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Effects of core stability exercises and cognitive tasks compared to general exercises and cognitive tasks on chronic non-specific back pain.

Two groups of exercise therapy approved for chronic low back pain in clinical guidelines are core stability exercises (CSE) and general exercises (GE) (1, 2). There is still no consensus on which exercises are superior to other exercises in reducing pain and disability in people with chronic non-specific low back pain (3). For example, Coulombe et al. (4) reported core stability exercises are more effective than general exercises. However, Saragiotto et al. (5) concluded that motor control exercises are not superior to other forms of interventions.

Studies found that combining cognitive and motor exercises helps to automate movements (6, 7) and postural control (7, 8). Therefore it is recommended to perform exercises in the form of dual tasks. Based on this, it seems that adding cognitive tasks to each group of CSE and GE can have a different effect on pain, disability, and postural control strategies. Therefore, this research aims to investigate the effect of CSE with cognitive tasks compared to GE with cognitive tasks on pain, disability, and postural control strategies of people with non-specific chronic back pain. It is also a gap of knowledge in which group of exercises can lead to appropriate postural control strategies and changing between the feedforward and feedback control in time.

Primary objectives:

1- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on the pain intensity of non-specific chronic low back pain patients.

2- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on the level of disability of non-specific chronic low back pain patients.

Secondary objectives:

1- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on postural stability (displacement range in the anterior-posterior direction on the Y axis, displacement range in the mediolateral direction on the X axis, velocity and total sway area), in the standing position of non-specific chronic low back pain patients.

2- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on postural control strategies (short-term effective diffusion coefficient, long-term effective diffusion coefficient, critical displacement, and critical time) in the standing position of non-specific chronic low back pain patients.

3- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on the level of fear of movement in non-specific chronic low back pain patients.

4- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on the level of fear avoidance behavior in non-specific chronic low back pain patients.

5- Comparison of the effect of core stability exercises with cognitive tasks compared to general exercises with cognitive tasks on the quality of life in non-specific chronic low back pain patients.

Methodology

The sample size of this study was calculated through G*Power software version 3.1.9.2 and based on primary outcome measures, including disability assessment, using the Oswestry disability index (ODI) questionnaire to the extent of 30% with a standard deviation of 3.85 and an effect size of

0.3 (9). Assuming three measurements will do in two groups, a correlation assumption of 0.5 between the measurements, 90% power, 5% type 1 error, and 26 participants with non-specific chronic low back pain (13 participants in each group) will enter the study. Considering the 30% possible dropout, equal to 7.8 people in total for both groups, the total number of participants in both groups will be 34 people.

It should be mentioned that we calculated the sample size using both the primary outcome measures of pain and disability. Since the sample size was larger on disability, we used this index to determine the study's sample size.

We will do sampling in a simple non-probability way among the people who refer to the physical therapy clinics of the Iran University of Medical Sciences. After selecting the participants, we will examine them for inclusion and exclusion criteria. If they meet the inclusion criteria and do not meet the exclusion criteria, they will sign the consent form. Afterward, the participants will complete the demographic information questionnaires and Mini-Mental Status Examination (MMSE) score.

primary outcome measures

Primary outcome measures in this study phase will include pain and disability. We will use visual analog scale (VAS) and the ODI questionnaire to evaluate primary outcome measures before and after the intervention period and after three months of follow-up.

secondary outcome measures

Primary outcome measures in this study phase will include postural stability parameters (displacement range in the anterior-posterior direction on the Y axis, displacement range in the mediolateral direction on the X axis, velocity and total sway area), postural control strategies parameters (short-term effective diffusion coefficient, long-term effective diffusion coefficient, critical displacement, and critical time), fear of movement, fear avoidance behavior, quality of life. A force plate (Kistler, 5691A) made in Switzerland will be used to evaluate standing postural control. It will measure the center of pressure (COP) trajectories with a frequency of 100 Hz. At first, each subject will stand on the force plate, similar to the study of Luca De & Collins (10), in a standard position with 10 degrees of external rotation of the feet so that the heels will be 3 cm apart (11). The measurement frequency will be 100 Hz (11, 12). For repeatability, foot placement will be marked on the force plate for all participants during the first test. During the trial, subjects will stand bare feet while their hands hang comfortably close to their body. Evaluations will be done in 8 conditions, including eyes open on a firm surface, eyes closed on a firm surface, eyes open on a firm surface with a cognitive task, eyes closed on a firm surface with a cognitive task, eyes open on foam, eyes closed on foam, eyes open on the foam with doing a cognitive task, eyes closed on the foam with a cognitive task. Each of the evaluations will last for 60 seconds, and according to the studies conducted in the field of generalizability of the variables of the postural control strategy (12, 13), Each condition consists of five trials. The average of these five trials will be used for the final analysis. The order of tests will be done randomly for each subject with eyes open and closed, as well as with and without cognitive tasks. During the evaluation with open eyes, participants will look at a screen at a distance of 4 meters, which is level with their heads. The subjects will stand still as much as possible and avoid sudden movements, deep breathing, and coughing. All tests will be recorded 5 seconds after the person will place on the force plate. A two-minute break will be taken between all five trials to control fatigue.

Participants will complete a postural task while listening to a continuous sequence of numbers as a cognitive task (14). This continuous sequence consists of 20 random three-digit numbers, each presented in three seconds. Then, a number (1 to 9) will be chosen randomly, and the participant

will count mentally how many times that number will be repeated in the string of randomly distributed numbers (for example, counting the number of times that the number 2 is repeated in the sequence 221, 326, 471, etc.). After the test, participants will present their answers. If the difference between the number calculated by the participant and the correct number is three or more, the test will be repeated. The three-digit sequences and the preselected digit will be changed on each trial to reduce the chance of memorization. Using fingers to count will be prohibited to maintain maximum cognitive effort.

Other secondary outcome measures in this study will include fear of movement, fear-avoidance beliefs, and quality of life, which will be determined using Tampa questionnaires and fear-avoidance beliefs questionnaire (FABQ), and SF-12.

Patients with non-specific chronic back pain will be randomly divided into two groups: A: intervention group, which includes core stability exercises with cognitive tasks, and group B: control group, which consists of general exercises with cognitive tasks. The patients will be treated for six weeks with a frequency of three sessions a week. For sixteen sessions, based on the exercise program provided by Shamsi et al. (15) (Appendix 7), which is modified from the exercise program of Koumantakis et al. (16). The training sessions for both groups include two parts with and without cognitive tasks so that in the first four sessions the exercises will be done without cognitive tasks and in the subsequent twelve sessions with cognitive tasks. The two groups will have similar types of cognitive tasks and the time of adding these tasks to the exercises.

Before starting the therapeutic exercise in each session, patients will warm up, including five minutes of cycling and eight stretching exercises (hamstring, quadriceps, tensor fascia/iliotibial band complex, and lateral trunk muscles on both sides) (15). Each stretch will be maintained for ten seconds and repeat ten times. The duration of warm-up exercises will be about 15-20 minutes.

Core stabilization exercises program

The first four sessions of the core stabilization exercises program (CSE) (appendix 1) aim to activate local muscles and improve their efficiency. Therefore, the exercises will be isometric with low loading in positions with minimal loading. It is essential to mention that to train the participants to be able to activate the muscles with different levels of contraction. First, they contract the deep muscles of their back and abdomen at their maximum capacity and then contract them again with 30% of the maximum contraction and maintain this level of contraction. This exercise will be repeated several times. Pressure biofeedback (17) will be used to train this level of contraction in the patients.

Cognitive tasks in this exercise program will be added to CSE from the fifth session, at the same time as the movement in other segments is started, along with maintaining the contraction of the transverse abdominal muscles and lumbar multifidus. Different cognitive tasks will be used in each session to avoid learning cognitive tasks.

General body exercise program

The general exercises (GE) (appendix 1) in this study will include the recruitment of large groups of abdominal flexor and lumbar extensor muscles. In this group, therapeutic exercises will not emphasize the activity of the local muscles.

According to Danneels et al. (18), patients with chronic back pain activate the spinal extensor muscles during CSE with 30% of their maximum contraction, while during GE, this contraction reaches about 60-70%. This amount of contraction has been used in previous studies to treat low back pain patients (15, 16). Accordingly, to balance the estimated total trunk muscle force output between the groups and to receive the same treatment dose in both groups, the training time will

be 20 minutes for CSE and 14 minutes for GE (the total training time for all sessions will be an order of 320 and 224 minutes).

Cognitive program

The exercises of the first four sessions in both groups will be done alone and without cognitive tasks. From the fifth session, cognitive tasks will be added to the exercises of both groups. The program of cognitive tasks in each session will be common in both groups and done simultaneously during CSE and GE. The cognitive tasks program will be as follows:

In the fifth and sixth sessions: 1) the patient will be asked to name the days of the week in reverse order. 2) Words will be presented to the patient by the therapist, and he will read those words backward.

In the seventh and eighth sessions, including 1) the patient will be asked to name the months of the year in reverse order. 2) Numbers between 200 and 300 will be counted in ascending order in three-digit intervals.

The cognitive tasks in the 9th and 10th sessions include 1) auditory stroop task, 2) counting random numbers between 100 and 200 3) counting numbers between 200 and 300 in ascending order in 7-digit intervals.

The cognitive tasks in the 11th and 12th sessions will be: 1) A text will be read to the patients, and they will state how many times a particular word was repeated in the text. 2) playing a string of two-digit random numbers and asking the patient to repeat those numbers 3) Counting backward numbers between 100 and 200 in three-digit intervals.

The cognitive tasks in the 13th and 14th sessions will be: 1) A text will be read to the individual, and he will identify how many times two specific words were repeated in the text. 2) N-Back task in which a number will be presented to the patient by the therapist, and the patient must say two numbers before that number (N=2). 3) The string of three-digit random numbers will be played, and the patients will repeat those numbers. 4) Counting numbers between 200-300 in reverse order in three-digit intervals.

The cognitive tasks in the 15th and 16th sessions will be: 1) A series of two-digit random numbers will be played for the patients, then they will repeat these numbers in reverse order. 2) A string of three-digit random numbers will be played into the patients, then they will repeat these numbers in reverse order. 3) A string of three-digit random numbers with more numbers will be played into the patient, then he will be asked to repeat these numbers in reverse order. 4) N-Back task in which a number will be presented to the patients by the therapist, and the patients must say 3 numbers before that number (N=3).

data analysis

Analysis of postural control Dynamics

The stabilogram diffusion analysis (SDA) method, as described by Collins and De Luca (11, 19), will be used to identify open-loop and closed-loop control strategies. In summary, the square of displacement (Δri) between consecutive COP data points -separated by a specific time interval (Δt)- will be calculated. Then, the square of displacements (Δri) in the specified time interval (Δt), from 0 to 10 seconds ($0 \leq (\Delta t) \leq 10$), will be calculated on average to make a graph of the average square displacement of COP ($\Delta r2$) versus Δt based on the following formula will be obtained:

N is the number of data points for the first 10 seconds of the COP data series, and for certain (Δt), m is the number of data intervals. Using this approach, an open-loop and closed-loop diagram (OLCL) (Figure 1) shows the squared value of COP displacement ($\Delta r2$) as a function of time interval (Δt). There are two recognizable regions in the OLCL diagram, named short-term (open

loop (OL) and long-term (closed-loop (CL)) regions, which are separated by critical time (OL Δt: critical time (Δt)c). the critical time is when the slope of the OLCL diagram changes. OLCL diagram will achieve three parameters: short-term diffusion coefficients, long-term diffusion coefficients, and critical point coordinates.

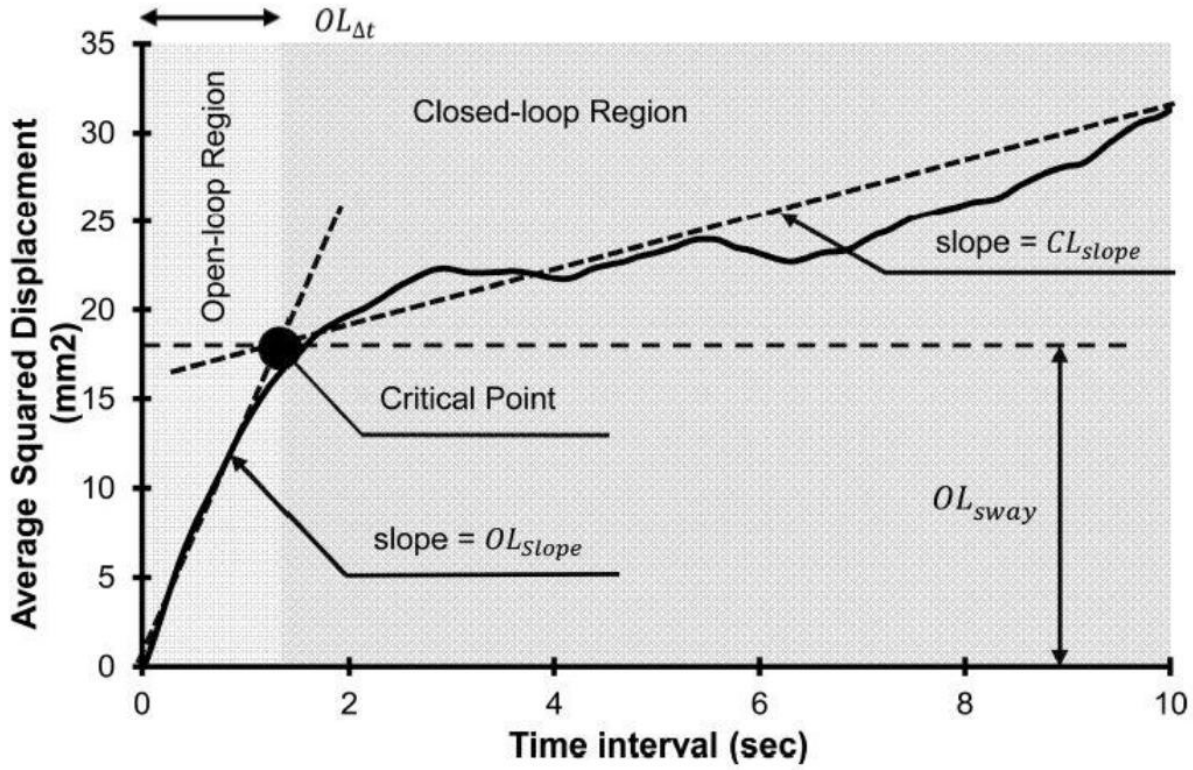

Figure 1. OLCL diagram

Postural stability analysis

COP displacement will be used to evaluate the postural control in a linear way. The COP signals will be filtered using a low-pass filter with a cut-off point of 10 Hz. COP parameters include:

1-Range of displacement in the anterior-posterior direction along the Y axis:

Range fore-aft (Rfa) = |YMax – YMi**n**|

2- Range of displacement in the mediolateral direction along the X axis:

Range sideways (Rsw) = |XMax – XMin|

3- The average velocity of total sway

4- Total sway area