Title: The effect of lumbar stabilization and walking exercises on chronic low back pain: A randomized controlled trial

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Materials and Method

This study was a prospective randomized controlled clinical trial with four groups: flexibility exercise (FE) group, walking exercise (WE) group, stabilization exercise (SE) group, and stabilization with walking exercise (SWE) group. Subjects in this study were part of a clinical trial (NCT02938169). The study and all procedures were approved by the Institutional Review Board of Seoul National University Bundang Hospital (B-1604-344- 004).

Subjects This study was conducted between May of 2016 and April of 2017. Patients complaining of chronic LBP were recruited from the rehabilitation outpatient clinic. The inclusion criteria were subjects aged over 20 years with intermittent chronic low back pain of more than 3 months. The exclusion criteria were as follows: a pain intensity of below VAS 40 sease, severe knee or hip arthritis that may interfere with walking exercise, pregnancy, and previous exercise treatment for lumbar paraspinalis muscles within 3 months. The physical examination was done by a PMR specialist.

Sample Size Calculation One way ANOVA power analysis was performed with the help of a statistical team to compare the average values of the four groups. As a result, the power of 82% was obtained when 10 patients were allocated to each group. As a result, 15 patients were assigned to each group to account for a dropout rate of 30%.

Randomization Consenting participants were randomly allocated to one of four study groups, following the predetermined and computer-generated random allocation sequences that were prepared by a statistician not involved in participant recruitment. The randomization schedule was only accessible by two individuals: the statistician and the primary investigators.

Blinding It was not possible to blind participants and physiotherapists given the nature of the exercise therapy and evaluation. One researcher blinded to group allocation measured the outcomes at pre-, immediately post-, and 6 weeks post-exercise program. Statisticians and primary investigators were unaware of the group allocation until data analyses were complete.

Exercise protocol Participants underwent each exercise for 30~60 minutes, 5 times a week, for a

total duration of 6 weeks. All participants were educated on the correct posture and abdominal bracing method, and received a pamphlet explaining good postures and abdominal bracing method for preventing LBP. Light abdominal bracing exercise (10-20% of maximal bracing) was recommended for all times; maximal bracing was recommended for 5-7 seconds, intermittently. The education session was performed at the clinic by a trained physical therapist at the first visit. Moreover, a printed pamphlet with instructions on how to perform the exercises was given to each patient. The exercises were performed at home All participants underwent a telephone interview every two weeks to confirm the current pain status, degree of exercise compliance, and to adjust the exercise level. Telephone communication also acted as an encouragement to exercise, promoting compliance.

The FE group received stretching exercise for the abdominal muscle, quadriceps, hamstring, tensor fascia lata, piriformis muscle, and quadratus lumborum muscles for 30 minutes. The WE group performed fast walking on flat ground with abdominal bracing for 30 minutes. The SE group was educated on IGLSE, focusing on the modifiable intensity level based on the exercise capacities of each participant. The IGLSE protocol consisted of two parts: stretching exercises and stabilization exercises. All participants performed stretching exercises for 5 minutes as a warm-up before beginning the stabilization exercises for 25 minutes. This program ranged from easy to difficult, based on participants' exercise capacity. Each exercise level had seven basic positions: supine, dead bug, side lying, prone, bird dog, bridge, and plank (five levels). We gradually increased the degree of instability until the most unstable posture was achieved. At the beginning, participants were placed into a level with moderate difficulty. To challenge the stabilization of all trunk muscles (anterior, lateral, and posterior), including the transverse abdominis, rectus abdominis, erector spinae and multifidus, internal oblique abdominals, and quadrates lumborum, participants were instructed to complete all five exercise positions in each session. Patients repeated each of the 7 postures 5 times for about 30 seconds each, to the best of their ability, for a total of 25 minutes.12, 13 The SWE group performed IGES for 30 minutes and walking for an additional 30 minutes.

Outcome measurement The primary outcome was the changes of VAS of LBP from the baseline to the follow-up. VAS was measured during rest and physical activity. The secondary outcomes included VAS of radiating pain measured during rest and physical activity, frequency of medication use (number of taking medications / day), endurances of specific posture (squared posture), and strength of lumbar extensor muscles. Endurance was measured in three postures (supine, side-lying, and prone)12 . The strength of lumbar extensor was measured with the manual muscle

tester (FEI 12-0380 Lafayette® Manual Muscle Tester, Fabrication Enterprises Inc., USA) in sitting position. In addition, Oswestry disability index and Beck depression inventory were measured to identify kinesiophobia, psycho-social aspects, and the disability for low back pain.

The first follow-up evaluation was done within 2 weeks after the completion of the 6-week exercise program, and all the initial evaluations were rechecked (immediately post-exercise program). The second follow-up evaluation was performed 12 weeks after the start of the program (6 weeks post-exercise program). At this evaluation, frequency and duration of exercise, as well as VAS of back pain and radiating pain during rest and physical activity were rechecked via telephone questionnaire to investigate the long-term compliance and effectiveness of the exercise treatment. Participants were advised to continue the exercise routine for the full duration of the program and that the second follow-up evaluation would be performed at the 12-week.

Statistical Methods SPSS 21.0 software (SPSS Inc, Chicago, IL, USA) was used for all statistical analyses. Wilcoxon signed rank test was used to compare the variables before and after the exercise in each group. Kruskal-Wallis test was used to compare the four groups. Repeated measures ANOVA was used to compare the pain scores (VAS) at various time points: first week (pre-exercise program), sixth week (immediately post-exercise program), and twelfth week (6 weeks post-exercise program). The results are presented as the mean ± standard deviation. P values of less than 0.05 were considered statistically significant.