

## Clinical Study

# Comparing Two Exercise Programmes for the Management of Lateral Elbow Tendinopathy (Tennis Elbow/Lateral Epicondylitis)—A Controlled Clinical Trial

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### Abstract.

**Aim:** To compare the effectiveness of supervised exercise programme as proposed by Stasinopoulos and colleagues with home exercise programme as proposed by Pienimaki and his coworkers in the treatment of lateral elbow tendinopathy. **Design:** Controlled clinical trial. **Setting:** Physiotherapy and rehabilitation centre. **Participants:** This trial was carried out with 60 patients, who had lateral elbow tendinopathy. **Intervention:** Group A ( $n = 30$ ) had received supervised exercise programme, once per day for 4 weeks. Group B ( $n = 30$ ) was treated with home exercise programme four to six times daily for 8 weeks. **Outcome measures:** pain, using a visual analogue scale, function, using a visual analogue scale for elbow function and the pain-free grip strength. Patients were evaluated at baseline, at the end of treatment (week 12), and 3 months (week 24) after the end of treatment. **Results:** Both the supervised and home exercise programme were found to be significantly effective in the reduction of pain and in the improvement of functional status. The supervised exercise programme resulted in significantly different improvement in comparison to those who received home exercise programme. **Conclusion:** A specific supervised exercise programme is superior to a specific home exercise programme in reducing pain and improving function in patients with LET at the end of the treatment and at the 3 month follow-up. Further research is needed to confirm our results.

**Keywords:** tennis elbow, lateral epicondylitis, eccentric training, pienimaki protocol, stasinopoulos protocol, lateral elbow tendinopathy

## 1. Introduction

Lateral elbow tendinopathy (LET), commonly referred to as lateral epicondylitis, lateral epicondylalgia, lateral epicondylolysis and/or tennis elbow is one of the most common lesions of the arm. However, LET is the most appropriate term to use in clinical practice because all the other terms make reference

to inappropriate aetiological, anatomical and pathophysiological terms [1]. The condition is usually defined as a syndrome of pain in the area of the lateral epicondyle [2–4] that may be degenerative or failed healing tendon response rather than inflammatory [5]. Hence, the increased presence of fibroblasts, vascular hyperplasia, proteoglycans and glycosaminoglycans together with disorganized and immature

collagen may all take place in the absence of inflammatory cells [5]. The origin of the extensor carpi radialis brevis (ECRB) is the most commonly affected structure [5]. It is generally a work-related or sport-related pain disorder. The dominant arm is commonly affected, the peak prevalence of LET is between 30 and 60 years of age [2, 6] and the disorder appears to be of longer duration and severity in women [2, 6, 7].

The main complaints of patients with LET are pain and decreased function [2, 8–12] both of which may affect daily activities. Diagnosis is simple, and a therapist should be able to reproduce this pain in at least one of three ways: (1) digital palpation on the facet of the lateral epicondyle, (2) resisted wrist extension and/or resisted middle-finger extension with the elbow in extension, and (3) by getting the patient to grip an object [1, 8–10].

Although the signs and symptoms of LET are clear and its diagnosis is easy, to date, no ideal treatment has emerged. Many clinicians advocate a conservative approach as the treatment of choice for LET [2, 8, 11]. Physiotherapy is a conservative treatment that is usually recommended for LET patients [11, 13, 14]. A wide array of physiotherapy treatments have been recommended for the management of LET [11, 15–17]. These treatments have different theoretical mechanisms of action, but all have the same aim, to reduce pain and improve function. Such a variety of treatment options suggests that the optimal treatment strategy is not known, and more research is needed to discover the most effective treatment in patients with LET [11, 18–20].

One of the most common form of treatment for LET is an exercise programme [8, 13, 21]. An exercise programme is used as the first treatment option for our patients with LET [22]. There are two types of exercise programme: home exercise programmes and exercise programmes carried out in a clinical setting. A home exercise programme is commonly advocated for patients with tendinopathies such as LET because it can be performed any time during the day without requiring supervision from a practitioner, and the patient visits the therapist once or twice per week for further instructions; whereas in the exercise programme carried out in the clinic, the patient visits the clinic every day to carry out the exercise programme under the supervision of the therapist. Therefore, the exercise programmes carried out in a clinical setting are called supervised exercise programmes [22, 23].

A home exercise programme in the management of LET was first proposed by Pienimäki et al. (1996) [24]. On the other hand, a supervised exercise programme in the treatment of LET was first proposed by Stasinopoulos and Stasinopoulos (2006) [25]. To our knowledge, there have been no studies to compare the effectiveness of these two exercise programmes for the management of LET. Therefore, the aim of the present article was to make a comparison of the effects of a home exercise programme (Pienimäki and his coworkers model) and a supervised exercise programme

(Stasinopoulos and his coworkers model) for the treatment of LET.

## 2. Methods

A controlled, monocentre trial was conducted in a clinical setting over 27 months to assess the effectiveness of a home exercise programme and a supervised exercise programme. A parallel group design was used because 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 [26]. Two investigators were involved in the study: (1) the primary investigator who evaluated the patients to confirm the LET diagnosis and administered the treatments (DS) and (2) a physiotherapist (PM) who performed all baseline and follow-up assessments, and gained informed consent. All assessments were conducted by PM who was blind to the patients' therapy group. PM interviewed each patient to ascertain baseline demographic and clinical characteristics, including patient name, sex, age, duration of symptoms, previous treatment, occupation, affected arm and dominant arm.

Patients over 18 years old who were experiencing lateral elbow pain were examined and evaluated in a private rehabilitation centre located in Athens between January 2008 and January 2010. All patients lived in Athens, Greece, were native speakers of Greek and were either self-referred or referred by their physician or physiotherapist.

Patients were included in the study if, at the time of presentation, they had been evaluated as having clinically diagnosed LET for at least 4 weeks. Patients were included in the trial if they reported (a) pain on the facet of the lateral epicondyle when palpated, (b) less pain during resistance supination with the elbow in 90° of flexion rather than in full extension and (c) pain in at least two of the following four tests [1]:

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

Patients were excluded from the study if they had one or more of the following conditions: (a) dysfunction in the shoulder, neck (radiculopathy) and/or thoracic region; (b) local or generalized arthritis; (c) neurological deficit; (d) radial nerve entrapment; (e) limitations in arm functions; (f) the affected elbow had been operated on and (g) had received any conservative treatment for the management of LET in the 4 weeks before entering the study [2, 24, 27].

All patients received a written explanation of the trial prior to entry into the study. All patients gave signed informed consent to participate in the study. The study was approved by

the Topical Research Ethics Committee and access to patients was authorised by the manager of the private rehabilitation centre.

The patients were allocated to two groups by sequential allocation. For example, the first patient with LET was assigned to the home exercise programme group, the second patient with LET to the supervised exercise programme group, and so on.

All patients were instructed to use their arm during the course of the study but to avoid activities that irritated the elbow such as grasping, lifting, knitting, handwriting, driving a car and using a screwdriver. They were also told to refrain from taking anti-inflammatory drugs throughout the course of the study. Patient compliance with this request was monitored using a treatment diary.

Communication and interaction (verbal and non-verbal) between the therapist and patient was kept to a minimum, and behaviours sometimes used by therapists to facilitate positive treatment outcomes were purposefully avoided. For example, patients were given no indication of the potentially beneficial effects of the treatments or any feedback on their performance in the pre-application and post-application measurements [28].

The supervised exercise programme according to Stasinopoulos and Stasinopoulos (2006) [25], consisting of slow progressive eccentric exercises of the wrist extensors and static stretching exercises of the ECRB tendon. Three sets of 12 repetitions of slow progressive eccentric exercises of the wrist extensors at each treatment session were performed, with 1-min rest interval between each set. Static stretching exercises of the ECRB tendon were repeated six times at each treatment session, three times before and three times after the eccentric exercises, with a 30 second rest interval between each repetition. Eccentric exercises of the wrist extensors were performed with the elbow on the bed in full extension, the forearm in pronation, the wrist in an extended position (as high as possible), and the hand hanging over the edge of the bed. From this position, patients flexed their wrist slowly while counting to 30, then returned to the starting position with the help of the other hand. Patients were told to continue with the exercise even if they experienced mild pain. However, they were told to stop the exercise if the pain became disabling. When patients were able to perform the eccentric exercises without experiencing any minor pain or discomfort, the load was increased using free weights. Static stretching exercises of the ECRB tendon were performed with the help of the other hand. The patient's elbow was placed in full extension, the forearm in full pronation, and the wrist in flexion and ulnar deviation according to the patient's tolerance. This position was held for 30–45 s each time and then released.

The patients in the home exercise group according to Pienimäki et al (1996) [24] protocol were trained in a four step exercise programme. They visited the physiotherapist once every other week for follow-up examination and to

receive a new, more intensive programme. The exercises started with slow fist-clenching, resisted wrist movements (flexion and extension), and wrist rotations with a stick (step 1), followed by movements (wrist flexion, extension, radial and ulnar deviation) against a band (step 2) and two-way resisted wrist rotations and pressing hands against a wall (step 3). The fourth step was a versatile occupational training programme such as soft ball compressing exercises, twisting a towel into a roll and etc. Every exercise period ended with stretching for at least 30 seconds in both flexion and extension and each individual exercise movement was done slowly while the patient counted to eight. The patients performed the exercise programme four to six times daily at home. Each programme included ten repetitions in two or three series for each exercise.

Supervised exercise programme was given five times a week for 4 weeks and the home exercise programme was administered for 8 weeks. Both exercise programmes were individualized on the basis of the patient's description of pain experienced during the procedure. The difference between both groups was that the supervision programme was given under the supervision of the physical therapist, whereas in the home exercise programme, the patients visited the physical therapist once per week for further instructions.

Pain, function and drop out rate were measured in the present study. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 12) and at 3 months (week 24) after the end of treatment.

Pain was measured on a visual analogue scale (VAS), where 0 (cm) was "least pain imaginable" and 10 (cm) was "worst pain imaginable". The pain VAS was used to measure the patient's worst level of pain over the previous 24 h before each evaluation, and this approach has been shown to be valid and sensitive of the VAS [29].

Function was measured using a VAS, in which 0 (cm) was taken as "no function" and 10 (cm) as "full function". Patients were instructed to report their overall level of elbow function over the previous 24 h before each evaluation, and this approach has been shown to be valid and sensitive of the VAS [29].

In addition, function was measured by pain-free grip strength. Pain-free grip strength is defined as the amount of force each patient is able to generate with an isometric gripping action before eliciting pain [28]. Force was measured in pounds with a Jamar hand dynamometer (Figure 1) that had adjustable handles to accommodate different hand sizes. The arm was placed in a standardised position of elbow extension, forearm pronation and internal rotation of the upper limb such that the palmar aspect of the hand faced posteriorly with the upper limb placed by the patient's side. Patients were then instructed to squeeze the dynamometer handles until they first experienced pain and then to release their grip [28]. The attained grip force was subsequently recorded, and the reading was not visible to the patient. Three measures of pain-free grip strength were recorded with a 30 s



**Figure 1:** Hand grip dynamometer.

rest interval between each measurement, and the mean value of these repetitions was calculated.

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

The change from baseline was calculated for each follow-up. Differences between groups were determined using the independent *t* test. The difference within groups between baseline and end of treatment was analysed with a paired *t* test. A 5% level of probability was adopted as the level for statistical significance. SPSS V.20 statistical software was used for the statistical analysis.

### 3. Results

Ninety three patients eligible for inclusion visited the clinic within the trial period. Fifteen were unwilling to participate in the study, and eighteen did not meet the inclusion criteria described above. The other 60 patients were sequentially allocated to one of the two possible groups: (a) home exercise programme ( $n = 30$ ; 20 men, 10 women; mean (SD) age 47.53 (5.88) years); (b) supervised exercise programme ( $n = 30$ ; 18 men, 12 women; mean (SD) age 47.61 (5.91) years). Patient flow through the trial is summarised in a CONSORT flow chart (Figure 2).

At baseline, there were more men in the groups (sixteen more in total). The mean age of the patients was about 48 years, and the duration of LET was about 4.5 months. LET was in the dominant arm in 92% of patients. There were no significant differences in mean age ( $P > 0.05$ , independent *t* test) or the mean duration of symptoms ( $P > 0.05$ , independent *t* test) between the groups. Patients had received a wide range of previous treatments (Table 1). Drug therapy had been tried by 80 %. All patients were manual workers.

**Table 1:** Previous treatments of participants.

	Home exercise programme(%)	Supervised exercise programme(%)
Drugs	23 (77)	25 (84)
Physiotherapy	4 (13)	4 (13)
Injection	3 (10)	1 (3)

Values are number (%)

Baseline pain on VAS was 8.80 (95% CI 8.41 to 8.99) for the whole sample ( $n = 60$ ; Table 1). There were no significant differences between the groups for baseline pain ( $P > 0.05$  independent *t* test; Table 2). At week 12, there was a decline in VAS of about 8 units (cm) in the supervised exercise programme and 5 units (cm) in the home exercise programme compared with the baseline ( $P < 0.0005$ , paired *t* test; Table 3). There were significant differences in the magnitude of reduction between the groups at weeks 12 and 24 ( $P > 0.0005$  independent *t* test; Table 3).

Baseline function on VAS was 3.50 (95% CI 3.31 to 4.35) for the whole sample ( $n = 60$ ; Table 2). There were no significant differences between the groups for baseline function ( $P > 0.05$  independent *t* test; Table 2). At week 12, there was a rise in VAS of approximately 5 units (cm) in the supervised exercise programme group and 2.2 units (cm) in the home exercise programme group compared with the baseline ( $P < 0.0005$ , paired *t* test; Table 3). There were significant differences in the magnitude of improvement between the groups at weeks 12 and 24 ( $P > 0.0005$  independent *t* test; Table 3).

Baseline pain-free grip strength was 26 lb (95% CI 25.12 to 27.1) for the whole sample ( $n = 60$ ; Table 2). There were no significant differences between the groups for baseline pain-free grip strength ( $P > 0.05$  independent *t* test; Table 2). At week 12, there was a rise in pain-free grip strength of approximately 37 units in the supervised exercise programme group and 20 units in the home exercise programme group compared with the baseline ( $P < 0.0005$ , paired *t* test; Table 3). There were significant differences in the magnitude of improvement between the groups at weeks 12 and 24 ( $P > 0.0005$  independent *t* test; Table 3).

There were no drop outs, no adverse effects were referred and all patients successfully completed the study.

### 4. Discussion

The results obtained from this controlled clinical trial are novel; as to date, there have been no data comparing the effectiveness of a home exercise programme based on Pienimaki et al. (1996) protocol [24] and a supervised exercise programme based on Stasinopoulos and Stasinopoulos (2006) model [25] for the reduction of pain and improvement of function in LET. The supervised exercise programme produced the largest effect at the end of the treatment and 3 months after

Table 2: Pain, function and pain-free grip strength over the 24 h before each evaluation.

	Pain (cm) (CI)		Function (cm) (CI)		Pain free grip Strength (lb) (CI)	
	HEP	SEP	HEP	SEP	HEP	SEP
Week 0	8.85 (8.40 to 8.96)	8.75 (8.35 to 8.99)	3.55 (3.31 to 4.01)	3.45 (3.42 to 4.35)	26.10 (25.60 to 27.11)	25.90 (25.11 to 26.55)
Week 12	3.85 (3.39 to 3.95)	0.80 (0.65 to 1.35)	5.75 (5.23 to 5.96)	8.45 (7.86 to 8.66)	46.2 (45.72 to 46.42)	62.93 (62.55 to 63.36)
Week 24	3.70 (3.33 to 3.81)	0.68 (0.52 to 1.19)	5.82 (5.34 to 6.01)	8.62 (8.07 to 8.89)	46.37 (45.88 to 46.85)	63.20 (62.7 to 63.5)

HEP, home exercise programme; SEP, supervised exercise programme

Table 3: Change in pain, function, and pain-free grip strength over the 24 h before each evaluation from baseline.

	Pain (cm)		Function (cm)		Pain free grip Strength (lb)		<i>P</i> Value
	HEP	SEP	HEP	SEP	HEP	SEP	
Week 12	-5	-7.75	2.20	5	20.10	37.03	<0.0005
Week 24	-5.15	-8.07	2.27	5.17	20.27	37.30	<0.0005

HEP, home exercise programme; SEP, supervised exercise programme. Values are mean visual analogue scores where 0 = least pain, function imaginable and 10 = worst pain, function imaginable. *P* Values for independent *t* test on change in VAS from baseline are shown.

the end of the treatment and the effect was maintained for the following three months without treatment.

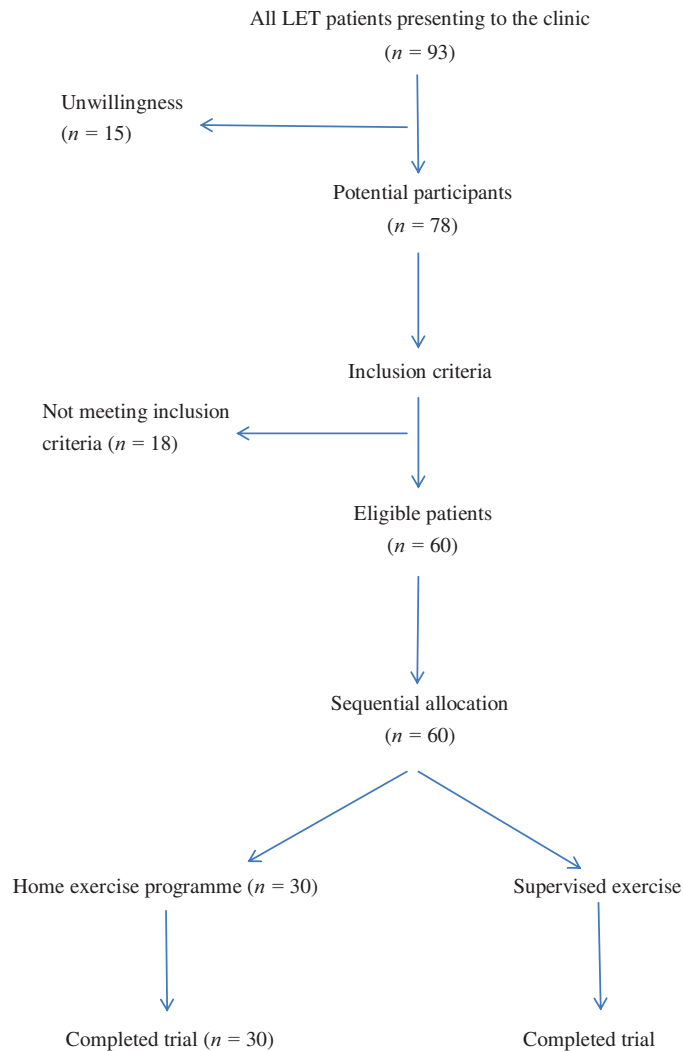
Although a home exercise programme can be performed any time during the day without requiring supervision from a therapist, our clinical experience has shown that patients fail to comply with the regimen of home exercise programmes [22]. Although many ways can be recommended to improve the compliance of patients with the home exercise programme such as phone calls, exercise monitors and better self-management education, it is believed that this problem can be really solved by the supervised exercise programmes performed in a clinical setting under the supervision of a therapist. It is believed because our experience has shown that many patients stopped the home exercise programme without giving explanations, whereas patients completed the supervised programme. One possible reason why they continue the supervised exercise programme could be the cost. In the supervised exercise programme, the patients visit the therapist more times than the home exercise programme, and this is more expensive. A future study will combine the both types of exercise programmes in order to maximize the compliance of the patients.

The two exercise programmes were administered in a totally different manner (types of exercises, intensity, frequency, duration of treatment). The better results were obtained by supervised exercise programme because this programme followed the physical therapy treatment that recommended today for the management of tendinopathy. Standard eccentric exercises offer adequate rehabilitation for tendon disorders, but some patients with tendinopathies do not respond to this prescription alone [30]. For this reason, clinicians combine eccentric exercises with static stretching exercises in the management of tendinopathies. Studies have shown positive results in the treatment of

tendon injuries using eccentric training and static stretching exercises [23, 25, 31–33]. The load of eccentric exercises was increased according to the patients' symptoms because the opposite has shown poor results [34]. Eccentric exercises were performed at a low speed in every treatment session because this allows tissue healing [5, 35]. Eccentric training and static stretching exercises appear to reduce pain and improve function, reversing the pathology of tendinopathy [36–39] as supported by experimental studies on animals [40]. The way that eccentric training and static stretching exercises achieves the goals remains uncertain as there is a lack of good quality evidence to confirm that physiological effects translate into clinically meaningful outcomes and vice versa.

Previous trials have found that a home exercise programme using eccentric training reduced the pain in patellar [41–44] and Achilles [45–50] tendinopathy. However, it was performed for about 3 months, twice daily, in all previous studies. In contrast, in the studies of Stasinopoulos and colleagues a supervised exercise program was administered for 1 month [23, 25, 31–33]. This difference can be explained by many observations such as the patients in the supervised exercise programme achieved a higher degree of compliance, the progression of the supervised programme was well conducted by the therapist, or the patients reported improvement to please the investigators. In addition, in the studies conducted by Stasinopoulos and his colleagues [23, 25, 31–33] a supervised exercise programme was administered for a month, and it may give good long-term clinical results in a shorter period of time than the home exercise programme. The patient compliance can explain this difference.

However, this trial does have some shortcomings. First, a power analysis was not performed. Second, although this study was not a randomised controlled trial because a genuine



**Figure 2:** Flow chart of the study.

randomisation procedure was not followed, the use of sequential allocation to allocate patients to treatment groups allowed a true cause and effect relation to be demonstrated. Third, no placebo (sham) or no treatment group was included in the present trial. The placebo (sham)/no treatment group is important when the absolute effectiveness of a treatment is determined. However, the absolute effectiveness of technique based interventions is difficult to investigate because a good and trustworthy placebo (sham)/no treatment control for exercise programmes appears to be difficult or impossible to devise, due in part to difficulties in defining the active element of these treatments. Absolute effectiveness also does not provide the therapists with information as to which is the most appropriate treatment for the management of a condition, in this case LET. Finally, the blinding of patients and therapists would be problematic in that case, if not impossible, because patients know if they are receiving the exercise programme treatment and therapists need to

be aware of the treatment to administer it appropriately. In addition to these weaknesses, structural changes in the tendons related to the treatment interventions were not shown, and the long-term effects (6months or more after the end of treatment) of these treatments were not investigated. Further research is needed to establish the effectiveness of an exercise program in the management of LET, the possible mechanism of action of this treatment approach, and the cost-effectiveness of such treatment, because reduced cost is an important issue for the recommendation of any given treatment.

In conclusion, the supervised exercise programme based on Stasinopoulos and Stasinopoulos (2006) model, consisting of eccentric and static stretching exercises, was superior to the (specific) home exercise programme of Pienimaki and his coworkers mode reducing the pain and improving the function in patients with LET at the end of the treatment and at follow-up.

## Conflict of interests

The authors declare that there is no conflict of interests.

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