

Comparison of efficacy of transcutaneous nerve stimulation and sensory discrimination education in patients with chronic low back pain

Submission date 31/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/12/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
3321; 078195

Study information

Scientific Title

Comparison of efficacy of transcutaneous nerve stimulation and sensory discrimination education in patients with chronic low back pain: a randomised interventional single centre treatment trial

Study objectives

This is a comparison of transcutaneous nerve stimulation and sensory discrimination education in patients with chronic low back pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Milton Keynes REC approved on the 2nd August 2005 (ref: 05/Q1603/34)

Study design

Randomised interventional single centre treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

Patients aged greater than 18 years with greater than 3 months chronic low back pain awaiting physiotherapy at the Nuffield Orthopaedic Centre will be asked to complete one week of diary record of pain. An average of one week of diary record of pain by linear analogue scale will be the baseline measure of the primary outcome measure. Patients will be excluded if they complete the diary on less than 3 days during this week.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

0 - 100 mm Linear Analogue Pain Scale (LAS) for back pain, taken daily for one week recording best, worst and average. Outcome was based on mean score of 7 daily average scores.

Secondary outcome measures

1. Oswestry Disability Index
2. Euroqol
3. DRAM
4. An open questionnaire to assess satisfaction and comments on treatment.

Measured at baseline, 3 weeks, 6 weeks and 3 months.

Overall study start date

01/01/2006

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Chronic low back pain
2. Aged 18 years or older, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 90. Actual sample size: 54 (reduced from 3-arm to 2-arm study)

Key exclusion criteria

1. Aged less than 18 years
2. Treatment likely to harm patient

Date of first enrolment

01/01/2006

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Old Road

Oxford

United Kingdom

OX3 7LF

Sponsor information

Organisation

Nuffield Orthopaedic Centre NHS Trust (UK)

Sponsor details

c/o Fiona Parker

Windmill Road

Oxford

England

United Kingdom

OX3 7LD

Sponsor type

Hospital/treatment centre

Website

<http://www.noc.nhs.uk/>

ROR

<https://ror.org/0036ate90>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 078195)

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	28/06/2008		Yes	No