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The effect of Capacitive and Resistive electric transfer on non-specific chronic low back pain

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ABSTRACT
The objective of this study was to evaluate the effect of Capacitive and Resistive electric transfer (CRet)-combined exercise therapy for participants with non-specific chronic low back pain (NSCLBP). Twenty-six received only the exercise program (E group, n = 15), or received both CRet and the same exercise program (E+CRet group, n = 11). Pain intensity, functional disability and trunk function were measured pre-, and post-intervention and there was also a 1-month follow-up period. Data analysis was performed for each index using the Mann–Whitney U test for comparisons between two groups at each time point, and the Wilcoxon signed-rank test for comparison between each time point within the group. The results of this study indicate that pain intensity was improved in both groups at post-intervention, also, the effect continued during follow-up period. In addition, functional disability was significantly improved in the E+CRet group at the post-intervention and during the follow-up period. The intervention effect on NSCLBP was higher in the E+CRet group than the E group. CRet, which is a form of deep thermotherapy, combined with exercise have a possibility of more effectiveness than exercise alone.

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KEYWORDS
Capacitive and Resistive electric transfer; non-specific chronic low back pain; exercise; pain intensity; functional disability

Introduction

It has been well documented worldwide that low back pain (LBP) is a common and costly condition (Allegri et al. 2016) Sixty to eighty percent of people will suffer at least one episode of LBP sometime in their lives (Frymoyer et al. 1991), and 22–65% of these will experience LBP during 1 year (Laslett et al. 1991; Walker 2000). LBP is usually divided into specific or non-specific subgroups; specific LBP is attributed to a recognizable and known pathology (e.g., infection, tumor, osteoporosis, lumbar spine fracture) and the non-specific LBP is due to unrecognizable unknown pathologies. Specific LBP occurs in approximately 2–5% of all patients with back complaints (Allegri et al. 2016), thus majority are non-specific. Non-specific chronic LBP (NSCLBP) lasting for more than 3 months, is more difficult to treat and the outcome maybe uncertain (Gordon and Bloxham 2016). Therefore, it is important to research the treatment of NSCLBP.

Non-pharmacological methods including a variety of physical agents are the cornerstone for the management of NSCLBP. Several management approaches have been used in NSCLBP with varying degrees of success. Physiotherapy is central to the overall management of LBP in the chronic phase. In clinical practice, various physiotherapeutic modalities including exercise therapy, manipulation, back care education, thermotherapy, cryotherapy, transcutaneous electrical nerve stimulation (TENS), and traction have been used (Farber and Wieland 2016; Hayden et al. 2005a; Poquet et al. 2016; Wegner et al. 2013). According to Cochrane reviews, exercise and superficial thermotherapy have moderate therapeutic evidence (French et al. 2006; Hayden et al. 2005a). Exercise is the most useful method in clinical practice, because it does not necessarily require specific machines and have been evidenced to treat LBP. Home exercises combined with therapist supervision have been identified as the most effective strategy for patients with NSCLBP (Hayden et al. 2005b). On the other hand, thermotherapy has been evidenced to treat LBP, but it is recommended to combine this with exercise therapy because the effect of thermotherapy alone is small. Additionally, thermotherapy is classified into superficial and deep subgroups. In general, superficial thermotherapy is referred to as the heat therapy that causes vasodilation and increases the temperature only in the skin and superficial tissues; while deep

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thermotherapy is that which causes vasodilation, and increases the temperature in the deep tissues. Thus, deep thermotherapy is considered to have better effect on LBP than superficial thermotherapy.

Previously, deep thermotherapy, ultrasound and diathermy were frequently used in clinical practice. These therapies improve hemoglobin saturation and increase the temperature of deep tissues more than superficial thermotherapy (Draper et al. 1998, 1999; Lehmann et al. 1978); however, these devices are infrequently being used to treat LBP due to some demerits. Ultrasound energy concentrates around bony tissues thus, ultrasound therapy has the risk of periosteal inflammation (Batavia 2004; Cameron 2009). In addition, ultrasound therapy covers a relatively small area, because its effect reportedly reaches only twice as much as the irradiation area of the transducer. As most diathermy devices with frequencies of 8–14 MHz produce excessive heat during treatment, which can cause skin burns, a protective device, called a polus, must be kept between the skin and electrode (Carr et al. 1995; Hui et al. 2011). Recently, a system of Capacitive-Resistive electric transfer (CRet), which is one of the methods used in diathermy, was developed as a form of deep thermotherapy (Kato et al. 2013). This device delivers radiofrequency (RF) energy, which passes between active and inactive electrodes, and generates heat in the human body (Hawamdeh 2014; Osti et al. 2015). CRet does not require a polus or surface-cooling system because it utilizes about 448 kHz, which is lower than that used in conservative diathermy, and it does not cause excessive heat generation between the skin and the electrode; thus, this is safer to use than other diathermy devices. In addition, our previous study showed that this device improves hemoglobin saturation and causes warmer deep tissues than the hot packs in superficial thermotherapy (Tashiro et al. 2017). The objective of this study was to evaluate the effect of CRet-combined exercise therapy for participants with NSCLBP.

Materials and methods

Participants

The participants, nurses or rehabilitation staffs were recruited from two hospitals in Kyoto, Japan within Apr 2016 to Apr 2017. Written informed consent was obtained from each participant in accordance with the guidelines of the Kyoto University Graduate School of Medicine and the Declaration of Helsinki, 1995. This study protocol was approved by the ethical review committee of the Kyoto University Graduate School of Medicine (C1177).

Inclusion and exclusion criteria

Participants were aged between 20 and 50 years with pain in the lower back between L1 and L5. They had LBP for duration of more than 3 months, as well as signs and symptoms that were interpreted as referred from the lumbar spine and no other organs. Participants were excluded by the use of questionnaires and interviews for the presence of underlying diseases or conditions such as malignancy, obvious disc herniation, osteoporosis, viscerogenic causes, infection or systemic diseases of the musculoskeletal system; neurologic or sciatic nerve root compression, radicular pain, sensory disturbances, loss of strength and reflexes; previous back surgery; evidence of previous vertebral fractures or major abnormalities; tumors of the spine; pregnancy; presence of devices such as heart pacemakers that may be affected by electrical stimulation; persons registered as disabled or those receiving any type of benefit because of their LBP.

Participants assigning

Participants were asked to attend initial evaluation in order to fill in questionnaire, supervised by a physiotherapist not involved in the patient therapies and blinded to the treatment group. We conducted an initial evaluation to 87 people and 33 people matched inclusion criteria; however, 3 people declined participating in this study after explaining this study. We assigned only the exercise program to participants in one hospital's staffs, and both CRet and the same exercise program to participants in the other hospital's staffs (Figure 1). Participants are concealed that the intervention conducted at other hospitals for blinding, and each participant were told that the intervention is good for LBP for aiming at reducing placebo effect.

Experimental procedure

The E group (n = 16) received only the exercise program, while the E+CRet group (n = 14) received both CRet and the same exercise program. Participants in both groups received 10 sessions of the intervention, two or three times a week, every other day. Exercises were uploaded to a closed website for the participants, and the number of execution was counted on this website. Participants were required not to take pain medications during the intervention and not to engage in any other exercise or treatment program. The measurements were performed pre-, and post-intervention and there was also a 1-month follow-up period.

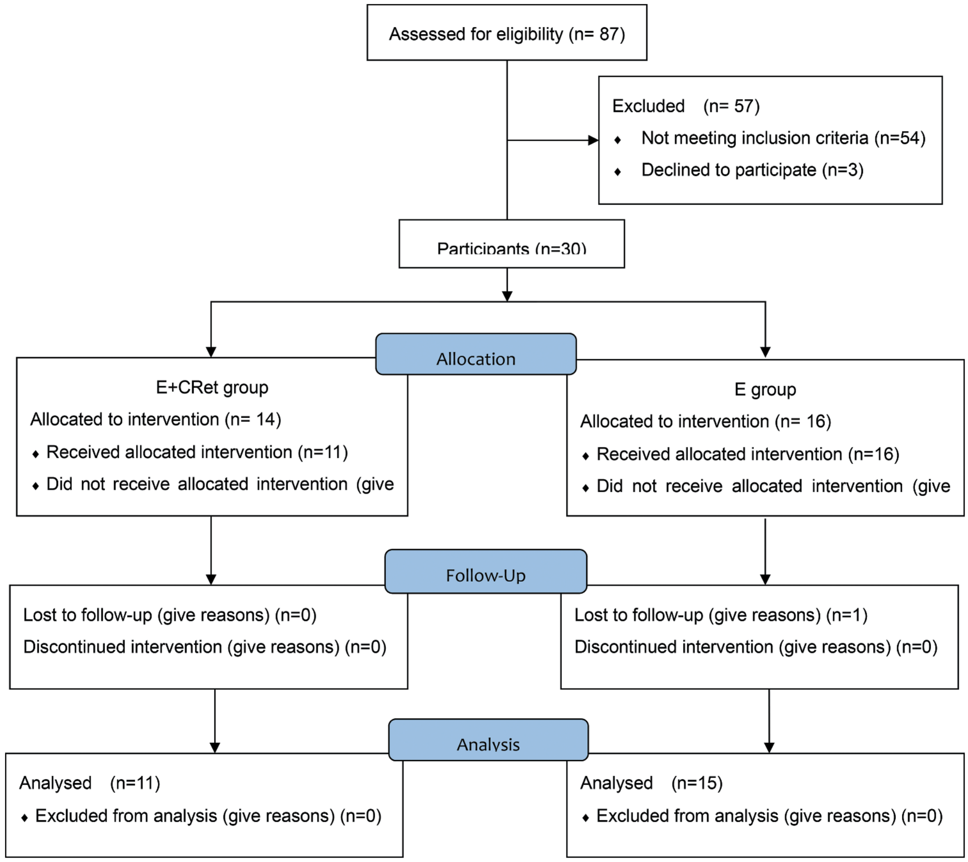

Figure 1. Flow diagram.

Intervention

Exercise therapy

A semi-supervised exercise program was developed. The program included McKenzie, Williams, cat and dog and bridge exercises, respectively, as well as posterior pelvic tilts, anterior and posterior hip and knee muscles stretches (Gordon and Bloxham 2016; Hayden et al. 2005b). We made a 7 to 8 minutes' video that combined these exercises as a home exercise program (Figure 2).

CRet intervention

Indiba® active Pro Recovery HCR 902 (Indiba S. A., Barcelona, Spain) was used for the CRet intervention (Figure 3). This device operates at a frequency of 448 kHz. A rigid circular metallic electrode with a diameter of 65 mm was used as active electrode while a large flexible rectangular metallic plate (measuring 200 × 260 mm) was used as the inactive electrode. The device delivered radiofrequency (RF) energy in two modes; capacitive (CAP) and resistive (RES) at the active electrode. The CAP electrode has a polyamide coating

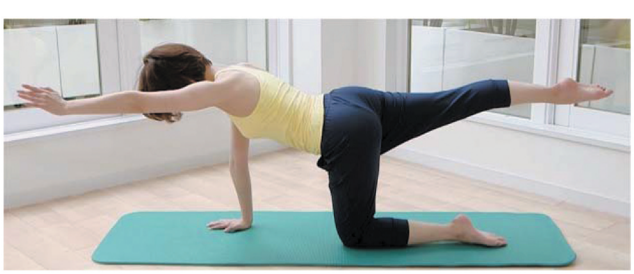

Figure 2. A schedule of the exercise program.

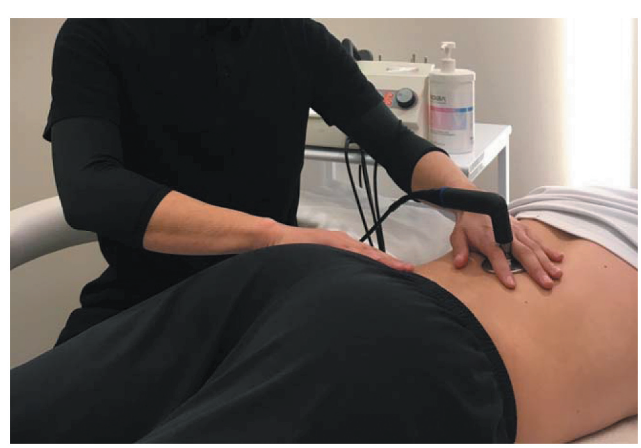

Figure 3. The Capacitive and Resistive electric transfer (CRet) intervention.

that acts as a dielectric medium, insulating its metallic body from the skin surface, thus it generates heat externally near the skin. The RES electrode is uncoated and the RF energy travels directly through the body into the inactive electrode; thus, it generates heat in the deeper parts of the body. There are several contraindications of CRet intervention (e.g. pregnancy, deep vein thrombosis, hypoesthesia, damaged skin, or presence of an implanted pacemaker).

In the E+CRet group, the participants applied a total of 15 minutes' intervention (5 minutes in CAP and 10 minutes in RES). We selected the intervention time based on our previous study to discover the CRet intervention effect on hemoglobin saturation and tissue temperature (Tashiro et al. 2017). A manufacturer-supplied conductive cream was employed as a coupling medium between the electrode and the skin surface during the intervention. The intervention was applied at the lower paraspinal muscle; therefore, the participants were asked to lie down in a prone position on a bed to receive it. The inactive electrode was placed on the skin of the epigastric area. The intensity was defined as 6 or 7 on a subjective 11-point analog scale that the participants used to self-report thermal sensing (0, no thermal sensing; 10, worst possible thermal sensing) according to the manufacturers' recommended safety instructions. We performed experiments to measure the applied power and found that 5 min of CAP and 10 min of RES intervention provided 7.1 ± 1.2 kJ and 60.3 ± 5.3 kJ, respectively, at previous study (Tashiro et al. 2017). The conductive cream was cleaned up after the thermal intervention.

Measurements

Demographic data

Data, including age, sex, and height were self-reported. Weight was measured in their street clothes without their shoes on a scale. Body mass index (BMI) was calculated by dividing the weight by square of the height. Data were collected at the study onset and end. In addition, the individual duration of the onset of LBP was recorded.

Pain intensity

Participants were asked to rate the intensity of their pain during the last week on a visual analogue scale consisting of a 100-mm line anchored with the word 'no pain' at one end and 'unbearable pain' at the other.

Functional disability

Functional disability was measured with the Oswestry Low Back Pain Disability Questionnaire. This comprised of 10 sections that asked questions about the difficulty in lifting, walking, sitting, etc., and the effect of these difficulties on their daily living activities and social life. Each section evaluated LBP in daily living activities and social life. Each section was scored on a 6-point-scale (0–5); with 0 representing no limitation and 5, the maximal limitation. The subscales added up to a total score of 50. The score was then doubled and interpreted as the percentage of the subject-perceived disability, where the higher the score the greater the disability.

Trunk function

The modified Kraus–Weber tests were administered to the participants according to the procedure described below (Moreira et al. 2012). The participants were shown how to do each test-item correctly and then they were asked to perform the same test-item to confirm their capacity. Test 1: 'Abdominals Plus Psoas' the subjects laid supine with their hands behind their necks. Their feet were held down by the examiner. On command, the subjects rose to sitting position. This was a test of the abdominal and psoas muscles strength. Test 2: 'Abdominals Minus Psoas' the subjects laid supine, with their hands behind their necks and their knees bent. Their feet were held down. On command, the subjects tried to rise up into sitting position. This was a further test of abdominal muscles strength without the psoas. Test 3: 'Psoas' – the subjects laid supine with their hands behind their necks and their legs extended. On command, their feet were lifted 25 cm (10 inches) above the ground and maintained at that height for 10 s. This was a test for the strength of the psoas and lower abdominal muscles. Test 4: 'Upper Back' – the subjects laid prone with pillows under their abdomen but far low enough to give a seesaw effect. The subjects held their hands behind their necks. The examiner held down their feet and asked them to raise up their chests, heads, and shoulders and maintain them at that position for 10 s. This test was for the strength of the upper back muscles. Test 5: 'Lower Back' – the subjects laid prone over pillows and placed their hands in front and rested their heads on them. The examiner held their chests down and asked them to lift their legs up without bending the knees and maintain that position for 10 s. This was the test for the strength of the lower back muscles. Test 6: 'Back and Hamstrings' – the subjects stood erect with their hands by the sides and feet held together. On command, they leaned down slowly to touch the floor with their fingertips. Their knees were kept straight and the leaning down position was maintained for 10 s. No bouncing to touch the floor was allowed. This tested the flexibility and the length of the back and hamstrings muscles. Each test was scored between 1 and 5 points and the total points were used in the data analysis.

Statistical analyses

Data analysis was performed for each index using the Mann–Whitney U test for comparisons between two groups at each time point, and the Wilcoxon signed-rank test for comparison between each time point within the group. Statistical analyses were performed using the SPSS version 20.0 (IBM Corp., Armonk, NY, USA), with a significance threshold of 0.05 in the Mann–Whitney U test, and 0.016 for the comparison of the 3 time points in the Wilcoxon signed-rank test.

Results

A total of 26 participants were analysed in the study: 15 in the E group, 11 in the CRet+E group. The E group had one dropout participant because of transferring her job, and the CRet+E group had three dropout subjects that two of them could not finish intervention within the intervention period, and another no longer continued the study because busyness of work. The background data and characteristics of the participants in each group have been shown in Table 1. There was no significant difference between the two groups.

Post-intervention effects

Within-group changes

Significant improvement in pain intensity was observed in both groups ($p < .016$), and functional disability was significantly different only in the E+CRet group. The changes in the Kraus–Weber test did not show any statistical significance, however, the scores improved in each group (Table 2).

Table 1. Background data and characteristics of patients in each treatment group.

	E group (n = 15)	E+CRet group (n = 11)	*P* value
Age (years)	33.7 (24.0–45.0)	32.9 (22.0–46.0)	NS
Female (n/%)	13/86.6	9/81.8	NS
Height (cm)	159.5 (151.2–171.2)	158.0 (152.4–172.5)	NS
Weight (kg)	55.4 (50.4–70.5)	54.3 (49.3–69.3)	NS
Body mass index	21.9 (19.5–25.1)	21.5 (18.9–25.2)	NS
Duration (months)	13.5 (4–80.5)	8.9 (5–60.5)	NS
Pain intensity (mm)	35.7 (5.0–83.0)	39.6 (9.0–74.0)	NS
ODI (%)	18.9 (4.0–34.0)	21.2 (4.0–42.0)	NS
KWT	20.4 (11.0–33.0)	18.3 (13.0–30.0)	NS

NS, non-significant.

Table 2. Changes of pain and trunk function in each group.

	Pre	Post	1-month follow-up
VAS (E+ CRet group)	39.6 (9.0–74.0)	10.1 (0–35.0)*§	10.3 (0–37.0)†
VAS (E group)	35.7 (5.0–83.0)	23.0 (0–52.0)*§	15.6 (0–60.0)†
ODI (E+ CRet group)	21.2 (4.0–42.0)	10.3 (4.0–16.0)*	10.1 (0–16.0)†
ODI (E group)	18.9 (4.0–34.0)	14.3 (2.0–20.0)	15.2 (0–20.0)
KW (E+ CRet group)	18.3 (11.0–30.0)	23.6 (12.0–37.0)	23.0 (15.0–37.0)
KW (E group)	20.4 (11.0–33.0)	24.5 (14.0–34.0)	24.2 (14.0–34.0)

*$p < 0.016$ pre vs post (Wilcoxon signed-rank test).
†$p < 0.016$ pre vs follow up (Wilcoxon signed-rank test).
§$p < 0.05$ E+CRet group vs E group (Mann–Whitney U test).

Between-group differences

Pain intensity showed significant difference between the two groups ($p < .05$). No significant difference was found between the two groups in terms of the functional disability and the Kraus–Weber test (Table 2).

Effects of intervention after 1-month follow up

Significant improvement in pain intensity and functional disability was observed in the CRet and Exercise group ($p < .016$); however, in the E group, pain intensity was significantly different only following the intervention, on the other hand, functional disability was not significantly different. The changes in the Kraus–Weber test did not show any statistical significance, however, the scores improved during the pre-intervention in each group (Table 2).

Discussion

The results of this study indicate that pain intensity was improved in both groups at post-intervention, also, the effect continued during follow-up period. In addition, functional disability was significantly improved in the E +CRet group at the post-intervention and during the follow-up period, thus the exercise combined CRet therapeutic approach was considered more effective for NSCLBP participants than the exercise approach alone.

The results showed that pain intensity improved after 10 sessions of intervention and continued over 1-month in both groups. There were several causes for the NSCLBP including the intervertebral disc, facets joint, muscle and fascia (Allegri et al. 2016). Exercise affected these causes and improved NSCLBP. In a study by Franca et al., segmental stabilization and strengthening exercises effectively reduced pain and functional disability in individuals with chronic low back pain (Franca et al. 2010). Exercises and movements caused alternate compression and relaxation of the articular cartilage, and ensured the movement of the synovial fluid into the articular cartilage as the area of pressure changed superficially (O'Sullivan et al. 1997). In addition, Sung investigated the changes in multifidus, paraspinal and abdominal muscle endurance as well as functional status after a 4-week supervised spinal stabilization exercise program among 16 patients presenting with chronic low back dysfunction. Results showed that pain intensity significantly improved from pre- to post- treatment. Sung concluded that a 4-week spinal stabilization exercise program significantly improved LBP and trunk functional status in patients presenting with low back dysfunction. In this study, exercise programs were configured for trunk stabilization, trunk movement, as well as anterior and posterior hip and knee muscles stretches. Thus, in this and the previous studies, exercise improved LBP in both groups.

The pain intensity of the E+CRet group during post-intervention was significantly lower than that of the E group. Thermal stimulation affected the pain reduction directly or indirectly by suppressing ischemia and spasticity or promoting tissue healing (Benson and Copp 1974; Lehmann et al. 1958). The stimulation of the temperature receptors increases vasodilation and alleviates the pain due to ischemia. The relief of the ischemic pain is due to the phenomenon of spasticity, which compresses the blood vessels. Ischemia may be improved by a reduction in spasticity that compresses blood vessels. In addition, vasodilation caused by hyperthermia improves tissue healing and encourages local pain sensory thresholds to recover to normal levels. Our previous study revealed that CRet improved hemoglobin saturation and warmed up deep tissues (Tashiro et al. 2017). Thus, CRet intervention suppressed ischemia, and spasticity and promoted the reduction of pain intensity better than the exercise alone intervention.

Furthermore, functional disability tended to improve in the E+CRet group than in the E group. Functional disability test asked questions about difficulty in lifting, walking, sitting, etc., and the effect of these difficulties on daily living activities and social life. Our previous study showed that CRet intervention improved muscle flexibility and blood circulation (Bito et al. 2019; Yokota et al. 2017). When soft tissues are warmed before stretching, elongation after stretching is maintained, the force required to achieve this elongation is small, and the risk of tissue rupture is reduced (Warren et al. 1971, 1976). Elastic deformation is obtained if thermal energy is applied to collagenous soft tissues such as tendons, ligaments, scar tissues, joint capsules, etc., before sustained stretching, that is, tissues are extended and maintained after cooling (Gersten 1955; Lehmann et al. 1970). It seems that functional disability has improved because the body changed to a condition that is less likely to cause damage even under various loads for the combination of CRet and exercise intervention. Thus, in this study, CRet intervention promoted the effect of the exercise program and improved functional disability.

This study had some limitations. Firstly, the participants were not divided randomly and small sample. However, blinding and consideration for aiming at reducing placebo effect were conducted, and there is significant difference in this study even though small sample. Normally, the standardized effect size is set to 0.8, α error = 0.05, β error = 0.20, and considering the possibility of 10% dropout during the experiment, 23 subjects in each group are required. However, at this time, the evidence of CRet is quite insufficient in the recent review (Binoy and Watson 2015; Duñabeitia et al. 2018). Thus, our study is meaningful even if the small sample. Secondly, the follow-up period is comparably shortly. Shortwave which is a slightly different frequency from CRet, some evidence of chronic back pain is also introduced in this review (Binoy and Watson 2015), but among them there are articles that have no follow-up, almost the same 6-week follow-up is used (Ahmed et al. 2009; Shakoor et al. 2008). Therefore, it is considered to be an important evidence accumulation even if short follow-up. Thirdly, the age range limited to the young adult population. For the elderly, the cause of low back pain is diversified, and there is a high possibility of being combined (spinal canal stenosis, compression fracture, deformation, etc.). The exercise intervention effect also reviewed for only elderly (Kuss et al. 2015), so elderly people were excluded and limited to young adults in this study. Despite these limitations, findings from the present study provide valuable information on the effect of the CRet intervention.

Conclusion

The intervention effect on NSCLBP was higher in the E +CRet group than the E group in this study. CRet, which is a form of deep thermotherapy, combined with exercise is capable of treating LBP have possibility more effective than exercise alone.

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Declaration of interest

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