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RESEARCH ARTICLE
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Effect of Stay Active Advice on Pain and Disability in Patients with Low Back Pain: a randomized controlled trial

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ABSTRACT

Background: Stay active advice is considered the 'first line' for treating patients with low back pain (LBP) and is recommended in all international guidelines. However, the current evidence in favor of the advice of staying active for patients with LBP is limited. Purpose: The purpose of the study was to study the effect of the advice of staying active on the Visual Analogue Scale (VAS) pain score and Oswestry disability index (ODI) in patients with low-risk non-specific low back pain (NSLBP).

Methods: Thirty-five patients with low-risk NSLBP for less than three months participated in this study. They were randomly assigned into two groups; Group 1: Stay active advice and Group 2: the control group; patients in this group were not given any advice at all and were asked to come after six weeks for re-assessment as the advice group. Data were collected using VAS and ODI at the baseline and after six weeks.

Results: Mixed design MANOVA revealed that the VAS pain score was significantly decreased at the six-week assessment compared to the baseline measurements in both groups ($p<0.05$) and was significantly lower in the Stay active group at the 6-week assessment compared to the Control group ($p =0.001$). Also, the ODI decreased significantly at the six-week assessment compared to the baseline measurements in both groups ($p<0.05$) but with no significant difference between the two groups for the VAS and ODI scores at the six-week assessment ($P>0.05$).

Conclusion: The advice of staying active is beneficial in reducing perceived pain intensity without deleterious effects on disability in patients with low-risk NSLBP.

Keywords: *Back pain, Advice of Staying Active, Pain, Disability*

INTRODUCTION

All developed nations have significant levels of low back pain (LBP), which is most frequently addressed in basic healthcare settings [1]. It is typically described as discomfort, stiffness, or muscle tension that is located above the inferior gluteal folds and below the costal border, with or without leg pain [2].

LBP is not an illness and cannot be used to make any kind of diagnosis. It now serves as a model for how the body reacts to both internal and exterior stimuli. LBP is a prevalent physical impairment with a significant economic impact, on par with illnesses including headache, heart disease, depression, and diabetes mellitus [3].

LBP is still the main cause of disability on a global basis, and it has a significant economic impact [4]. This global health issue presents difficult clinical management issues [5].

In the rehabilitation program for patients with chronic LBP, improving a patient's level of physical fitness and restoring normality to their activities of daily living (ADL) has long been a priority. This was solely based on the premise that physical inactivity causes lower back discomfort to become chronic [6].

A critical component of the suggested course of treatment for acute LBP is to advise the patient to continue their active lifestyle [7] [8]. However, the evidence currently available is limited and shows little to no benefits in pain alleviation, functional improvement, or sick leave compared to resting in bed for individuals with acute LBP [9].

So, the current study aimed at filling this gap and expanding the previous findings by investigating the effect of the Stay active advice on the level of perceived pain and functional disability in patients with low-risk nonspecific low back pain (NSLBP) (with a total score of three or less based on the STarT Back Tool score).

MATERIALS AND METHODS

Design

A randomized controlled trial was conducted at the Faculty of Physical Therapy, Cairo University, Egypt to investigate the effect of the stay active advice on the level of perceived pain and Oswestry disability questionnaire score in patients with low risk NSLBP. This study was approved by the Research Ethical Committee of the Faculty of Physical Therapy, Cairo University. The practical aspect lasted for 18 months (from June 2021 till January 2023).

Patients

Thirty-five patients with low-risk NSLBP; symptoms of unknown origin, for less than three months participated in this study. They were randomly assigned using statistically random tables into two groups; Group 1: Advice of staying active (n=18) and Group 2: the control group (n=17). There were no significant differences in the mean values of the patient's age, body mass, and height between the two tested groups. All patients were referred by an orthopedist to participate in this study. Patients were screened for eligibility within the Physiotherapy Department based on the referral details. Each patient signed an informed consent form before the beginning of any assessment.

Patients were included in the study if they were

1. Between 18 - 65 years of age
2. Able to stand and walk without assistance.
3. Classified as low risk of poor outcome with a total score of three or less based on the STarT Back Tool score [10].

Patients were excluded from the study if they had

1. Low back pain for more than three months
2. Any neurological disease or balance deficits
3. Systemic infection or current pregnancy
4. Severe musculoskeletal deformity (scoliosis or kyphosis)
5. Significant anatomical leg length inequality
6. Injury to the lower extremity that would interfere with testing
7. Neurological signs
8. Pain below the knee consistent with a disc herniation
9. serious spinal complications (e.g., vertebral fracture, tumor or infection) and Spinal stenosis
10. Confounding conditions such as extreme obesity
11. Previous spinal surgery.

Instrumentations

The level of subjective pain was measured using the Visual Analogue Scale (VAS). It is a 10-cm line with labels at each end indicating no discomfort and excruciating pain. Patients were only asked to choose the line segment that best represented their level of pain. The patient's pain intensity score was calculated as the distance from the "no pain" end to the mark they made [11].

Pain-related disability in patients with LBP was assessed using the Oswestry Disability Index Questionnaire (ODQ). Due to its ease of use, speed, and low cost, physical therapists frequently utilize it to identify the level of functional impairment. The ODQ was created to determine the level of disability experienced during ADL. The ODQ is divided into ten categories, each of which addresses a different aspect of daily life, such as pain severity, self-care, lifting, walking, sitting, standing, sleeping, sex life (if appropriate), social life, and travel. In order to provide an overall percentage score of the disability, patients were asked to choose the most appropriate statement for each ADL (rated in accordance with the severity of the symptoms) [12].

Procedure

The VAS pain score and Oswestry disability questionnaire score were measured at the beginning and after six weeks for the two tested groups. This study passed through four phases; initial assessment, intervention, re-assessment phase, and statistical analysis.

Initial Assessment Phase

Prior to the assessment, a brief orientation session about the nature of the study, aims, the used instruments and the tasks to be achieved were explained to each patient before starting the measurements to be familiar with the study. All inclusion and exclusion criteria were checked out and the weight and height were measured. Each patient signed an informed consent of participation.

The recorded data sheet was filled in for each patient. The baseline measures; are pain score and Oswestry disability index. Initially, each patient was asked to determine the intensity of perceived pain on the VAS pain scale. Then he/she completed the Oswestry low-back-pain disability questionnaire.

Intervention Phase

In the current study, patients were randomly assigned by sealed envelopes, numbered in an order prepared from a random number table into two groups; Group 1: Advice of staying active, Group 2: No advice (the control group).

Advice of staying active (Group 1)

The patients were advised to stay as physically active as possible and continue their everyday activities as normally as possible.

The controls (Group 2)

Patients in this group were not given any intervention or advice and were asked to come after six weeks for re-assessment.

Re-assessment phase

The same testing procedures that were conducted during the initial assessment phase were repeated again after six weeks for all the patients

Statistical analysis

The Statistical Package for Social Science (SPSS) version 25 for Windows was used for all statistical calculations. As a first step to parametric analysis, data were initially screened using the Kolmogorov-Smirnov and Shapiro-Wilks normality tests for the assumption of normality. In addition to looking for extreme scores, this was done by checking for the presence of considerable skewness and kurtosis. After it was determined that the data did not defy the normality assumptions, parametric analysis was employed.

In the current study, the independent variables were the tested groups and the assessment time, and the dependent variables were the VAS pain score and Oswestry disability questionnaire score. It was intended to compare the two tested groups; the Advice of staying and the control group; at the baseline and after six weeks for all dependent variables.

The mixed design Multivariate Analysis of Variance (MANOVA) was used to compare the two tested groups and between the tested times for all dependent variables. To identify the source of significance for each of the dependent variables, many pairwise comparison tests with

subsequent Bonferroni correction to the alpha level were carried out. The family-wise alpha level was set at 0.05.

Sample Size

A prospective sample size was calculated based on a previous study conducted by Olaya-Contreras et al. [13] a total sample size of 40 patients was the minimum to detect differences between and within the tested groups. The Sample size was calculated using G*Power program (University of Düsseldorf, Düsseldorf, Germany) with a power level 0.8, alpha level 0.05 and an effect size of 0.0625.

RESULTS

A total of 50 patients were assessed for eligibility. Ten patients were excluded from the study, as they did not meet the inclusion criteria or because of other reasons. Forty patients were then randomized for allocation and subdivided into two groups: the advice of staying active group 1 (n = 20), and the control group 2 (n = 20). Five patients dropped out of the study. Data from the thirty-five patients, who completed the study to the end were analyzed.

Data analysis

Regarding the level of perceived pain, the 2x2 mixed design MANOVA revealed a significant reduction in the mean values of the VAS pain scores of the stay active group and the control group at six weeks' assessment compared to the baseline measurements (p = 0.001). Moreover, the levels of perceived pain were significantly reduced in the Stay active group at the 6-week assessment compared to the Control group (p =0.001).

Concerning the disability index assessed by the Oswestry Disability Questionnaire score, the subsequent multiple pairwise comparison tests revealed a significant improvement in the Oswestry disability questionnaire scores in the stay active group and the control group at six weeks' assessment compared to the baseline measurement (p = 0.001). On the other hand, there was no significant difference in the Oswestry disability questionnaire scores for the advice of staying active group compared to the Control group at six weeks' assessments (p = 0.968).

TABLE 1: Summary of the results of the VAS pain scores for the two tested groups at the two tested time intervals

VAS pain score				
Mean ± SD	Stay active advice (Group1)		Control (Group2)	
	Baseline assessment	6-week assessment	Baseline assessment	6- week assessment
	6.69±1.60	2.11± 0.67	7.29 ± 1.04	4.47±2.18
Test of within-subject effects (Time)			F=73.70	P=0.001*
Test of Between-subject effects (group)			F=8.306	P= 0.007*
Interaction			F=5.539	P=0.006*
Multiple Pairwise Comparison tests				
	Stay active advice Group1		Control Group2	
Baseline Vs 6-week assessments	P=0.001*		P=0.001*	
Multiple Pairwise Comparison tests				
	Baseline assessment		6-week assessment	
Group 1 Vs Group 2	P=0.202		P=0.001*	

* Significant at alpha level < 0.05.

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TABLE 2: Summary of the results of the ODI scores for the two tested groups at the two tested time intervals

The Oswestry disability index score				
Mean ± SD	Stay active advice (Group1)		Control (Group2)	
	Baseline assessment	6-week assessment	Baseline assessment	6- week assessment
	27.98 ± 8.44	16.01 ± 5.88	27.15 ± 11.35	15.91 ± 8.51
Test of within-subject effects (Time)			F=44.471	P=0.001*
Test of Between-subject effects (group)			F=0.278	P= 0.602
Interaction			F=0.621	P=0.541
Multiple Pairwise Comparison tests				
	Stay active advice Group1		Control Group5	
Baseline Vs 6-week assessments	P=0.001*		P=0.001*	
Multiple Pairwise Comparison tests				
	Baseline assessment		6-week assessment	
Group 1 Vs Group 2	P=0.806		P=0.968	

* Significant at alpha level < 0.05.

DISCUSSION

The findings of the current study revealed a significant reduction in the VAS pain scores and Oswestry disability questionnaire scores of the two tested groups; the advice of the stay active group and the control group; at the six weeks' assessment compared to the baseline measurements with a significant improvement in the stay active advice group compared to the control group regarding the pain level. On the other hand, the differences were not significant between the two groups at six weeks of assessment concerning the disability.

Being active is advised because it can assist to maintain or improve muscle endurance, flexibility, and strength, all of which can help to lessen discomfort and enhance function. Movement reduces muscle spasms, stops the weakening of muscles, makes the back more flexible, and enhances the quality of life. Also, maintaining an active lifestyle may help avoid the emergence of secondary issues like sadness, anxiety, and muscular deconditioning, which can result from prolonged inactivity [14].

Beta-endorphin levels, which have been demonstrated to be lower in physically active males than in sedentary men, may be due to the positive benefits of exercise on pain perception and psychological discomfort [15]. Depression has been linked to higher levels of resting beta-endorphin, and exercise has been shown to lower resting plasma beta-endorphin and elevate mood [16].

The reduction in the level of pain and disability that was found in the tested groups in the current study were in line with earlier findings that was reported by Wand et al. [17]. The researchers compared the effect of early active physiotherapy treatment; including biopsychosocial education, manual therapy, and exercise with the advice to stay active in patients with acute LBP. The researchers found significant reductions in the levels of perceived pain and disability in the two tested groups at the six weeks follow-up. The change in the mean (SD) of pain and disability in the group who received early active physiotherapy treatment were from 5.8 (2.1) to 2.4 (2.0) and 12.7 (6.0) to 4.5 (4.5), respectively. Regarding the Advice to Stay Active group, the researcher found change in the mean (SD) of pain and disability were from 5.2 (2.4) to 3.3 (2.5) and 10.1 (6.2) to 6.3 (5.9), respectively. All measures at long-term follow-up showed that neither pain

nor disability was significantly different between the two groups

Our findings are also confirmed by those reported by Forest et al. [18] who conducted a randomized control trial (RCT) to compare between the effect of advice with the effect of a traditional physiotherapy program on the level of disability in patients with LBP. The researchers found that the Oswestry disability index (ODI) scores were significantly decreased in the two tested groups after two months. The mean (SD) change in the ODI scores at 2 months from baseline for patients receiving physiotherapy and advice only for LBP were −2.65 (9.34) (with an effect size 0.24) and −1.33 (9.29) (with effect size 0.12), respectively. However, the researchers found no significant differences between the groups in the ODI score at 12 months.

On the other hand, the beneficial effect of stay active advice in decreasing pain and disability is contradictory with the findings reported by Dahm et al. [9]. They concluded that patients with sciatica have little or no difference between the two approaches. The researchers also found little or no difference between those who received advice to stay active, exercises or physiotherapy. They recommended further research as it may have an important impact on the estimate of effect and is likely to change the confidence in it. This controversy might be due to the different recruited sample. In the current study, patients with neurologic deficits (e.g. patients with radiation and nerve root involvement) were excluded from the study.

Furthermore, the findings of this current study are contradictory with the findings reported by Rozenberg et al. [19]. The researchers compared the effect of bed rest with the effect of normal activity in patients with acute LBP. This study showed that continuing normal activity with acute LBP was equivalent to bed rest for the back pain assessed by a VAS on day six or seven, as well as at one and three months. The researchers also reported that the results for the functional disability were similar for the two groups. The researchers claimed that the assessment of the results might have been biased because the patient's treating physician who had a particular idea concerning the rule of bed rest or activity in the treatment of acute LBP was the investigator. Because of this, controversy might have occurred between the researcher's findings and that of the current study.

Despite the fact that all worldwide guidelines recommend staying active, LBP clinical practice guidelines typically gave an inadequate description of suggested strategies. The precise advice given to patients with LBP has not received much attention. Advice interventions' content, delivery strategy, and treatment plan are less well defined. Patients need counsel regarding LBP and how to treat it, according to the evidence. Therefore, this current study covered the aspects of the advice intervention itself (e.g., content, method of delivery, regimen). All patients in the stay active guidance group receive the advice in a single session during an individual face-to-face counselling session.

Furthermore, Direct comparisons between the advice on staying active and controls to managing LBP are lacking in the literature. Most of the previous studies compared the advice with either bed rest or active intervention. Trials did not provide information on the effectiveness of advice compared with no intervention. It's debatable whether encouraging patients to continue with their normal activity levels during acute LBP is preferable to allowing them to follow their own preferences. A strength of this trial is the use of a control group to determine the efficacy of the stay active advice to reduce pain and disability and to promote physical activity.

This study was limited by

Inability to infer the findings on chronic LBP as our study was conducted on the course of acute and subacute LBP. Not allowing conclusions either of long-term effects on pain, or recurrence/work absence due to chronic LBP. The short-term effects were examined because the pain intensity decreased linearly over the follow-up period.

CONCLUSIONS

From the current study, it was concluded that the advice of staying active is beneficial in reducing perceived pain intensity but has no deleterious

effect on the disability index in patients with low-risk NSLBP. The current study indicates the opportunity within healthcare to help early return to work following an episode of LBP, using the stay active advice.

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CONFLICT OF INTEREST

The authors have no conflicts of interest.

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