intensity decreased by 85.69% (7.20 ± 0.90 to 1.03 ± 1.00, p < 0.005) in IG, and 79.89% (7.11 ± 0.80 to 1.43 ± 0.88, p < 0.005) in CG. Moreover, between group analysis showed significant differences between groups (p = 0.049).

From baseline to follow-up, back pain intensity reduced by 51.53% (7.20 ± 0.90 to 3.49 ± 1.84, p < 0.005) and 54.57% (7.11 ± 0.80 to 3.23 ± 1.85, p < 0.005) in IG and CG, respectively, without any significant differences between groups (p = 0.515). Whereas from the end of the intervention to follow-up back pain was increased significantly both in IG (1.03 ± 0.92 to 3.49 ± 1.84, p < 0.005) and CG (1.43 ± 0.88 to 3.23 ± 1.85, p < 0.005) (Figure 2).

Results of within analysis of both groups and between analysis of groups are presented in Tables 4 and 5, respectively.

**Range of hip flexion (RHF) during SLRT**
The within-group analysis showed that RHF during SLRT of the affected leg increased significantly in both groups at all time points compared to baseline.

From baseline to three weeks of the intervention, RHF during SLRT of affected leg increased by 40.82% (48.29 ± 12.30° to 68 ± 10.66°, p < 0.005) in IG, and 32.49% (50.14 ± 11.73° to 66.43 ± 11.48°, p < 0.005) in CG. In contrast, the between-group analysis showed no significant differences between groups (p = 0.560).

From baseline to the end of the intervention, RHF during SLRT of affected leg improved by 66.85% (48.29 ± 12.30° to 80.57 ± 8.47°, p < 0.005) in IG, and 48.44% (50.14 ± 11.73° to 74.43 ± 9.53°, p < 0.005) in CG. In addition, the between-group analysis showed significant differences between groups (p = 0.002).

**Table 3. Demographic and clinical characteristics of participants at baseline.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group (Mean ± SD)</th>
<th>Control group (Mean ± SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>42.37 ± 10.32</td>
<td>38.94 ± 8.33</td>
<td>0.131</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.14 ± 4.49</td>
<td>24.58 ± 4.15</td>
<td>0.135</td>
</tr>
<tr>
<td>VAS (0–10)</td>
<td>7.20 ± 0.90</td>
<td>7.11 ± 0.80</td>
<td>0.700</td>
</tr>
<tr>
<td>RHF during SLRT of the affected leg (°)</td>
<td>48.29 ± 12.30</td>
<td>50.14 ± 11.73</td>
<td>0.507</td>
</tr>
<tr>
<td>RHF during SLRT of the unaffected leg (°)</td>
<td>72.57 ± 15.69</td>
<td>72.57 ± 14.01</td>
<td>0.895</td>
</tr>
</tbody>
</table>

BMI = Body Mass Index, VAS = Visual Analogue Scale, RHF = Range of hip flexion, SLRT = Straight leg raising test.

Figure 2. The comparison of VAS scores between the end of the intervention and follow-up. (*) indicates statistically significant difference, VAS = Visual Analogue Scale.
### Table 4. Summary of results of within-group analysis.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Timepoint</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>P-value</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>VAS (0 – 10)</td>
<td>Baseline</td>
<td>7.20 ± 0.90</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>At 3 weeks</td>
<td>2.94 ± 1.11</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td></td>
<td>At 6 weeks</td>
<td>1.03 ± 1.00</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td></td>
<td>Follow up</td>
<td>3.49 ± 1.84</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td>RHF during SLRT of the affected leg (*)</td>
<td>Baseline</td>
<td>48.29 ± 12.30</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>At 3 weeks</td>
<td>68 ± 10.66</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td></td>
<td>At 6 weeks</td>
<td>80.57 ± 8.47</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td></td>
<td>Follow up</td>
<td>72 ± 14.76</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td>RHF during SLRT of the unaffected leg (*)</td>
<td>Baseline</td>
<td>72.57 ± 15.69</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>At 3 weeks</td>
<td>82.43 ± 11.21</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td></td>
<td>At 6 weeks</td>
<td>86.71 ± 6.30</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td></td>
<td>Follow up</td>
<td>79.71 ± 11.18</td>
<td>0.001</td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale, RHF = Range of hip flexion, SLRT = Straight leg raising test. This table shows the changes in clinical outcomes at different time points compared to baseline values in the same group.

### Table 5. Summary of results of between-groups analysis.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Baseline</th>
<th>At 3 weeks</th>
<th>At 6 weeks</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>P-value</td>
<td>Mean ± SD</td>
<td>P-value</td>
</tr>
<tr>
<td>VAS (0 – 10)</td>
<td>IG 7.20 ± 0.90</td>
<td>0.700</td>
<td>2.94 ± 1.11</td>
<td>0.951</td>
</tr>
<tr>
<td></td>
<td>CG 7.11 ± 0.80</td>
<td></td>
<td>2.91 ± 0.82</td>
<td></td>
</tr>
<tr>
<td>RHF during SLRT of the affected leg (*)</td>
<td>IG 48.29 ± 12.30</td>
<td>0.507</td>
<td>68 ± 10.66</td>
<td>0.560</td>
</tr>
<tr>
<td></td>
<td>CG 50.14 ± 11.73</td>
<td></td>
<td>66.43 ± 11.48</td>
<td></td>
</tr>
<tr>
<td>RHF during SLRT of the unaffected leg (*)</td>
<td>IG 72.57 ± 15.69</td>
<td>0.895</td>
<td>82.43 ± 11.21</td>
<td>0.129</td>
</tr>
<tr>
<td></td>
<td>CG 72.57 ± 14.01</td>
<td></td>
<td>80 ± 9.63</td>
<td></td>
</tr>
</tbody>
</table>

IG = Intervention group, CG = Control group, VAS = Visual Analogue Scale, RHF = Range of hip flexion, SLRT = Straight leg raising test. This table shows comparison of clinical outcomes in both groups at different time points.
From baseline to follow-up, RHF during SLRT of affected leg enhanced by 49.1% (48.29 ± 12.30° to 72 ± 14.76°, p < 0.005) and 39.33% (50.14 ± 11.73° to 69.86 ± 15.07°, p < 0.005) in IG and CG, respectively, without any significant differences between groups (p = 0.549). However, from the end of the intervention to follow-up, RHF during SLRT of affected leg decreased significantly in IG (80.57 ± 8.47° to 72 ± 14.76°, p < 0.005), whereas in CG it was decreased, but the difference was not significant (74.43 ± 9.53° to 69.86 ± 15.07°, p = 0.072) (Figure 3).

Additionally, RHF during SLRT of unaffected leg enhanced significantly (p < 0.001) in both groups without any significant differences between groups (p > 0.150) at all time points compared to baseline. Results of within-group analysis of both groups and between analysis of groups are presented in Tables 4 and 5, respectively.

Discussion
Deep abdominal muscles, including the superficial muscles, transversus abdominis, and multifidus, are essential for lumbar segmental stability. Reduction in the strength of these muscles causes lumbar instability and inflexibility, which eventually lead to CLBP. Research demonstrated that strengthening exercises enhance these muscles' strength and endurance, consequently improving the spine stability and reducing LBP. Strengthening exercise is a safe and low-cost intervention to improve pain and disability in patients with LBP. Lumbar extensor strengthening exercise is an effective therapeutic tool as it provides measurable physiologic adaption to the therapy.

In addition, strength deficits in hip muscle are frequently reported in patients with LBP. Researchers showed that hip strengthening exercise was beneficial for improving pain and disability in patients with LBP. Jeong et al. showed that hip strengthening exercise plus lumbar stabilization exercises were more effective in improving CLBP than lumbar stabilization alone exercise. In another study, Chang et al. suggested to add hip strengthening exercise with trunk muscle strengthening exercise to train patients with LBP. In this study, patients in IG received six weeks of back and hip strengthening exercises. Results showed that back pain intensity reduced significantly at three weeks and the end of intervention compared to baseline.

![Figure 3. The comparison of the RHF during SLRT between the end of the intervention and follow-up. (* indicates statistically significant difference, RHF = Range of hip flexion, SLRT = Straight leg raising test).](image-url)
Moreover, researchers showed a strong correlation between SLRT and various parameters that signify the patients' pain level. SLRT reflects the severity of LDH and the degree of nerve root compression. SLRT also indicates the extent of the outcome as research showed that a positive postoperative SLRT was associated with an inferior outcome. If the patient feels radiating pain along the course of the sciatic nerve and below the knee between 30 and 70 degrees of hip flexion, then the SLRT is considered positive. In this research, RHF during SLRT of both affected and unaffected legs increased significantly in IG in all time points that indicated the improvement in sciatica due to nerve compression.

Activities-of-daily-living instruction (ADLI) is a useful tool to train patients with LBP to meet the daily demands with proper ADL technique and enables them to perform tasks efficiently without increasing direct demand on injured areas. Therefore, it helps to increase spinal stability, limit LBP, and improve their recovery. In this study, patients in both IG and CG were instructed to follow ADLIs during the intervention and at least three months after the intervention. Results demonstrated that back pain intensity and RHF during SLRT improved significantly in both groups at all time points. However, patients in both groups followed ADLIs in combination with other interventions; hence we could not establish the effectiveness of ADLIs alone to improve back pain and sciatica due to LDH. In addition, after the intervention, the patients were asked to follow the ADLIs for at least three months. Outcomes evaluated at follow-up indicated that VAS scores increased and RHF decreased in both groups compared to the end of the intervention, which indicated that only ADLIs were insufficient to sustain the improvements. Nevertheless, after the intervention, the patients were neither supervised nor instructed. Therefore, we could not confirm whether the patients followed the ADLIs as they were trained.

Furthermore, it is also essential to evaluate whether the improvements achieve the minimally clinically significant difference (MCID) to be regarded as clinically relevant and justify whether the patients can perceive the effects of an intervention as a benefit. MCID is regarded as the minimal change in score in the domain of interest, which correlates with the patient's perception of beneficial change or recovery. Any improvement is considered meaningful if the amount of change exceeds the MCID threshold. A minimum change of 30% in pain intensity measured with VAS is usually considered as MCID when the difference is compared with the baseline. In this study, VAS score changes in both IG and CG in all time points compared to baseline attained MCID threshold to be regarded as clinically significant.

Limitations
The major limitations of this study are the relatively small sample size and the absence of long-term follow-up. Moreover, in this study, we evaluated only pain intensity and RHF during SLRT outcomes. Other measurements, including functional disabilities, quality of life, fear-avoidance belief of patients, and intervention cost-effectiveness, were missed. In addition, as we conducted the study at one medical institution, it is difficult to generalize the findings to every LDH patient.

Conclusion
This study showed that back and hip strengthening exercises combined with ADLIs were effective in alleviating back pain and sciatica due to LDH. However, only ADLIs did not seem to be adequate to sustain improvements after the intervention. Therefore, it is required to suggest the patients follow ADLIs and perform strengthening exercises regularly. However, due to the limitations of the study, we are unable to unambiguously state the effectiveness of the therapy. Future studies with larger sample sizes and long-term follow-up are needed to justify the effectiveness of this therapy to obtain clinically significant changes. Moreover, assessment of other outcomes and cost-effectiveness of the therapy is also required. The pre-and post-intervention MRI and ultrasound images can be evaluated to observe the changes in muscle function, size, symmetry, and fatty infiltration, which can clinically prove the effectiveness of the therapy.

Data availability
Underlying data
Mendeley Data: Effectiveness of strengthening exercise plus activities of daily living instructions in reducing pain in patients with lumbar disc herniation. https://doi.org/10.17632/mzsnj6mnsw.3

The project contains the following underlying data:

- Main Raw Data.xlsx

Reporting guidelines
The project contains the following data:

- CONSORT Checklist.doc
- CONSORT Flow Chart.jpg

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

Acknowledgments

The authors are grateful to the participants, physiotherapists, and supervisors of the study. The authors are indebted to Dr. Wahid for his kind contribution.

References


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