Approved by Hacettepe University Clinical Researches Ethics Boards
and Last Revised in 25.07.2018
[NCT ID not yet assigned]

Study Protocol based on CONSORT Statement
(Consolidated Standards of Reporting Trials)

Learning of Motor Control Exercises with Different Methods and its Effects on Treatment Outcomes in Patients with Chronic Non-specific Low Back Pain: A Randomised Controlled Trial

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Introduction

Item 2a. Scientific background and explanation of rationale.

Non-specific low back pain is defined as low back pain not attributable to a recognizable, known specific pathology (1). According to The Turkish Statistical Institute,, it is the most common health problem in The Turkish Population (2).

For this common problem, European Guidelines for the Management of Chronic Nonspecific Low Back Pain defined exercise as first line treatment (3). There are various exercise approaches for the treatment. Treatment effect sizes of these approaches are generally same, motor control exercises better than general exercises (4,5).

For see the full effect of exercise treatment, exercise adherence should be high. In patients with chronic non-specific low back pain, the complex nature of the core-stabilization exercises decreases the exercise adherence (6,7). Some novel studies show that multimedia learning can increase efficiancy of complex skill learning and can be better from classic face to face learning (8,9). Therefore, we designed this study to determine the effect of multimedia learning on the effectiveness of motor control exercise therapy.

Item 2b. Specific objectives or hypotheses

In this study, we planned to determine if multimedia learning is better than standard face-to-face learning for core stabilization exercises.

Methods

Item 3a. Description of trial design (such as parallel, factorial) including allocation ratio

This will be a block randomized (Block number was 10.), allocation ratio 1:1, assesor blinded, controlled, parallel-group study conducted in the Hacettepe University, Turkey.

Item 4a. Eligibility criteria for participants.

Inclusion Criteria:
- Chronic (>3 month), non-specific low back pain
- 25- 55 years old
- Have a capacity can understand exercise instructions (Montreal Cognitive Assessment > 21)
- Being a computer-literate

Exclusion Criteria:
- Root nerve signs
- Cauda equina syndrome
- Fracture in the vertebra
- Tumor
- Have a neurologic disease
- History of spine surgery
- Knowing motor control exercises
- Visual impairment
- Hearing loss

Item 4b. Settings and locations where the data were collected

This study will carry out at the Back and Neck Health Unit at Hacettepe University Faculty of Physiotherapy, Ankara, Turkey. Anticipated data collection date between June 2019 and September 2019.

Item 5. The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.

Conventional treatment will be applied to both groups. Conventional treatment includes application of superficial temperature, soft tissue relaxation techniques and joint mobilizations. Only difference between groups will be exercise teaching methods. Each patient will receive an equal session routine physiotherapy treatment and the treatment will take an average of 60 minutes. On the other hand, individualization of the program will be done according to the criteria of transition to upper exercise, and it will be recorded when each patient has a higher exercise.

The exercise program will be performed according to the protocol of Hicks et al. And no medical device will be used.

The exercise program which will be use in the study for both groups (10,11):

First Session:

- Patient will be watch a pain physiology multimedia video prepared by study team. If patient have a question after watching the video, will be encouraged to ask her physiotherapist.
- The anatomy and kinesiology of the trunk stabilization, and motor control exercise principles will be explained to patient. For this purpose, face-to-face group receive information from physiotherapist with help of pictures while multimedia learning group watch a video with animations and narrations prepared by study team and reviewed by a specialist team.

2-16. seasons:

- Exercies Program
  - Transversus abdominus (30 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver (30 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver + heel slides (30 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver + leg lifts (20 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver + bridging (20 repetitions with 8-s hold, then progress to 1 leg)
    - Abdominal Draw-in Maneuver + standing (30 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver + standing row exercise (20 repetitions per side with 6-s hold)
    - Abdominal Draw-in Maneuver + walking (30 repetitions with 8-s hold)
  - Paraspinals/multifidi
    - Abdominal Draw-in Maneuver + Quadruped arm lifts (30 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver + Quadruped leg lifts (30 repetitions with 8-s hold)
    - Abdominal Draw-in Maneuver + Quadruped alternate arm and leg lifts (30 repetitions with 8-s hold)
  - M. Quadratus lumborum and m. obliquus abdominis
    - Side support with knees flexed (30 repetitions with 8-s hold)
    - Side support with knees extended (30 repetitions with 8-s hold)

- Home exercise program: The patient will be asked to perform the given exercise 20 minutes a day.

- Multimedia exercise videos will be included 2D animations with compatible narrations. This videos prepared based on cognitive theory of multimedia learning, and tested with Learning Object Review Instrument version 2.0 by an board of ten years experienced physiotherapy experts.

Item 6a. Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Evaluation of the severity of pain:

Visual Analog Scale will be used before the treatment, at before and after every treatment session and at the third month after the treatment. This scale is a 100 millimeter line drawn horizontally on an A4 sheet of paper. The left end of the line shows “no pain at all”, the right end shows “my pain is as bad as it could be”, while the remaining part shows the intermediate values. The patient is asked to mark the severity of the pain on the chart. Validity and reliability were made. The minimal clinical significance difference in chronic low back pain was 20 millimeters.

Evaluation of Disability

Disability will be evaluated by Oswestry Diability Scale 2.0 Turkish version. This version contains 10 multiple-choice questions that question how low back pain affects a person in his or her daily life. Each question has 6 options. As the disability increases, the score of each problem increases. In the worst case you can get 50 points. The last point is the patient's score 100.

Evaluation of Walking-Distance and Spatiotemporal Variables of Walking

The 6-minute walk test, which measures how far the patient can walk in 6 minutes, will be used to measure functional durability. The time-distance variables of the walk will be evaluated by Optogait (Microgait Company, Bolzano, Italy). The hiking band and the Optogait device are clinical devices. The OptoGait system includes 10 data retention bars positioned parallel to each other between 1.20 m (10m x 1.20m). On each rod, 96 LED diodes are placed at a height of 3 mm from the ground, 1 cm apart. According to the design of the device, when the patient passes between two bars positioned parallel to the floor, the device detects the communication interruptions between the bars caused by his

feet. Calculates the duration and location. In addition, timing, size and distance are detected, time-distance characteristics are automatically calculated (12,13). OptoGait not only identifies numerical data, but also enables it to perfectly synchronize with the events that detect the images of the tests performed via small cameras that can be positioned freely (13).

Evaluation of Progress Rate

A transition date to the upper exercise will be recorded. The duration of the entire program will be calculated in days.

Exercise Compliance

The Exercise Adherence Rating Scale (EARS), which evaluates exercise compliance, will be administered 2 times to determine change at eight weeks and third month. This scale consists of 3 parts: A, B, C. Section A, consists of 6 items not included in the scale scoring. Section B consists 6 items, and every item have five point likert scale and describes how to do the recommended home exercise. Minimum point for this section 0, and maximum point is 24. The higher score shown exercise adherece is high. Section C is the section that evaluates the reason for the absence of compliance with the recommended home exercise and contains 10 items, every item have five point likert scale. Sections are calculated to result in a possible score between 0 and 40. The higher score shown exercise adherece is high.

Also, patients will be questioned with Visual Analog Scale in every session and at 3 months after treatment if he / she is doing home exercises. For the Visual Analog Scale, a horizontal line of 10 centimeters on A4 paper will be used. Most right point of the scale represents “I've never done my exercise.” while mot left point of the scale “I've done all my exercise.”. The patient will be asked to mark the appropriate place.

Learning Forms

The following question will be used to classify the learning styles of people exercising. Although there are scales that question academic learning styles, there is no scale that questions a new skill learning. Based on the previously developed scales, the following question was formed.

What do you do first to learn a new job (eg, cooking, changing a car tire, a dance figure)? (Please give the number of the routes you use in order of priority.)

- I follow the maker, ask someone to show them or look at the picture books (This option questions the use of visual strategy)
- I try it myself, I try to do this (This option questions the use of motion kinesthetic senses)
- I would like someone to tell (this option questions the use of auditory senses)

Item 7a. How sample size was determined

For the calculation, version 2.9.1.2 of the G * Power software was used (14). The preliminary (a priori) power calculation protocol, the effect size for the pain variable, was calculated as 1.23 based on a study by Amit et al (15). Type I error probability was 0.05 and power was accepted as 0.80. The distribution rate of groups 1 is assumed. As a result, the number of people to be taken for each group is calculated as 12. Assuming that the loss of patients during the treatment will be 10%, it is expected to complete the study with 30 patients in total.

Item 8a. Method used to generate the random allocation sequence

We used sequentially numbered, opaque sealed envelopes (SNOSE), for randomization with block size 10 and allocation ratio 1:1. Participanst will be erolled to the study by MD Erkan Sümer, and asiggned to the intervention by Özlem Ulger with use of SNOSEs.

Item 11a. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

The patient's group will not be written on the evaluation paper, so they will be kept from researcher Aynur Demirel.

Item 12a. Statistical methods used to compare groups for primary and secondary outcomes

For descriptive statistics of quantityative variables; average, median, standard deviation, inter-quartile width will be given while for qualitative data; numbers and percentages will be used.

If the parameters provide normal distribution conditions, then parametric tests will be used for analysis. For the data to be considered significant, it will be desirable to be in the range of $p < 0.05$.

For intra-group and inter-group comparisons, the ANOVA test (in-between interactions) will be used which examines the intergroup and intergroup interaction. G-power software will be used to determine the power of statistical tests.

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