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Improving sensory function after carpal tunnel surgery

Submission date
16/01/2014

Recruitment status
No longer recruiting

Registration date
16/01/2014

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study is looking at the effect of a home based sensory relearning programme in patients who continue to have sensory loss after a surgery to treat carpal tunnel syndrome (numbness or tingling sensation in hands and fingers). Numbness or loss of finger sensation can continue after surgery especially in patients with a long duration of symptoms and more severe pre-surgical impairment. Patients find it difficult to use their hand in everyday tasks like picking up small objects. Sensory relearning can be taught to patients and has been shown in nerve injuries to improve the sensibility and function of the hand. The aim of this study is to find out the effect of sensory relearning in a large group of patients.

Who can participate?
Patients who have undergone carpal tunnel decompression surgery 12 months ago or more

What does the study involve?
Patients are sent a short screening questionnaire asking them to indicate whether they have sensory impairments and to rate the severity of it. Those who report mild or worse sensory impairments are invited for a clinical assessment of hand sensibility using validated tests of sensory function. Those in whom sensory impairment is confirmed by these tests are then invited to participate in the study. Consenting patients are randomly allocated to receive either sensory relearning for 6 weeks or standard practice. All patients are reassessed at 6 and 12 weeks after the initial assessment and the results between the two groups are compared to establish whether sensory relearning improves sensory function.

What are the possible benefits and risks of participating?
Those who receive sensory relearning may find improvement in their sensory function.

Where is the study run from?
The study is being undertaken at the Norwich Clinical Trials Unit (UK) in collaboration with the Department of Orthopaedics at the Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2014 to July 2015

Who is funding the study?
National Institute for Health Research (NIHR) (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
15771

Study information

Scientific Title
A pragmatic, assessor-blinded randomized trial of the clinical effectiveness of a 6-week sensory relearning home programme on tactile function of the hand after carpal tunnel decompression

Acronym
IMPACTS

Study objectives
Is a 6-week patient-led home programme of sensory relearning effective in improving tactile gnosis and function of the hand in patients with long-term sensory impairments after carpal tunnel decompression?

Ethics approval required

Old ethics approval format

Ethics approval(s)
East of England Norfolk REC, 23/12/2013, ref: 13/EE/0419

Study design
Randomised; Interventional; Design type: Not specified, Treatment

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Stratified blocked randomisation (random permuted block lengths of 2,4 and 6 stratified by STI score at baseline (≤3 points)) will be used. The randomised sequence will be generated independently by the Clinical Trials Unit data manager and held on a dedicated website.

Patients are randomised to two groups:
1. Sensory Re-learning: A standardised Sensory Relearning (SR) home programme will be given to patients including materials, instructions and a diary. Patients will be shown how to carry out the exercises and asked to practise these daily over 6 weeks. Short but frequent sessions (at least 3 times per day of around 10 minutes each) will be encouraged.

2. The control group will not be given any active treatment, which is current standard practice. They will be asked to continue using their hand as they have before.

At the end of their trial participation (final 12 week follow-up assessment) patients in the control group will be given a standardised information sheet which will enable them to replicate the materials from common items available at home and exercises if they wish.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Tactile gnosis assessed by Shape-texture identification test; Timepoint(s): 6 weeks and 12 weeks

Secondary outcome measures
1. Locognosia; Timepoint(s): 6 and 12 weeks
2. Michigan Hand Questionnaire; Timepoint(s): 6 and 12 weeks
3. Moberg pick-up test; Timepoint(s): 6 and 12 weeks
4. Touch threshold; Timepoint(s): 6 and 12 weeks

Overall study start date
15/02/2014

Completion date
15/06/2015

Eligibility

Key inclusion criteria
For part 1 screening:
Patients who have had a carpal tunnel decompression at the NNUH Dept of Orthopaedics at least 12 months earlier, aged 18 or over.

For part 2 trial: patients who have had their hand sensation assessed, in whom at least 2 out of 3 sensory tests show results below normal and who have given fully informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 124; UK Sample Size: 124

Key exclusion criteria
1. Patients who do not appear to be able to give fully informed consent or do not consent to being randomised (that is those who express a strong preference for the treatment)
2. Patients in whom the sensory tests are within normal range

Date of first enrolment
15/02/2014

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

Sponsor details
Earlham Road
Norwich
England
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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
NIHR Senior Research Fellowship; Grant Codes: NIHR-SRF-2012-05-119

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	01/11/2016		Yes	No
HRA research summary			28/06/2023	No	No