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Tactile acuity training for patients with chronic low back pain

Submission date
24/01/2012

Recruitment status
No longer recruiting

Registration date
06/02/2012

Overall study status
Completed

Last Edited
28/02/2014

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Tactile acuity (the keenness of the sense of touch) can be measured using the two-point discrimination test. This is the minimal distance between two points that can be detected on the skin surface. Tactile acuity is poor in patients with chronic pain conditions such as chronic regional pain syndrome and phantom limb pain (the sensation of pain in a limb that is missing /amputated). Tactile acuity training in these conditions can improve tactile acuity and, more importantly, it can reduce pain. The reduction in pain is strongly related to improvement in tactile acuity. Patients with chronic low back pain have poor tactile acuity. However, it is not known if tactile acuity training will improve pain and functioning in this patient group.

The main aim of this study was to investigate the how well tactile acuity training worked on pain and function for patients with persistent low back pain. The secondary aim of this study was to investigate how well tactile acuity training works on tactile acuity performance for patients with persistent low back pain.

Tactile acuity training has previously required considerable amounts of patient-therapist contact e.g. 30 minutes daily for two to three weeks. This level of contact may not be practical within the current NHS structure. As such, the intervention within this study had a large home exercise component delivered by an informal carer (friend/relative).
Another aim of this study was to find out what patients and informal carers thought of the home exercise part of the intervention.

Who can participate?
Participants were individuals ≥18 years of age with chronic low back pain and their informal carer.

What does the study involve?
Participants were randomly divided into two groups: the intervention group who received usual care physiotherapy and tactile acuity training or the placebo group who will receive usual care physiotherapy and placebo training.

Tactile acuity training involved two types of training: five point discrimination training and graphaesthesia training. In the former, five areas of the back are stimulated using either a pen top or a wine bottle cork. The participant provides feedback as to which area was stimulated and whether the pen top or bottle cork was used. The carer will then say if the patient was correct or not. In the graphaesthesia test, 60 letters would be traced onto the patients back using the carers finger and the patient asked to guess which letter was drawn. The carer then says if the patient was correct or not. The placebo training involves skin stimulation but no effort by the patient to describe what is happening e.g. they provide no feedback to the carer and vice versa.

Tactile acuity/placebo training involved three training sessions with a physiotherapist in the first two weeks of usual physiotherapy care. The remaining sessions were delivered as part of a home training package delivered by the informal carer (friend/relative).

Participation in the study lasted as long as usual care physiotherapy which was decided by the treating therapist (usually four to six weeks). Additionally, participants along with their informal carers were asked to take part in a focus group once all participants had completed their treatment. In this focus group we explored the attitudes of participants and their carers towards the intervention.

What are the possible benefits and risks of participating?
The risks associated with this study were minor. The likelihood of harm was low and the consequences would be small. Previous research using a very similar intervention and placebo group reported no adverse effects or risks and direct email correspondence with previous authors have confirmed this.

It was possible that the informal carers (friend/relative) would undergo some degree of psychological stress as a result of having to deliver the home training package. Arguably, an individual who is likely to be stressed by this was unlikely to volunteer. However, the informal carer received a high standard of training and support and the fact that no adverse effects or side effects were previously reported was emphasised. It was also emphasised that the informal carer could withdraw from the study at any time, without giving a reason, with no consequences. These measures should have helped to reduce any undue stress.

Where is the study run from?
The study was run from the Physiotherapy Department at the Friarage Hospital, Northallerton, UK.

When is study starting and how long is it expected to run for?
The study ran from February 2012 to January 2013.

Who is funding the study?
The study was funded by the Teesside University Research Fund administered by Teesside University (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/NE/0328

Study information

Scientific Title
Tactile acuity training for patients with chronic low back pain: A pilot randomised controlled trial

Study objectives
There will be a statistically significant difference in pain and function between the tactile actuity training group and the placebo training group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East C Northern & Yorkshire, UK, 06 January 2012, ref: 11/NE/0328

Study design
Pilot randomised controlled 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 contact Dr Cormac Ryan (C.Ryan@tees.ac.uk) to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
Tactile acuity training in the lower back region versus Sham Tactile Acuity (palcebo/control)

Placebo (control group)
The placebo intervention will be delivered on three occasions in the physiotherapy department by the Physiotherapist and daily at home by an informal carer (friend/relative) as part of the home training package over the course of treatment. The training takes 30 minutes. There are two components to the placebo intervention.

1. Tactile stimulation:
Will involve marking 8 number dots on the back area in most pain with a hypoallergenic pen specifically designed for skin use. These sites will be separated by the distance of the predetermined two point discrimination ability. The sites are then stimulated in a random order using either a big (wine bottle cork) or small (pen top) probe, again randomly applied. The interstimulus interval is 15 seconds. Three 6 minute blocks of 24 stimuli are performed with 3 minutes rest between blocks in accordance with previous protocols. The participant does not interact with the stimulus. Instead they engage in some other activity e.g. read a book or watch TV. The tactile stimulation session is performed daily and each session should provide 72 stimuli over 24 minutes.

2. Back writing:
The area of most pain will have letters, approximately 1 inch high traced onto it. The researcher /informal carer will trace a series of 60 letters with the tip of their finger. Again no interaction with the patient will occur. This should take approximately five minutes.

Intervention group
The intervention will be delivered on three occasions in the physiotherapy department by the Physiotherapist and daily at home by the informal carer as part of the home training package over the course of treatment. The training takes 30 minutes. There are two components to the intervention.

1. Tactile acuity training:
Will involve marking 5-8 numbered dots on the back area in most pain. These sites will be separated by the distance of the predetermined two point discrimination ability. The sites are then stimulated in a random order using either a big (wine bottle cork) or small (pen top) probe, again randomly applied. The interstimulus interval is 15 seconds. Three 6 minute blocks of 24 stimuli are performed with 3 minutes rest between blocks in accordance with previous protocols. The participant will concentrate on the stimulus saying which of the five points has

been stimulated and which probe was used. If after a number of sessions the participant begins to give the correct answers >90% of the time the marks should be moved 10% closer to one another making the task more difficult. The tactile stimulation session is performed daily and each session should provide 72 stimuli over 24 minutes.

2. Back writing training:
The area of most pain will have letters, approximately 1 inch high traced onto it. The researcher will trace a series of 60 letters in a random order. The patient will be asked to guess which letter has been traced on their back. The first session is attended by the researcher, the participant and a friend/relative of the participant. At the training progresses patients may become very good at guessing the letter and the tester can make the game harder by writing the letters quicker or smaller. The training can be further progressed by writing words instead of individual letters. Numbers can also be written and added together to make the training more difficult and more varied.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain (Numerical Rating Scale)
2. Function (Roland Morris Disability Questionnaire)

Secondary outcome measures
Qualitative feedback about the intervention via interviews & focus groups

Overall study start date
01/02/2012

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. More than 18 years of age
2. Pain duration of more than 6 months
3. Non-specific low back pain with or without leg pain
4. No red flags indicating potential serious pathology
5. No clinical signs of peripheral neuropathy such as:
5.1. Reduced muscle power
5.2. Loss of sensation or loss of reflex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Not having an informal carer (friend/relative) willing to facilitate with the home program
2. Being unable to write/speak English
3. Have learning difficulties or are not capable of giving consent

Date of first enrolment
01/02/2012

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Team Lead of Extended Services
Northallerton
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Sponsor information

Organisation
James Cook University Hospital (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.southtees.nhs.uk/

ROR
https://ror.org/02vqh3346

Funder(s)

Funder type
University/education

Funder Name
University Research Fund (URF), Teesside University (UK)

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	26/02/2014		Yes	No