

The treatment and advice for tennis elbow study

Submission date 23/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/04/2016	Condition category 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?
Results article	results	02/09/2013		Yes	No
Results article	results	01/10/2014		Yes	No
Protocol article	protocol	11/12/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes