

# The treatment and advice for tennis elbow study

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/04/2016	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Danielle van der Windt

**Contact details**  
Arthritis Research Campaign National Primary Care Centre  
Keele University  
Keele  
Staffordshire  
United Kingdom  
ST5 5BG

## Additional identifiers

**Protocol serial number**  
PB-PG-0407-13189

## Study information

**Scientific Title**  
Improving the effectiveness of pain relief for tennis elbow in Primary Care: the use of transcutaneous electrical nerve stimulation (TENS) for the management of tennis elbow

**Acronym**

TATE

### **Study objectives**

This study will test whether the addition of transcutaneous electrical nerve stimulation (TENS) to advice and exercise in patients who consult their GP with tennis elbow is more effective than advice and exercise alone for reducing pain.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

To be submitted to South Staffordshire Research Ethics Committee on 01/04/2009 - pending

### **Study design**

Single-centre pragmatic randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Tennis elbow

### **Interventions**

Primary care management alone (control intervention):

A study clinician (nurse or physiotherapist) trained to deliver the study interventions will provide patients with the tennis elbow information leaflet and will reinforce the messages on advice, and education contained within. Patients will be informed of the usually self-limiting nature of tennis elbow and advised that while the elbow pain persists, they should avoid repetitive elbow extension, forceful elbow activities or activities that provoke pain wherever possible. Potential ergonomic impact factors derived from sporting or working activities will be discussed and self-management in the form of rest/avoidance suggested, although absolute rest of the arm will not be advocated. In addition, the patient will be advised to gradually increase activity once acute pain has settled down and some basic progressive exercises will be explained.

Primary care management plus patient-controlled TENS:

In addition to the control intervention described above, patients will be given a TENS machine and instructed on how to use it. They will be shown how to apply the TENS locally, to the lateral aspect of the elbow and forearm and will be encouraged to use the TENS machine at least once per day for a 30 - 45 minute treatment session for each day that symptoms persist. Patients may use the TENS machine more often if they wish. The TENS parameter settings will be high frequency (110 Hz) pulse duration of 200 ms (frequency and pulse duration will be pre-programmed) with a self-selected intensity described as of strong but tolerable sensation (measured as amplitude mA). Patients will be informed that they should experience an uncomfortable (but not painful) tingling sensation and that they may experience muscle contractions and a local cooling of the area. Patients will be encouraged to use the TENS machine for a minimum of six weeks unless their symptoms have fully resolved before then.

All patients will attend one appointment to receive the study intervention from the treating clinician and then self-manage their treatment for up to six weeks depending on symptoms.

Baseline questionnaires will be completed after written informed consent and before randomisation. Follow up will be by postal questionnaires at 6 weeks, 6 months and 12 months. Patients will also be given a 14 -day daily diary to complete after their clinic attendance and return to the research centre on completion.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

The average intensity of elbow pain over the past 24 hours measured using a numerical rating scale (NRS) (where 0 = no pain and 10 = worst pain imaginable). This measure will be collected at baseline, and postal questionnaires at 6 and 12 months as well as at 6 weeks and in the daily diary.

### **Key secondary outcome(s)**

1. Pain and limitation in function (Patient-rated Tennis Elbow Evaluation (PTEE)
2. Days sick leave and ability to carry out usual activities
3. Self reported global change in elbow pain (5-point adjectival scale: much better - much worse)
4. Illness Perception Questionnaire short-form (IPQ-R)
5. General Health: the EuroQoL EQ-5D, 12-item short form (SF-12) and 6-dimensions short form (SF-6D)
6. Health care resource use (including visits to health care professionals, and use of co-interventions and analgesics)
7. Beliefs and expectations of treatment (IPQ-R and specific items)
8. Satisfaction with treatment, feasibility, and applicability of TENS (0-10 NRS), measured with daily diary and 6-week follow up
9. Compliance with treatment (adherence to advice/exercise, and use of TENS in minutes per day in the TENS group), measured with daily diary and 6-week questionnaire

### **Completion date**

30/06/2011

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 18 years and over, either sex
2. Consult their GP with a new episode of tennis elbow (i.e. adults with pain and tenderness in the lateral region of the elbow, increasing on pressure on the lateral epicondyle and on resisted dorsiflexion of the wrist)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. A history of inflammatory arthritis or gross structural abnormality of the elbow
2. Contraindications to TENS (pacemakers, epilepsy, dermatological conditions, abnormal sensation in the affected arm, indwelling electrical pumps/pacemakers and pregnancy)
3. Neuropathic pain
4. Inability to independently apply TENS, complete written questionnaires, or read instruction leaflets written in English

**Date of first enrolment**

15/05/2009

**Date of final enrolment**

30/06/2011

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Keele University**

Staffordshire

United Kingdom

ST5 5BG

## Sponsor information

**Organisation**

Keele University (UK)

**ROR**

<https://ror.org/00340yn33>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research - Research for Patient Benefit (RfPB) (ref: PB-PG-0407-13189)

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	02/09/2013		Yes	No
<a href="#">Results article</a>	results	01/10/2014		Yes	No
<a href="#">Protocol article</a>	protocol	11/12/2009		Yes	No