

Cover page

Official Title of the study:

Investigation of Real-time Diagnostic Ultrasound as a Means of Biofeedback Training in Transversus Abdominus Re-education of Patients With Non-specific Low Back Pain: Prospective Randomized Controlled Pilot Study

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Background: It is believed that ultrasound-guided imaging of activation/contraction of the deep abdominal muscles (such as transversus abdominis) is useful for assisting deep muscle re-education, which is often dysfunctional in non-specific low back pain (NSLBP).

Objective: This pilot study's objective was to evaluate the use of real-time ultrasound (US) as a feedback device for transverse abdominis (TrA) activation/contraction during an exercise program in chronic NSLBP patients.

Methods: Chronic NSLBP patients are recruited and randomly assigned to an US-guided or control group. The same motor control-based exercise program is applied to both groups. All patients receive physiotherapy twice per week for 7 weeks. Outcome measures, test at baseline and post-intervention, include Numeric Pain Rating Scale (NPRS), TrA activation level (measured through a pressure biofeedback unit-based developed protocol), seven established motor control tests, Roland-Morris Disability Questionnaire (RMDQ) and Hospital Anxiety and Depression Scale (HADS).

Statistical Analysis Plan: Analysis of variance utilizing a two-way mixed analysis of variance (ANOVA) model for dependent measures of two factors (treatment group and time point of measurement) of which only one is repeated (time point of measurement) is performed to determine whether there were between- and within-group differences before and after treatment. Independent samples' t-test and paired samples' t-test are also used for differences between and within groups, respectively. An χ^2 test was also conducted for differences on the motor control tests and the TrA activation level procedure across the groups.