ISRCTN12912789 https://doi.org/10.1186/ISRCTN12912789

Effects of Transcutaneous Electrical Nerve Stimulation (TENS) and exercise on knee Osteoarthritis (OA): a randomised controlled trial

Submission date
25/07/2007

Recruitment status
No longer recruiting

Registration date
03/10/2007

Overall study status
Completed

Last Edited
24/04/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Shea Palmer

Contact details
Faculty of Health and Social Care
University of the West of England
Blackberry Hill
Bristol
United Kingdom
BS16 1DD
+44 (0)117 328 8919
Shea.Palmer@uwe.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRF/06/1

Study information

Scientific Title

Study objectives
Null Hypothesis:
There is no statistically significant difference in assessed outcomes between the effects of TENS and OA knee group, sham TENS and OA knee group or OA knee group alone in people with knee OA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Cambridgeshire 2 Research Ethics Committee on the 5th September 2007 (ref: 07/H0308/209). Site-specific approval added 11th September 2007.

Study design
A randomised sham-controlled trial with three parallel arms.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Participants will receive either:
1. TENS and OA knee group
2. Sham TENS and OA knee group
3. OA knee group alone

TENS intervention:
Those participants allocated to receive either active or sham TENS will receive a 30-minute appointment to be trained in the use of their TENS machine. They will receive a TENS device for

their personal use from the date of TENS instruction and throughout the 6 week duration of the OA knee group. Information will detail the existence of different TENS devices, that some do not produce perceptible sensations, and that participants may receive an active or inactive device (in line with principles of fully informed consent). Those patients receiving active TENS will be instructed to select parameters that generate a 'strong but comfortable' tingling sensation within or close to the site of pain. Those receiving sham TENS will be instructed to select parameters that are within the middle range of those available. Dummy devices (the displays are active but there is no current output) will be used to administer sham TENS. All patients will be instructed to use the device as much as needed. Telephone support will be provided by the TENS instructor as requested by participants and this will be logged.

OA knee group:
Two senior therapists will be trained to deliver the OA knee groups. To maximise consistency, the same therapist will aim to lead all six sessions of each group and a standardised instruction protocol supporting PowerPoint slides will be used for the education component. All participants will take part in the OA knee group. This will involve a group of up to 12 patients attending for 1 hour (30 minutes of education and 30 minutes of group exercise) on six consecutive weeks. The education programme aims to enhance patients' ability to self-manage their knee OA. It includes setting personal objectives, advice on pacing, managing flare-ups, information about diet, medical management of OA and local community exercise opportunities, alongside advice about long-term adherence to exercise. The exercise component includes 5 minute warm up, followed by a circuit of twelve exercises aimed at improving lower limb strength, proprioception and function. Each exercise has specific ideas for progression which patients advance onto as able over the 6-week programme. During the first session each exercise is performed for 1 minute, with 1 minute between exercises to move to the next station. On the subsequent five sessions each exercise is performed for 2 minutes with 1 minute in between. All patients are taught home exercises during the second session and advised to perform them daily.

Performance of home exercises is checked on week 3 and as requested by the patients thereafter.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function subscale (at baseline, 3, 6, 12 and 24 weeks).

Secondary outcome measures
1. Total Western Ontario and McMaster Universities Osteoarthritis Index score and pain and stiffness subscale scores (at baseline, 3, 6, 12 and 24 weeks)
2. Knee extensor torque (quadriceps strength) (at baseline, 3, 6, 12 and 24 weeks)
3. Patient global assessment of change (at 3, 6, 12 and 24 weeks)
4. Self efficacy for exercise (at baseline and 24 weeks)
5. Self-reported exercise adherence (at baseline, 3, 6, 12 and 24 weeks)
6. Logged TENS usage time (at 6 weeks)

Overall study start date
01/10/2007

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Patients referred to United Bristol Healthcare NHS Trust (UBHT) for physiotherapy with a diagnosis of knee OA will be invited to participate. The clinical and radiographic criteria of the American College of Rheumatology (ACR) will be applied, whereby a diagnosis of knee OA will require each patient:
1. To complain of knee pain
2. To have radiographic (X-ray) evidence of osteophytes
3. To meet at least one of the following three criteria:
3.1. 50 years or older
3.2. Morning stiffness that lasts for less than 30 minutes
3.3. Crepitus on active movement

Where available, X-rays taken within the last 12 months will be used. Otherwise, new X-rays will be ordered. Following appropriate training and assessment of competence, the principal investigator will screen all X-rays for evidence of osteophytes. All X-rays will later be reported on in detail by Professor John Kirwan (Rheumatology Consultant, UBHT) and graded for severity as described in previous work carried out at UBHT.

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
261 (87 in each arm)

Key exclusion criteria
1. Co-morbidities that would prevent participation in the exercise programme (such as severe respiratory or cardiac disease)
2. Unable to mobilise independently either unaided or with the use of one stick
3. Unable to participate fully in group activities for other reasons such as dementia
4. Contraindications to TENS
5. Previous experience of using TENS

Where there is any doubt, a medical practitioner from the Rheumatology Department at UBHT will be available for advice on the inclusion of patients with co-morbidities.

Date of first enrolment

01/10/2007

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Faculty of Health and Social Care
Bristol
United Kingdom
BS16 1DD

Sponsor information

Organisation
University of the West of England (UK)

Sponsor details
Coldharbour Lane
Bristol
England
United Kingdom
BS16 1QY
+44 (0)117 965 6261
Robin.Means@uwe.ac.uk

Sponsor type
University/education

Website
http://www.uwe.ac.uk

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Research organisation

Funder Name
Physiotherapy Research Foundation (UK) (ref: PRF/06/1)

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?
Results article	results	01/03/2014		Yes	No