

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

<b>Submission date</b> 31/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/12/2012	<b>Condition category</b> 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?
<a href="#">Results article</a>	results	28/06/2008		Yes	No