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RESEARCH

Transcutaneous electrical nerve stimulation as adjunct to primary care management for tennis elbow: pragmatic randomised controlled trial (TATE trial)

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Abstract

Objective To investigate the effectiveness of supplementing information and advice on analgesia and exercise from a general practitioner with transcutaneous electrical nerve stimulation (TENS) as a non-drug form of analgesia to reduce pain intensity in patients with tennis elbow.

Design Pragmatic randomised controlled trial in primary care.

Setting and 38 general practices in the West Midlands, UK.

Participants 241 adults consulting with a first or new (no consultation in previous six months) clinical diagnosis of tennis elbow.

Interventions Participants were randomly allocated to either primary care management alone, consisting of a consultation with a general practitioner followed by information and advice on exercises, or primary care management plus TENS to be used once a day for 45 minutes over six weeks (or until symptom resolution) for pain relief.

Outcome measures The primary outcome was self reported intensity of elbow pain (0-10 rating scale) at six weeks. Primary and secondary outcomes were measured at baseline and at six weeks, six months, and 12 months by postal questionnaire. Analysis was by intention to treat.

Results 121 participants were randomised to primary care management plus TENS and 120 to primary care management only (first episode, n=197 (82%); duration <1-3 months, n=138 (57%)). Adherence to exercise and TENS recommendations reported at six weeks was low; only 42 participants in the primary care management plus TENS group met a priori defined adherence criteria. Both intervention groups showed large improvements in pain and secondary outcomes, especially during the first six weeks of follow-up. However, no clinically or statistically significant differences were seen between groups at any follow-up timepoint. At the primary endpoint (six weeks), the between group difference in improvement of pain was −0.33 (95% confidence interval −0.96 to 0.31; P=0.31) in favour of the primary care management only group, with adjustment for age, sex, and baseline pain score.

Conclusions This trial does not provide evidence for additional benefit of TENS as an adjunct to primary care management of tennis elbow. Poor adherence to interventions is evidence of the challenges of implementing self management treatment strategies in primary care.

Trial registration Current Controlled Trials ISRCTN87141084.

Introduction

Tennis elbow is the most common condition affecting the elbow and is characterised by localised pain over the lateral epicondyle and reduced forearm function. It affects 1-3% of the population, and predominantly occurs in the dominant arm of patients aged 35-55 years.[1-3] Tennis elbow is often referred to clinically as lateral epicondylitis, but the inflammatory component of the condition, which is usually seen only in the acute presentation, is debated, and the term epicondylosis has been suggested to reflect the degenerative tendinopathy that develops.[4] The condition can have a major effect on normal daily activities, and up to 30% of patients report absence from work (four to five days on average).[1 5] Common risk factors for onset have been identified as repetitive handling of heavy loads, forearm rotating motions, strong gripping force, and working postures that combine force or load handling with raised arms.[6-8] Diagnosis is usually straightforward, with clear clinical signs and symptoms. The condition is normally self limiting, lasting 6-24 months; up to 20% of patients report symptoms that persist for more than 12 months. Many patients have recurrences.[9-11]

Common interventions include rest and analgesia, non-steroidal anti-inflammatory drugs, corticosteroid injections, and

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physiotherapy. Literature to substantiate these show that limited evidence supports the efficacy of (topical or oral) non-steroidal anti-inflammatory drugs, which are reported to have small effect sizes and only relieve pain in the short term.[12 13] The adverse effect profiles of oral non-steroidal anti-inflammatory drugs also need to be considered, especially in older adults or those with comorbid conditions. Previous trials, including one from our own group, have shown that corticosteroid injections produce substantial reductions in pain in the short term but are associated with an initial worsening of pain and increased risk of long term recurrence.[14-16] Physiotherapy treatments, including exercise and mobilisation, may provide short term pain relief but show minimal benefit over rest and advice in the medium to long term, making this a less cost effective treatment option.[8 17 18] Consequently, a need exists for interventions that provide pain relief without risking adverse effects. Transcutaneous electrical nerve stimulation (TENS) is an inexpensive, safe, non-drug analgesic that is advocated as an adjunct to other treatments for musculoskeletal pain and promotes self management by patients.[19 20] A meta-analysis of randomised placebo controlled trials showed TENS to be efficacious when applied adequately in patients with painful chronic musculoskeletal conditions.[21]

The aim of this pragmatic trial was to investigate whether TENS, as a patient controlled adjunct to primary care management for tennis elbow (information and advice on analgesia and simple exercises), can provide superior pain relief and functional improvement compared with primary care management alone.

Methods

Study design

This was a multicentre, pragmatic randomised clinical trial with two parallel arms. An independent trial steering committee and a data monitoring committee reviewed the progress of the trial.[22]

Setting and participants

Participants were recruited from 38 general practices in the West Midlands region of the United Kingdom. These practices covered primarily urban areas, with some rural and inner city areas, generating a source population broadly representative of the UK population. Male and female patients aged 18 years and over who consulted their general practitioner with a first or new (no consultation in previous six months) clinical diagnosis of tennis elbow were eligible to take part. We defined tennis elbow as pain and tenderness over the region of the common extensor tendon origin that increased on resisted dorsiflexion of the wrist or on grip.[23]

Participants were required to speak, read, and write English and to give written informed consent. Exclusion criteria for the trial were treatment for tennis elbow with physiotherapy or corticosteroid injection in the previous six months; history of inflammatory arthritis, neuropathic pain, or gross structural abnormality of the elbow; contraindications to TENS (including epilepsy, dermatological conditions, abnormal sensation in the affected arm, indwelling electrical pumps/pacemakers, and pregnancy)[24 25]; and inability to apply TENS independently. General practitioners were prompted about the trial and eligibility of patients by a "pop-up" screen on entering a relevant diagnostic code for tennis elbow into their electronic medical records. General practitioners without appropriate electronic record systems were provided with a manual prompt card. A study nurse gave an information leaflet to patients identified as suitable and interested in participation in the trial and asked them to provide written consent to further contact.

All patients who consented to further contact continued to receive treatment from their general practitioner in the form of general advice about the condition and prescription for an analgesic where appropriate (for example, paracetamol or co-codamol). Patients receiving pain relieving drugs were permitted to continue these at a stable dose during the trial. We asked general practitioners to avoid corticosteroid injections or referral to physiotherapy for the first six weeks of the patient's participation in the trial. Within two working days of receipt of the faxed consent, the study nurse telephoned patients to provide further detailed information about the trial, confirm eligibility, and make an appointment for the tennis elbow clinic.

At the tennis elbow clinic, a study nurse obtained written informed consent, optionally including permission for review of medical records, and participants completed a baseline questionnaire before randomisation. Patients who the study nurse did not consider eligible or who did not wish to continue participation were given information and advice on managing their elbow problem according to usual practice.

Randomisation and blinding

Consenting patients were randomly allocated in a one to one ratio to either primary care management alone or primary care management with TENS. Before the start of the trial, the study coordinator, who was not involved in the selection and inclusion of patients, organised the preparation of numbered, opaque, sealed, and tamper-proof envelopes containing the treatment allocation. The study statistician generated the random sequence (based on simple randomisation) by using a computerised random number generator; this was concealed from all study personnel throughout the study. At the research clinic, after final enrolment and baseline assessment, the study nurse allocated a sequential study number to the participant and gave him or her the corresponding randomisation envelope. The participant then met with the treating clinician (physiotherapist or nurse), and the envelope was opened. These procedures ensured the independent selection of patients alongside concealed allocation of treatment. After allocation, we could not blind treating clinicians or study participants to their allocated intervention. The study nurse who was responsible for follow-up measurements remained blind to treatment allocation throughout the trial.

Interventions

After randomisation, the treating clinician delivered the allocated treatment. Patients in both treatment arms were told that they could access their general practitioner for ongoing care in the usual way if their elbow pain became worse, but they were encouraged to follow the protocol regimens for six weeks in the first instance. Patients with bilateral symptoms were advised that treatment was applicable to both arms but were asked to report on their elbow with the worst symptoms for trial purposes. Full details of the interventions have been published previously and are briefly summarised below.[22]

Primary care management

Treating clinicians gave participants advice on activity, self management, and progressive exercises based on recommendations freely available from Arthritis Research UK.[26] This information was summarised in a trial information leaflet.

Primary care management plus patient controlled TENS

In addition to the primary care management described above, participants in this arm were given a TENS machine (TensCare Touch Easy) with 50×50 mm, self adhesive, re-useable electrode pads (TensCare REF TC 5050). They were shown how to apply the TENS and instructed to use it at least once a day for one 45 minute (pre-programmed duration) session on each day that symptoms of pain persisted. They were also advised that they could use the TENS machine more frequently if they wished.

TENS is assumed to achieve analgesia through stimulation of afferent peripheral nerves and the subsequent activation of the pain gate mechanism within the spinal cord and the descending pain inhibitory mechanisms including endogenous opiates in the spinal cord and brain stem.[27 28] Explicit anti-inflammatory action is not widely acknowledged, although some people have argued that TENS may affect local tissue healing.[28]

We selected the TENS dose (based on parameter selection, stimulation time, and frequency) on the basis of our previous laboratory work,[29-31] the findings of which are confirmed in more recent literature.[32-38] This dose is most likely to achieve analgesia and comprises asymmetrical biphasic waveform, continuous high frequency (110 Hz) stimulation, with a pulse duration of 200 μs (all of which were pre-programmed and fixed by the manufacturer within the TENS unit), and intensity (mA), which the participants selected as a tolerable "very strong tingling/buzzing" sensation without this being painful. Two electrode pads were applied to the lateral aspect of the elbow and forearm. Participants were advised to use the TENS machine for a minimum of six weeks when their pain was present. They were provided with a trial specific booklet regarding the use and maintenance of the machine and electrodes, in addition to instructions on how to apply the TENS at home.

Outcome measures and follow-up

We used postal questionnaires to measure outcomes before randomisation at baseline and subsequently at six weeks (the primary endpoint), six months, and 12 months. We sent reminder letters at two and four weeks after the first mail-out to participants who did not respond. The study nurse, who remained blind to treatment allocation, telephoned participants who did not respond to the reminder letters to collect minimum data on the primary outcome and selected secondary outcomes.

As the main focus of the trial was reduction in pain, the primary outcome was intensity of elbow pain over the previous 24 hours scored on a 0-10 numerical rating scale. For analysis, we calculated the difference in pain scores between baseline and follow-up to compare differences between the two groups in change in pain intensity at six weeks', six months', and 12 months' follow-up. Secondary outcomes were self reported global change in elbow pain (five point adjectival scale: "much better" to "much worse"), pain and limitation in function (patient-rated tennis elbow evaluation[39]), number of days of sick leave due to tennis elbow, general health (EuroQoL EQ-5D,[40] and SF-12 physical and mental component summary scores[41]), and changes in health beliefs and perceptions (illness perceptions questionnaire[42]).

We collected the following variables at baseline to assess the prognostic similarity of the intervention groups: age, sex, work status, history of elbow pain, previous treatments, intensity and duration of symptoms, other coexisting pain problems, and expectations and preferences regarding treatment for tennis elbow. Process measures assessed at six weeks included satisfaction with treatment received and with the result of the treatment (0-10 numerical rating scale). To establish adherence to treatment protocols, we included questions to capture the frequency of performing exercises in both groups and the frequency and duration of using TENS in the primary care management plus TENS group.

At the tennis elbow clinic, the study nurse issued a diary to be completed daily by participants over the first two weeks of treatment and returned by post. Participants were requested to record intensity of elbow pain in the previous 24 hours (0-10 numerical rating scale), sick leave or inability to carry out usual activities owing to elbow pain, number and type of analgesics taken per day, and, for those in the primary care management plus TENS group, the use of TENS (minutes a day).

Sample size

In two previous trials of tennis elbow in primary care,[8 23] a 25% reduction in pain (mean 1.5 (SD 2.6) point change from baseline on a 0-10 scale) was found in usual care intervention groups at four to six weeks' follow-up. The overall mean baseline pain score was 6 points in both trials. According to Farrar et al,[43] a 20% reduction in pain (on a numerical rating scale) is clinically relevant. To detect a 20% difference between intervention groups (1.2 points, assuming a 2.7 point (45%) reduction in pain score in the primary care management plus TENS group and a 1.5 point (25%) reduction in the primary care management only group, with a pooled SD of 2.6), we needed complete data for 198 patients (99 in each study group) for 90% power at a 5% two tailed significance level. To take account of a predicted maximum 15% loss to follow-up, we needed 117 participants per treatment group. The recruitment target was thus 120 patients per group (240 patients in total).

Statistical analysis

The primary data analysis was by intention to treat, with full analysis of all patients as randomised carried out using multiple imputation datasets with chained equations in Stata version 12; the number of imputed datasets was 20 to align approximately with the proportion of missing data, as is recommended.[44] We did a sensitivity analysis taking a per protocol approach on participants adhering to recommendations for exercise and TENS use, defined a priori as TENS use/exercises performed at least once a day on at least four days a week for a period of at least four weeks (excluding participants who recovered completely or were much better within two weeks after randomisation).

Analyses of treatment effect were by linear regression for numerical outcomes, or logistic/ordinal regression for any categorical outcomes, adjusting for the following baseline covariates: age, sex, pain intensity (primary outcome measure), and corresponding baseline value for secondary outcome measures. We pooled estimates across all imputed datasets to provide overall estimates of mean treatment effect and standard error. Statistical significance was at the 5% (two tailed) level.

Results

Study population

We assessed 422 patients for eligibility and recruited 241 patients between September 2009 and October 2011. Figure 1⇓ illustrates the recruitment and retention of participants. Telephone screening was used effectively to identify patients who were ineligible or unable/unwilling to attend the clinics. We randomised 121 patients to primary care management plus TENS and 120 to primary care management only. Their mean

age was 48 years, and 132 (55%) were male. Nearly half of all participants (43% in both groups) reported symptoms of more than three months' duration.

The two treatment groups were comparable in terms of demographic and clinical characteristics at inclusion with the exception of bilateral elbow pain, which was more commonly reported in the primary care management plus TENS group (n=20 (17%) *v* n=6 (5%)) (table 1⇓). Follow-up rates for the primary outcome measure (pain intensity) were 93% (n=113) for the primary care management plus TENS group and 83% (n=100) for the primary care management only group at the primary end point of six weeks. Follow-up rates were higher for the primary care management plus TENS group than for the primary care management only group at all other time points, particularly at long term follow-up (n=98 (81%) *v* n=83 (69%) at 12 months). Participants lost to follow-up were a mean of 4 years younger than responders in both treatment groups. Between group differences existed in sex and baseline mean pain scores for non-responders versus responders to follow-up questionnaires (primary care management plus TENS group 10% more male non-responders than responders, primary care management only group 8% fewer male non-responders; primary care management plus TENS group baseline pain score 0.5 higher for responders than non-responders, primary care management only group 0.2 lower for responders). This indicated that missing data did not fit with an assumption of missing completely at random, emphasising the importance of an intention to treat analysis based on imputed datasets.

Treatment received and adherence to treatment recommendations

All 241 participants attended the tennis elbow clinic and received information and advice about exercise, and all 121 allocated to the primary care management plus TENS group received a TENS machine. However, seven participants in the primary care management only group also reported using TENS during the first six weeks, having obtained a TENS machine themselves or through another care provider. Of those who responded to follow-up questionnaires, 29 (28%) in the primary care management plus TENS group and 26 (30%) in the primary care management only group reported the use of pain medication at six weeks' follow-up. Of those reporting working at baseline, 5 (11%) in the primary care management plus TENS group and 5 (12%) in the primary care management alone group took time off work. No adverse reactions to treatment were recorded.

The number of participants responding to the six week questionnaire who completed adherence questions and fulfilled our pre-defined criteria for adherence was low—42/90 (47%) responders in the primary care management plus TENS group and 29/70 (41%) responders in the primary care management only group. When we used substantially less stringent criteria based on the use of TENS only, all 90 responders in the primary care management plus TENS group reported using TENS at least once in the six week period and 63 (90%) responders in the primary care management only group reported not using TENS.

Added effects of TENS

Table 2⇓ shows the results of the intention to treat analysis for the primary outcome measure of pain intensity. We saw a large (>25%) within group improvement in pain intensity in both groups, with most improvement occurring in the first six weeks (fig 2⇓), but no significant differences existed between the groups at any time point. Differences between the groups for mean change in pain intensity (positive values indicating differences in favour of primary care management plus TENS) were −0.33 (95% confidence interval −0.96 to 0.31; P=0.314) at six weeks, 0.20 (−0.81 to 0.42; P=0.526) at six months, and 0.45 (−0.15 to 1.06; P=0.139) at 12 months. Between group differences for pain intensity were also small and non-significant during the first two weeks post-randomisation on the basis of analysis of mean daily ratings in the diary (table 2⇓).

The per protocol analysis based on the small number of participants who adhered to treatment recommendations during the first six weeks (using the a priori definition) showed similar results for the primary endpoint, although at 12 months we found a significantly larger reduction in pain for primary care management plus TENS compared with primary care management only.

Table 3⇓ shows the results for the secondary outcome measures. At six weeks' follow-up, 74 (61%) participants in the primary care management plus TENS group reported being much better compared with baseline, compared with 89 (74%) in the primary care management only group. By 12 months, these proportions had increased to 104 (86%) and 105 (88%). Other secondary outcome measures (pain and function on the patient-rated tennis elbow evaluation, illness perceptions, and general health) also showed small, non-significant differences between groups.

A significant difference existed in overall satisfaction with care and information received in favour of primary care management plus TENS (P=0.005), although the between group difference in satisfaction with the outcome of care was not significant.

Discussion

This multicentre, randomised clinical trial found no additional benefit of supplementing a package of primary care management (consisting of a consultation with a general practitioner, information, and advice) with self administered transcutaneous electrical nerve stimulation for the treatment of tennis elbow. Although large within group improvements occurred for pain and other outcomes in both groups, adherence to both treatment protocols was low, and we found no important or statistically significant differences between the intervention groups. The only exception was seen in participants in the primary care management plus TENS group, who were more satisfied with their overall care and the information they received, although no difference existed between the groups in terms of satisfaction with the outcome of their intervention. This may therefore merely reflect an increased satisfaction with receiving the additional intervention.

Comparison with relevant findings from other published work

Two previous trials have evaluated TENS in patients with tennis elbow,[45 46] but these trials had different objectives, included small patient samples (20 and 12 participants per group, respectively), assessed very short term effects (24 hours and five days), and insufficiently reported details of the TENS intervention. Our study is the first adequately powered primary care study in which evidence based TENS treatment protocols were used. Hence, interpretation of our findings through direct comparisons with results from these previous trials is problematic.

The results of Cochrane reviews are inconsistent in terms of the strength of evidence for the efficacy of TENS in musculoskeletal conditions, reporting either positive effects or inconclusive evidence.[47-49] These reviews have been criticised for failing to

give adequate consideration to the fidelity of delivering the TENS intervention within individual trials in terms of treatment frequency and dose. A meta-analysis of the use of TENS in chronic musculoskeletal conditions (38 studies; 1227 participants), which explicitly considered methodological rigour and fidelity of TENS application, reported highly significant reductions in pain with the use of TENS compared with placebo.[21] Abundant laboratory studies also show identifiable and dose dependent physiological pain reducing effects of TENS compared with placebo, although the vast majority of these studies reported only very short term effects (1-24 hours).[29-37] Despite this support for efficacy of treatment, in our pragmatic trial TENS failed to show additional pain relieving effects even in the very short term, over and above the effect of primary care management alone.

Adherence to TENS

The role of adherence to treatment and protocol fidelity may be an important factor in interpreting our findings and understanding the implications for practice. We assessed adherence by using self reported data, which may be affected by recall bias.[50] The response to adherence questions was low (90/121 (74%) for primary care management plus TENS and 70/120 (58%) for primary care management only), which further increases the uncertainty about adherence in our trial. On the basis of self report data, only a small number of participants (42 for primary care management plus TENS, 29 for primary care management only) reported performing exercises and using the TENS machine according to our a priori defined recommendations of application frequency (at least four times a week for a period of at least four weeks). We therefore did four additional per protocol analyses to investigate non-adherence according to less stringent rules, including an analysis in which adherence to TENS was defined without consideration of adherence to exercise (supplementary tables A and B). These further sensitivity analyses also included low numbers of adherers (for example, 56 participants reporting adherence to TENS recommendations regardless of exercise adherence and 90 reporting using TENS at least once in the six week period). The results of these additional sensitivity analyses concur with the intention to treat analysis, showing little or no evidence of a difference between the groups in pain outcomes or of a dose-response relation during the first six weeks. A larger reduction in pain seemed to occur for participants who adhered to treatment recommendations in the TENS group at 12 months' follow-up. However, this long term effect is unexpected, especially in the light of an absence of effect in the short term, and is based on very small numbers.

Efficacy of TENS depends on the (accepted) principle that an optimal effect requires an adequate dose.[21] We endeavoured to ensure adequate and standardised TENS dosing through fixed parameter settings (frequency, pulse duration, and treatment time), but participants were still required to select an appropriate intensity (strong sensation) themselves, raising the possibility that those who did adhere to TENS protocols may have administered an inadequate dose.

The reasons for the poor levels of adherence to TENS in our study are not known, but other authors have suggested that daily 45 minute sessions may be too demanding and that patients who do not perceive an immediate effect may lack motivation to continue with treatment.[49] Furthermore, patients have reported that the process of fitting TENS electrodes can be difficult and awkward.[51]

Our trial was designed to assess effectiveness in routine primary care, with TENS being implemented as a patient controlled intervention. Supervised application of TENS could potentially improve adherence to TENS treatment protocols, but this would be impractical and overly expensive in a primary care setting. More generally, our results provide further evidence of the challenges of implementing effective self management treatment strategies and changing patients' behaviour, as recently reported for the management of long term conditions in primary care.[52 53] Future studies might investigate the delivery of TENS and patients' adherence within primary care to establish if this can be improved in other ways, and if so whether this is associated with larger effects of TENS.

Strengths of study

Our findings are generated from the largest trial to date to evaluate primary care management interventions for tennis elbow. Comparing our findings with previous trials of primary care interventions,[8 18 23] our results show very similar patterns of clinically meaningful (more than 25%) improvement in pain and function in both groups. This provides support for the generalisability of our findings and possibly for the notion that tennis elbow in most patients can be managed successfully in primary care by using a brief intervention consisting of advice and information. We cannot determine to what extent the observed improvements in pain and function were the result of spontaneous recovery from tennis elbow, as our trial did not include a no-treatment control group.

The objective of this trial to investigate a safe, inexpensive, and patient controlled intervention to provide pain in relief in tennis elbow was directly derived from the results of our previous trials on the effectiveness of primary care interventions for tennis elbow.[8 23] Our TENS intervention protocol was based directly on laboratory based research,[29-31] bridging the first translational gap from research to practice. Referrals into the study were made from a large number of general practices (n=38), and we achieved high follow-up rates for the primary endpoint. Our sample size was sufficiently large to detect clinically important differences in reduction of pain intensity, and our pragmatic design enhances the generalisability of our findings to primary care, making efforts to standardise care in accordance with general practitioners' practice.

Limitations of study

We set out to investigate the clinical effectiveness of enhancing a self management approach for tennis elbow with the potentially effective treatment of TENS. Our methods for assessing adherence were based on self report and affected by low response rates, but the substantial lack of adherence in both groups as reported by participants responding to the adherence questions is likely to have contributed to the absence of an effect for both primary and secondary clinical outcomes. Measures of satisfaction suggest that TENS with advice and education was an acceptable intervention; nevertheless, we failed to engage the patients sufficiently to ensure protocol fidelity.

In pragmatic trials of this nature, implementing a double blind design is impossible because of the interventions being used, so we cannot comment on the efficacy of TENS. High levels of follow-up (86%) were achieved for the primary outcome at the primary endpoint, but differential and higher non-response was seen at the longer term follow-up points, with the primary care management only group showing lower completion rates. We thought that standardising primary care and offering good advice and information to all participants was important, so the

trial did not investigate the effectiveness of TENS versus a no-intervention control.

Implications of findings

This trial was designed as a pragmatic trial, investigating the additional effects of TENS as a patient controlled intervention and delivered in the real world of primary care. Adherence was low, and we consider this to be an important outcome suggesting that patients are unlikely to engage with a self management intervention for tennis elbow as offered in this trial. Despite limited adherence to recommendations, both intervention groups showed meaningful reductions in pain intensity over six weeks, which supports the recommendations cited in clinical algorithms to provide patients with tennis elbow with analgesia and ergonomic advice in the first instance and reassure them that in most cases the condition will recover without the need for additional intervention. Adding TENS confers no additional benefit.

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Contributors: All authors contributed to the study concept and design. LSC, AML, EEM, and DAvdW were involved in acquisition of data. LSC, AML, JS, EMH, and DAvdW analysed and interpreted the data. All authors were involved in drafting or writing the manuscript and critically revising it for important intellectual content. DAvdW and EMH supervised the study. AML is the guarantor.

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Ethical approval: Ethical approval was obtained from the South Staffordshire Local Research Ethics Committee in May 2009 (reference No 09/H1203/31). All participants gave written informed consent.

Data sharing: Participants did not give informed consent for data sharing, but the data are anonymised and the risk of identification is low. Data from the trial may be available from the corresponding author at l.s.chesterton@keele.ac.uk subject to agreement about the use of the data.

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What is already known on this topic

A need exists for safe, self administered interventions to provide pain relief for patients with tennis elbow

Corticosteroid injections produce large short term effects but are associated with post-injection worsening of pain and recurrence of symptoms in the long term; physiotherapy has better long term outcomes but is more costly

Transcutaneous electrical nerve stimulation (TENS) has been advocated to provide safe and effective pain relief in a range of musculoskeletal conditions and can be administered by patients themselves

What this study adds

This is the largest trial to date evaluating primary care management strategies for tennis elbow

The results show that supplementing primary care management (information and advice on analgesia and exercise) with self administered TENS does not provide additional clinical benefits

This is likely to be partly due to poor adherence to treatment recommendations

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Tables

Table 1| Baseline characteristics of trial participants by study group. Values are numbers (percentages) unless stated otherwise

Characteristics	Primary care management plus TENS (n=121)	Primary care management only (n=120)
Mean (SD; range) age, years	47.8 (10.2; 25-79)	49.6 (9.1; 30-71)
Male sex	67 (55)	65 (54)
Previous episode of tennis elbow, n (%)	22 (18)	22 (18)
Previous steroid injection	8 (7)	11 (9)
Previous physiotherapy	8 (7)	5 (4)
Both elbows affected	20 (17)	6 (5)
Right hand dominance	113/120 (94)	111 (93)
Duration of tennis elbow:		
<1 month	10 (8)	10 (8)
1-3 months	59 (49)	59 (49)
4-6 months	29 (24)	36 (30)
>6 months	23 (19)	15 (13)
Preference for TENS	38/120 (32)	41/117 (35)
Mean (SD) pain intensity in past 24 hours	5.3 (2.0)	5.4 (2.1)
Mean (SD) PRTEE:		
Pain subscale	26.5 (8.5)	27.1 (8.7)
Specific activities	27.6 (13.0)	27.6 (15.5)
Usual activities	17.4 (8.9)	16.9 (9.7)
Function subscale	22.5 (10.1)	22.3 (11.5)
Total score	49.0 (16.9)	49.4 (18.6)
IPQR subscales*:		
Timescale (acute/chronic)	72 (60)	68 (57)
Consequences	84 (69)	72 (60)
Personal control 1	58 (48)	56 (47)
Personal control 2	108 (89)	91 (76)
Treatment control	80 (66)	81 (68)
Illness coherence	39 (32)	31 (26)
Timeline (cyclical)	60 (50)	58 (48)
Emotional representation	61 (50)	56 (47)
Employed	88 (73)	93 (78)
Full-time	70 (80)	70 (75)
Widespread pain†	33 (27)	25 (21)
Mean (SD) SF12-PCS	40.0 (9.9)	41.8 (9.3)
Mean (SD) SF12-MCS	48.9 (11.2)	51.5 (10.6)
Mean (SD) EuroQoL EQ5D	0.63 (0.27)	0.67 (0.22)

EQ5D=5 dimension rating of general health (scale range from −0.59 to 1.00 (higher scores indicate better general health); IPQR=illness perceptions questionnaire (eight dimensions rated on 5 point Likert-type scales ranging from “strongly agree” to “strongly disagree”); PRTEE=patient-rated tennis elbow evaluation (pain subscale 0-50, specific activities subscale 0-60, usual activities 0-40, function subscale 0-50; higher scores indicate greater pain/limitation); SF-MCS=mental component summary of 12 item short-form questionnaire (subscale range 0-100, higher scores indicate better general health); SF-PCS=physical component summary of 12 item short-form questionnaire (subscale range 0-100, higher scores indicate better general health); TENS=transcutaneous electrical nerve stimulation.
*Descriptive summaries of frequencies (%) presented are based on “strongly agree” and “agree” responses to individual subscale items.
†American College of Rheumatology definition based on contralateral pain.[55]

Table 2| Results for primary outcome measure (change in pain intensity*) at 6 weeks, 6 months, and 12 months

	Mean (SD)			
	Primary care management plus TENS	Primary care management only	Mean difference (95% CI)†	P value†
6 weeks				
Primary (ITT) analysis‡	1.9 (2.5)	2.2 (2.9)	−0.33 (−0.96 to 0.31)	0.314
Per protocol sensitivity analyses§	2.0 (2.1)	2.3 (2.3)	0.23 (−0.71 to 1.18)	0.624
6 months				
Primary (ITT) analysis‡	3.3 (2.8)	3.6 (3.0)	−0.20 (−0.81 to 0.42)	0.526
Per protocol sensitivity analyses§	4.0 (2.5)	3.5 (2.6)	−0.50 (−1.39 to 0.39)	0.268
12 months				
Primary (ITT) analysis‡	4.1 (2.6)	3.8 (3.0)	0.45 (−0.15 to 1.06)	0.139
Per protocol sensitivity analyses§	5.0 (2.0)	4.0 (3.0)	−0.99 (−1.88 to −0.10)	0.030
Diary				
Mean over week 1‡	0.6 (1.7)	0.6 (2.2)	0.13 (−0.33 to 0.59)	0.569
Mean over week 2‡	1.0 (1.9)	1.1 (2.5)	0.00 (−0.52 to 0.52)	0.996

ITT=intention to treat; TENS=transcutaneous electrical nerve stimulation.

*Pain intensity question: "In the last 24 hours, on average, how intense was your elbow pain, on a 0 to 10 scale, where 0 is 'no pain' and 10 is 'worst pain imaginable'?" Evaluation focused on change in pain rating from baseline to each follow-up time point.

†Adjusted for age, sex, and baseline pain intensity score.

‡Primary analysis (on 241 participants: 121 in primary care management (PCM) plus TENS group, and 120 in PCM only group) through full intention to treat.

§Per protocol analysis of patients adhering to treatment protocol: that is, participants who did not report full recovery within 2 weeks, including 42 from PCM + TENS group who at 6 weeks reported use of exercises and TENS at least four times a week for at least 4 weeks and 29 from PCM only group who at 6 weeks reported performing exercises (but no use of TENS) at least four times a week for at least 4 weeks.

Table 3| **Results for secondary outcome measures at 6 weeks, 6 months, and 12 months (intention to treat analysis)**

	6 weeks			6 months			12 months		
	PCM plus TENS (n=121)	PCM only (n=120)	Between group comparison*	PCM plus TENS (n=121)	PCM only (n=120)	Between group comparison*	PCM plus TENS (n=121)	PCM only (n=120)	Between group comparison*
PRTEE	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**
Pain	17.9 (12.1)	17.6 (13.8)	0.70 (–2.24 to 3.63)	11.5 (10.7)	11.7 (13.9)	–0.07 (–3.17 to 3.02)	8.7 (11.1)	10.3 (14.0)	–1.53 (–4.63 to 1.57)
Specific activities	19.1 (16.0)	16.5 (18.9)	2.66 (–1.16 to 6.48)	9.9 (13.2)	10.1 (17.2)	–0.08 (–3.90 to 3.75)	6.6 (11.7)	8.3 (14.4)	–1.68 (–4.78 to 1.43)
Usual activities	13.1 (10.6)	12.0 (11.1)	0.99 (–1.55 to 3.52)	7.4 (8.6)	7.8 (11.5)	–0.50 (–3.03 to 2.04)	5.4 (8.7)	6.2 (9.7)	–0.95 (–3.14 to 1.24)
Function	16.1 (12.7)	14.3 (14.2)	1.76 (–1.25 to 4.77)	8.7 (10.5)	8.9 (14.1)	–0.30 (–3.40 to 2.80)	6.0 (9.8)	7.3 (11.6)	–1.34 (–3.87 to 1.19)
Total score	34.0 (23.9)	31.8 (26.7)	2.41 (–3.22 to 8.05)	20.2 (20.6)	20.6 (27.2)	–0.37 (–6.34 to 5.60)	14.6 (20.0)	17.5 (24.7)	–2.93 (–8.30 to 2.43)
Global change	**No (%)**	**No (%)**	**OR (95% CI)**	**No (%)**	**No (%)**	**OR (95% CI)**	**No (%)**	**No (%)**	**OR (95% CI)**
Much better	35 (29)	45 (38)	0.63 (0.38 to 1.04)	75 (62)	71 (59)	1.13 (0.62 to 2.06)	84 (69)	79 (66)	1.16 (0.60 to 2.25)
IPQR	**No (%)**	**No (%)**	**OR (95% CI)**	**No (%)**	**No (%)**	**OR (95% CI)**	**No (%)**	**No (%)**	**OR (95% CI)**
Timescale	70 (58)	62 (52)	1.33 (0.74 to 2.38)	47 (39)	52 (43)	0.96 (0.54 to 1.73)	43 (36)	50 (42)	0.75 (0.43 to 1.31)
Consequences	44 (36)	42 (35)	1.06 (0.62 to 1.83)	36 (30)	34 (28)	0.97 (0.57 to 1.65)	22 (18)	25 (21)	0.72 (0.40 to 1.29)
Personal control 1	71 (59)	68 (57)	0.94 (0.53 to 1.67)	84 (69)	74 (62)	1.31 (0.73 to 2.35)	92 (76)	88 (73)	0.98 (0.55 to 1.73)
Personal control 2	98 (81)	96 (80)	0.89 (0.48 to 1.66)	99 (82)	92 (77)	0.93 (0.50 to 1.75)	106 (88)	100 (83)	1.07 (0.61 to 1.89)
Treatment control	75 (62)	71 (59)	1.00 (0.53 to 1.86)	77 (64)	66 (55)	1.32 (0.70 to 2.50)	76 (63)	67 (56)	1.34 (0.71 to 2.52)
Illness coherence	19 (16)	28 (23)	0.81 (0.45 to 1.46)	18 (15)	25 (21)	0.82 (0.44 to 1.52)	12 (10)	15 (13)	0.97 (0.54 to 1.73)
Timeline (cyclical)	60 (50)	57 (48)	1.14 (0.63 to 2.08)	61 (50)	62 (52)	0.85 (0.42 to 1.71)	56 (46)	53 (44)	1.22 (0.68 to 2.20)
Emotional	49 (40)	46 (38)	1.04 (0.61 to 1.78)	35 (29)	35 (29)	0.88 (0.50 to 1.55)	33 (27)	29 (24)	0.85 (0.45 to 1.60)
General health	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**
SF-PCS	43.8 (11.5)	45.1 (12.0)	–0.36 (–2.90 to 2.18)	46.4 (12.8)	48.6 (13.4)	–1.09 (–4.22 to 2.03)	47.5 (13.8)	49.4 (13.9)	–0.85 (–3.94 to 2.24)
SF-MCS	49.8 (12.6)	51.2 (12.4)	0.11 (–2.46 to 2.68)	50.0 (13.3)	49.9 (15.3)	1.53 (–1.81 to 4.87)	51.1 (12.3)	49.0 (14.3)	3.35 (0.14 to 6.56)
EQ-5D	0.69 (0.30)	0.73 (0.27)	–0.02 (–0.09 to 0.05)	0.76 (0.26)	0.79 (0.26)	–0.01 (–0.08 to 0.05)	0.77 (0.28)	0.79 (0.25)	0.00 (–0.06 to 0.06)
Satisfaction	**Mean (SD)**	**Mean (SD)**	**Mean difference (95% CI)**						
Overall treatment received	7.1 (3.3)	5.9 (4.0)	1.19 (0.25 to 2.12)	—	—	—	—	—	—
Results of treatment	5.8 (3.2)	5.4 (3.9)	0.49 (–0.39 to 1.37)	—	—	—	—	—	—
Information received	8.1 (2.6)	7.1 (3.5)	1.01 (0.26 to 1.76)	—	—	—	—	—	—

Table 3 (continued)

	6 weeks			6 months			12 months		
	PCM plus TENS (n=121)	PCM only (n=120)	Between group comparison*	PCM plus TENS (n=121)	PCM only (n=120)	Between group comparison*	PCM plus TENS (n=121)	PCM only (n=120)	Between group comparison*
Perceived helpfulness of treatment	**No (%)**	**No (%)**	**OR (95% CI)**						
Pain relief	96 (79)	79 (66)	1.69 (0.94 to 3.01)	—	—	—	—	—	—
Elbow movement	92 (76)	73 (61)	1.51 (0.84 to 2.72)	—	—	—	—	—	—
Elbow function	92 (76)	74 (62)	1.52 (0.84 to 2.77)	—	—	—	—	—	—

EQ-5D=five dimension rating of general health (scale range from –0.59 to 1.00 (higher scores indicate better general health); IPQR=illness perceptions questionnaire (eight dimensions rated on 5 point Likert-type scales ranging from “strongly agree” to “strongly disagree”); OR=odds ratio; PCM=primary care management; PRTEE=patient-rated tennis elbow evaluation (pain subscale 0-50, specific activities subscale 0-60, usual activities 0-40, function subscale 0-50; higher scores indicate greater pain/limitation); SF-MCS=mental component summary of 12 item short-form questionnaire (subscale range 0-100, higher scores indicate better general health); SF-PCS=physical component summary of 12 item short-form questionnaire (subscale range 0-100, higher scores indicate better general health); TENS=transcutaneous electrical nerve stimulation.

*By linear regression for numerical outcomes and logistic/ordinal regression for categorical outcomes (with estimates pooled across imputed datasets); adjusted for age, sex, baseline pain intensity, and corresponding baseline value.

Figures

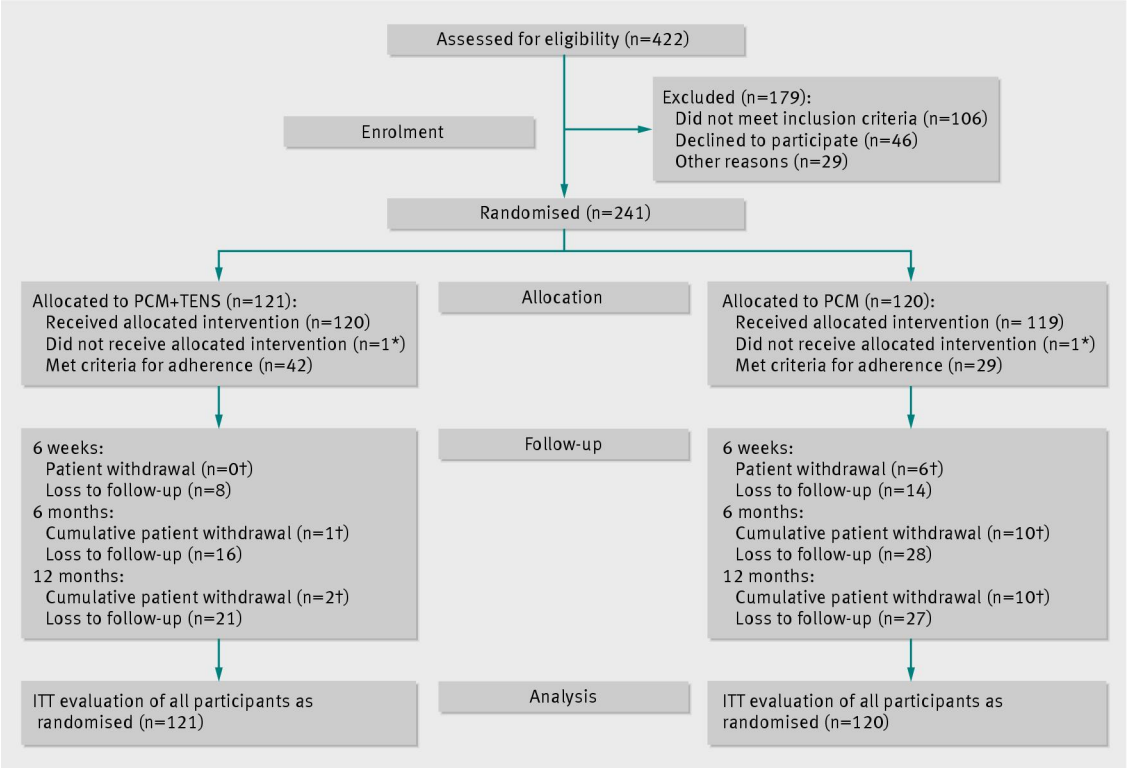

Fig 1 Flow chart showing recruitment and retention of participants. ITT=intention to treat. *One participant in primary care management (PCM) plus transcutaneous electrical nerve stimulation (TENS) arm and one participant in PCM only arm were withdrawn from study owing to subsequent ineligibility (both patients were deemed not to have tennis elbow). †Reasons for participants' withdrawal from follow-up assessment: PCM plus TENS arm—two did not want to continue; PCM arm—five did not want to continue, two were better and did not want to continue, one had a family bereavement, one expressed personal reasons, and one did not give a reason

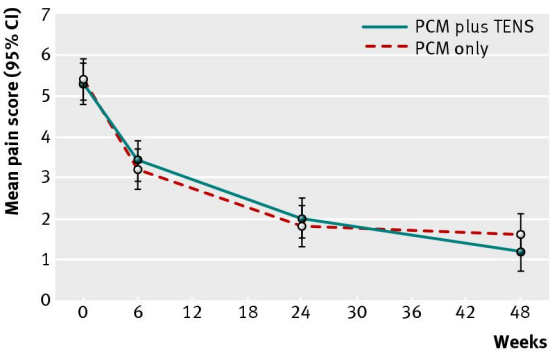

Fig 2 Course of pain intensity (unadjusted mean (95% CI) scores, 0-10 numerical rating scale) for two intervention groups during trial. PCM=primary care management; TENS=transcutaneous electrical nerve stimulation