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448 khz Capacitive Resistive Monopolar Radiofrequency and a Supervised Exercise Programme in Patients with Lateral Elbow Tendinopathy? A Research Protocol

Dimitrios Stasinopoulos[1]*, Antonis Constantinou[2], Areti-Zoi Cheimonidou[3] and Dimitrios Lamnisos[4]

[1]Assistant Professor of Physiotherapy, Department of Physiotherapy, Faculty of Health and Caring Sciences, University of West Attica, Member of Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM), Athens, Greece

[2]Physical Therapist/Clinical Trainer, Cyprus Musculoskeletal and Sports Trauma Research Centre (CYMUSTREC), Department of Health Sciences, Physiotherapy Program, School of Sciences, European University of Cyprus, Nicosia, Cyprus

[3]Physical Therapist/Clinical Trainer, Department of Health Sciences, Physiotherapy Program, School of Sciences, European University of Cyprus, Nicosia, Cyprus

[4]Chairperson/Assistant Professor of Biostatistics, Co-ordinator of Msc in Public health, Department of Health Sciences, Cyprus Musculoskeletal and Sports Trauma Research Centre (CYMUSTREC) Physiotherapy Program, School of Sciences, European University of Cyprus, Nicosia, Cyprus

***Corresponding Author:** Dimitrios Stasinopoulos, Assistant Professor of Physiotherapy, Department of Physiotherapy, Faculty of Health and Caring Sciences, University of West Attica, Member of Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM), Athens, Greece.

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Abstract

Background: One of the two most common tendinopathies of the upper limb is Lateral elbow Tendinopathy (LET). An exercise programme consisting of static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors, Tendon Neuroplastic Training (TNT) of wrist extensors, and strengthening of rotator cuff, scapula muscles exercises and supinator has been recommended for the management of LET. 448 kHz Capacitive Resistive Monopolar Radiofrequency (CRMRF) is usually used as a supplement to exercise programme. The purpose of the present article will be to make a comparison of the effects of an exercise programme consisting of TNT of wrist extensors, static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors and strengthening of supinator, rotator cuff and scapula muscles exercises and an exercise programme consisting of TNT of wrist extensors, static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors and strengthening of supinator, rotator cuff and scapula muscles exercises and 448 kHz CRMRF for the treatment of LET.

Methods/Design: LET patients will participate in this randomized clinical trial (RCT). Patients will be allocated to two groups randomly. Group A will be treated with TNT of wrist extensors, static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors and strengthening of supinator, rotator cuff and scapula muscles exercises and group B will be treated with TNT of wrist extensors, static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors and strengthening of supinator, rotator cuff and scapula muscles exercises and 448 kHz CRMRF. All patients will receive 20 treatments totally (5 treatments/week for 4 weeks). Pain (visual analogue scale), function (visual analogue scale) and pain-free grip strength will be evaluated at the end of treatment, at 3 months follow-up and at 6 months follow up. The independent t test will be used to determine the differences between groups. A paired t test will be used to determine the difference within groups. The level for statistical significance will be 5% level of probability. SPSS 21.00 will be used for the statistical analysis

Discussion: The present RCT will be evaluate the effectiveness of 448 kHz CRMRF as a supplement to exercise programme in patients with LET.

Trial Registration: The Cyprus Ethics Committee will approve the study.

Keywords: *Monopolar Radiofrequency; Lateral Elbow Tendinopathy (LET); Extensor Carpi Radialis Brevis (ECRB)*

Introduction

The most appropriate term to use in clinical practice is Lateral elbow tendinopathy (LET) because all the other terms such as lateral epicondylalgia, lateral epicondylosis, lateral epicondylitis and/or tennis elbow make reference to inappropriate pathophysiological, aetiological and anatomical terms [1]. One of the most common lesions of the arm work-related or sport-related pain disorder is LET. LET is a syndrome of pain in the area of the lateral epicondyle [2] that may be failed healing tendon response or degenerative rather than inflammatory [3]. Hence, vascular hyperplasia, proteoglycans and glycosaminoglycans, the increased presence of fibroblasts together with disorganized and immature collagen may all take place in the absence of inflammatory cells [4]. The origin of the extensor carpi radialis brevis (ECRB) is the most commonly affected structure [4]. The dominant arm is commonly affected, between 30 and 60 years of age is the peak prevalence of LET [2,5] and the disorder appears to be severed and of longer duration in women [3,6].

The main complaints of patients with LET are decreased function and pain [2,3]. A therapist should be able to reproduce the symptoms by: (1) resisted wrist extension and/or resisted middle-finger extension with the elbow in extension, (2) getting the patient to grip an object and (3) digital palpation on the facet of the lateral epicondyle [2,3,5].

No ideal treatment has emerged for LET management. A conservative approach is advocated by many clinicians as the treatment of choice for LET [2,3,7,8]. Physiotherapy is usually recommended for LET patients [2-9]. A wide array of physiotherapy treatments has been recommended for the management of LET [10-14]. Such a variety of treatment techniques suggests that the optimal treatment management is not known and more research is needed to find out the most effective treatment approach in patients with LET [10-14].

An exercise programme is the most common physiotherapy treatment for LET [2-14]. There are two types of exercise programs: home exercise programs and exercise programs carried out in a clinical setting. A home exercise program is commonly advocated for patients with LET because it can be performed any time during the day without requiring supervision by a physiotherapist. Our clinical experience, however, has shown that patients fail to comply with the regimen of home exercise programs [15]. This problem can be solved by exercise programs performed in a clinical setting under the supervision of a physiotherapist. For the purposes of this report, ‘‘supervised exercise program’’ will refer to such programs. Therefore, such a supervised exercise program will be used in the present trial.

Although a supervised exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period. One such modality is 448 kHz Capacitive Resistive Monopolar Radiofrequency (CRMRF) which is a relatively new treatment approach, but it is reported to be used by clinicians worldwide. To our knowledge, the effectiveness of 448 kHz CRMRF in the management of LET has not been investigated. It is possible to combine, a supervised exercise programme with 448 kHz CRMRF to see if the combination of the above reported therapeutic approaches offers superior results to supervised exercise programme alone in LET patients. Therefore, the aim of the present article will be to make a comparison of the effects of an exercise programme consisting of Tendon Neuroplastic Training (TNT) of wrist extensors, static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors and strengthening of supinator, rotator cuff and scapula muscles exercises with 448 kHz CRMRF and an exercise programme consisting of consisting of Tendon Neuroplastic Training (TNT) of wrist extensors, static stretching exercises of wrist extensors, isometric of wrist extensors, concentric - eccentric training of wrist extensors and strengthening of supinator, rotator cuff and scapula muscles exercises without 448 kHz CRMRF for the treatment of LET.

Methods

To assess the effectiveness of an exercise programme with 448 kHz CRMRF in the management of LET a randomized controlled, monocentre trial will be conducted in the Cyprus Musculoskeletal and Sports Trauma Research Centre (CYMUSTREC) for 12 months. Crossover designs are limited in situations where patients are cured by the intervention and do not have the opportunity to receive the

other treatments after crossover, therefore a parallel group design will be used [16]. Three investigators will participate in the study: (1) a physiotherapist (AC) who will perform all baseline and follow-up assessments, and will gain informed consent a physiotherapist, (2) a physiotherapist, (AZC), who will administer the treatments. and (3) the primary investigator, (DS) who will evaluate the patients to confirm the LET diagnosis and will allocate patients to groups. AC will interview each patient to ascertain clinical characteristics, including patient name, sex, age, duration of symptoms, previous treatment, occupation, affected arm and dominant arm and baseline demographic.

To demonstrate statistical clinical significance for all outcome measures on lateral epicondylitis a sample size of 25 subjects per group is sufficient. Measuring pain relief and functional outcomes in response to physiotherapeutic interventions such as low-power laser light, clinical effects of 20% had been reported as clinically meaningful in placebo-controlled studies. Baseline variance for pain and functional outcomes will be set at 25% in this study. Power calculations will recommend that 25 patients per group is sufficient to detect a 20% change in outcome measures, assuming that variance will be equivalent to 25% with a 5% significant level and 80% of power. The formula that will be used to determine the proper sample size will be:

$N = 16\sigma^2/d^2$

where d^2 is the effect size and σ^2 is the variability of the data. For example, in our trial $\sigma = 25$ and $d = 20$. Therefore the above formula is $N = 16(25^2)/(20^2) = 16\chi625/400 = 25$.

Patients over 18 years old with lateral elbow pain will been evaluated and examined in the CYMUSTREC in Nicosia between April 2020 and April 2021. All patients will live in Cyprus, will speak Greek and will be either referred by their physician or physiotherapist or self-referred.

Patients will participate in the study if, at the time of presentation, they will have been clinically diagnosed LET for at least 4 weeks. Patients will participate in the trial if they report (a) less pain during resistance supination with the elbow in 90◦ of flexion rather than in full extension and (b) pain on the facet of the lateral epicondyle when palpated and (c) pain in at least two of the following four tests [7]:

1. Handgrip dynamometer test.
2. Mill's test (full passive flexion of the wrist).
3. Tomsen test (resisted wrist extension).
4. Resisted middle finger test.

Patients will not participate in the study if they have one or more of the following conditions: (a) radial nerve entrapment; (b) dysfunction in the shoulder, neck (radiculopathy) and/or thoracic region; (c) neurological deficit; (d) had received any conservative treatment for the management of LET in the 4 weeks before entering the study; (e) the affected elbow had been operated on (f) limitations in arm functions; and (g) local or generalized arthritis [16-20].

A written explanation of the trial prior to entry into the study will be received by all patients. All patients will sign an informed consent to take part in the study. The Cyprus Ethics Committee will be approving the study.

The allocation of the patients to two groups will be done randomly by drawing lots. Patients in Group A will be treated with a supervised exercise programme and patients in Group B will be treated with the supervised exercise programme and 448 kHz CRMRF.

All patients will be instructed to use their arm during the course of the study but to avoid activities that will irritate the elbow such as knitting, lifting, driving a car, using a screwdriver, grasping and handwriting. They will also be informed to refrain from taking pain killer drugs or other conservative treatment throughout the course of the study. A treatment diary will be used to monitor Patient compliance.

Interaction (verbal and non-verbal) and communication between the patient and therapist will be kept to a minimum, and behaviours sometimes used by physiotherapists to facilitate positive treatment outcomes will be purposefully avoided. For example, patients will be given no feedback on their performance in the pre-application and post-application measurements indication or any of the potentially beneficial effects of the treatments [21].

In both groups the elbow will be on the bed extended, the forearm pronated, the wrist in extension (and the hand hanging at the edge of the table. From this position, subjects will flex their wrists and then return to the extension (starting position). In the starting position, subjects will carry out an isometric contraction of wrist extensors. When the isometric contraction will finish the subjects will carry out the eccentric - concentric contraction and so on. The exercise will involve isolated wrist extension and flexion paced to an external audio/visual cue on the patients' smartphone (PR Metronome; http://eumlab.com/pro-metronome/). Subjects will be to track the movement and listen to the sound of the metronome with their eyes. Each beat will be ten seconds apart, so that the pace of the metronome will be settled to 6 beats per minute. This will allow a ten second eccentric, concentric and isometric phase [22].

Both groups will perform three sets of 15 repetitions of slow progressive exercises of the wrist extensors at each treatment, with 1-minute rest interval between each set. Subjects will be informed to continue with the exercise even if they complain of mild pain. However, subjects will be informed to stop the exercise if the pain becomes disabling. The disabling and mild pain will be monitored asking the subjects to rate the pain on VAS before and after treatment period. The definition of mild pain will be below 4 on VAS whereas the definition of disabling pain will be above 8 on VAS [17,19]. When subjects are able to carry out the exercise programme without experiencing any discomfort or pain, free weights will be used to increase the load.

Both treatment groups will perform static stretching exercises of the wrist extensors. Three times before and three times after the exercises six times totally will be repeated the static stretching exercises at each treatment session, with a 30 second rest interval between each repetition. The other hand will help to be performed the static stretching exercises of the wrist extensors. The patient's elbow will be placed in extended position, the forearm in pronated position, and the wrist in ulnar deviation and flexion according to the patient's tolerance. 30 - 45 seconds will be holding this position each time and then releases [17-20].

Furthermore, the scapular and rotator cuff muscles will be strengthened. The strengthening exercises will be included (i) shoulder lateral rotation and medial with the elbow in 90° and 0° of abduction; (ii) shoulder abduction to 90^0 with flexed elbow: (iii) scaption and (iv) diagonal pattern from flexion to extension [23]. Upper trapezius, rhomboids, serratus anterior and levator scapulae will be also strengthened [24]. Each exercise will be carried out twice at each treatment with 12 repetitions in each set and 1 min rest interval between each set [25]. Subjects will be informed to continue with the exercise even if they will complain of mild pain. However, subjects will be informed to stop the exercise if the pain became disabling. When subjects will be able to carry out the strengthening exercises without experiencing any discomfort or pain, the load will be increased using therabands or free weights.

Finally, the supinator will be strengthened. Strengthening exercises of the supinator will be carried out with the elbow extended on the table, the forearm pronated, the wrist in mid - position and the hand hanging over the edge of the table. From this position, the patient will supinate their arm slowly while counting to 15 using chronometer, then return to the starting position (pronation) [26].

The above reported exercise programme will be followed five times per week for 4 weeks and will be individualized on the basis of the patient's description of pain experienced during the process.

In group B patients will receive 448 kHz CRMRF intervention. The CRMRF at 448 kHz will be delivered using 'INDIBA Activ 902', a new factory calibrated device with a peak power of 200 W and 450VA, which deliver continuous-wave RF energy in two modes: Capacitive (CAP) and Resistive (RES), using metallic electrodes via a coupling medium. The CAP mode will be delivered in thermal dose (according

to patient feedback on his perception of moderate heating) in muscles around the elbow. CAP mode will be delivered 5 minutes for each muscle. The RES mode will be delivered in thermal (thermia or hyperthermia) in continuous wave. The RES mode will be delivered for 10 minutes. Finally, CAP mode in non-thermal dose will be delivered in the symptomatic area for 5 minutes. The return electrode will be placed in the scapular area. Treatment will be delivered once per day for five consecutive days providing twenty sessions in total.

Function, drop-out rate and pain will be measured in the present trial. Each subject will be evaluated at the beginning of the treatment (week 0), at the end of treatment (week 4), at 3 months after the end of the treatment (week 16) and at 6 months (28 weeks) after the end of treatment.

A visual analogue scale (VAS) will be used to measure pain. 0 (cm) on VAS means "least pain imaginable" and 10 (cm) on VAS means "worst pain imaginable". The pain VAS will measure the patient's worst level of pain over the previous 24 h before each evaluation, and this approach has been shown to be sensitive and valid of the VAS [27].

A visual analogue scale (VAS) will be used to measure function. 0 (cm) on VAS means "no function" and 10 (cm) on VAS means "full function". Subjects will be informed to report their overall level of elbow function over the previous 24h before each measurement, and this approach has been shown to be sensitive and valid of the VAS [27].

Moreover, pain-free grip strength will be used to measure function. The definition of Pain-free grip strength is the amount of force each patient is able to generate with an isometric gripping action before monitoring pain [21]. A Jamar hand dynamometer that had adjustable handles to accommodate different hand sizes will be used to measure force in pounds. The elbow will be placed in extension, forearm in pronation and internal rotation such that the palmar aspect of the hand faced posteriorly with the arm placed by the patient's side. Subjects will be then informed to squeeze the dynamometer handles until they will first experience pain and then to release their grip [21]. The attained grip force will be subsequently recorded. The reading will not be visible to the subjects. Three measures of pain-free grip strength will be determined with a 30 seconds rest interval between each effort, and the mean value of these repetitions will be calculated.

The rate of drop-out will also be used as an indicator of treatment outcome. Reasons for patient drop out will be categorised as follows: (1) not returned for follow-up; (2) request for an alternative treatment and (3) a withdraw without reason.

The change from the beginning of the treatment will be calculated for each follow-up. The independent t test will be used to determine the differences between groups. A paired t test will be used to analyze the difference within groups between beginning of the treatment and end of treatment. The level for statistical significance will be adopted as a 5% level of probability. The statistical analysis will be carried out using the SPSS 21.00 statistical software.

Discussion

The main aim of this RCT is to investigate the effectiveness of two physiotherapy treatments in improving function, strength, and pain in LET patients at the end of treatment, at 3 months follow-up and at 6 months follow up. It is expected to examine the following null hypothesis: "there is no difference in function and pain for subjects undergoing physiotherapy intervention with or without using 448 kHz CRMRF intervention". Many treatments have been recommended for the management of LET. However, there is not the gold standard treatment. Eccentric contraction is recommended [28,29] over other types of contractions for the management of LET. On the other hand, Malliaras and his colleagues [30] proposed that therapists should consider eccentric-concentric loading alongside or instead of eccentric loading. Martinez-Silvestrini., *et al.* [31] concluded that, unlike Achilles tendinopathy, LET is often related to forceful grip activities requiring isometric contraction, which would be more beneficial than eccentric contraction in LET. Recently, isometric exercises have been recommended to manage and reduce tendon pain improving the strength at the angle of contraction without producing inflammatory signs [32]. The exercise program in LET should include strengthening exercises for supinator, rotator cuff and scapular muscles [33,34].

Moreover, proprioception is also reduced in LET patients [35]. Techniques to improve the reduced proprioception is also recommended. Furthermore, tendon neuroplastic training (TNT) is needed combining isometric or isotonic strength training with an externally paced audio or visual cue [36]. Finally, stretching has positive effects in the management of tendon injuries such as LET. The aim of stretching is to orientate the new collagen fibres, experience consequently less strain during joint motion and lengthen the muscle-tendon unit [37-39]. Although a supervised exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period. One such modality is 448 kHz CRMRF which is a relatively new treatment approach, but it is reported to be used by clinicians worldwide. Many clinicians think that Shortwave Diathermy (SWT) and 448 kHz CRMRF is the same. However, the 448 kHz CRMRF differs from SWT mainly in two ways - firstly the operating frequency (SWT commonly operates at 27.12 MHz) and secondly, unlike SWT it is applied using a coupling medium since CRMRF cannot be delivered through air [40]. Hence, one hypothesized advantage of 448 kHz CRMRF over SWT is that scattering of the RF waves is potentially considerably lower [40]. The present trial will be the first trial to examine the effectiveness of 448 kHz CRMRF on chronic LET. One previous study assessed the effectiveness of this treatment on chronic knee osteoarthritis [40]. However, LET and knee osteoarthritis are two different conditions and the results are not comparable. The findings of these two trials will encourage the design of future well-designed trials that might produce strong evidence for the effectiveness of 448 kHz CRMRF on sports/musculoskeletal injuries.

A course of 448 kHz CRMRF treatment will be applied in the present study based on manufacturers' claims. It is a dose-response modality and the optimal treatment dose has obviously not yet been discovered. Future studies are needed to standardize 448 kHz CRMRF parameters in the management of LET (acute, chronic and calcific).

Conclusion

This is the first trial to examine the efficacy of 448 kHz CRMRF in the treatment of LET. It is expected, the conclusion of the trial to improve the scientific knowledge providing evidence that using 448 kHz CRMRF is an effective and safe tool in the treatment of LET symptoms, specifically function and pain.

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Availability of Data and Materials

Not applicable.

Authors' Contributions

DS conceived of the idea, developed the design of this trial, developed the intervention and wrote the article. AC recruited participants and are responsible for data acquisition. AZC provided advice on the study design and contributed to the content of the article. DL planned the statistical analysis. All authors read and approved the final manuscript.

Competing Interests

The authors declare that they have no competing interests.

Consent for Publication

Not applicable.

Ethics Approval and Consent to Participate

The study will be approved by the Cyprus Ethics Committee. All patients will receive a written explanation of the trial prior to entry into the study. All patients will give signed informed consent to participate in the study. The patients will be free to abandon the study at any time without the obligation to give any explanation.

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