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The treatment and advice for tennis elbow study

Submission date	Recruitment status	[X] Prospectively registered
23/02/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
15/05/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

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
England

United Kingdom

Study participating centre

Keele University
Staffordshire
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Sponsor information

Organisation
Keele University (UK)

Sponsor details
c/o Professor Peter Croft
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Sponsor type
University/education

Website
http://www.keele.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	11/12/2009		Yes	No
Results article	results	02/09/2013		Yes	No
Results article	results	01/10/2014		Yes	No