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Sensory Re-learning after Carpal Tunnel syndrome

Submission date
28/07/2011

Recruitment status
No longer recruiting

Registration date
28/07/2011

Overall study status
Completed

Last Edited
19/01/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Carpal tunnel syndrome (CTS) is a common condition that causes pain, numbness and tingling in the hand and fingers. The median nerve runs the length of the arm, and is responsible for controlling sensation and movement in the thumb and first three fingers. In order to enter the hand, this nerve must run though a narrow passage of small bones and tough fibres in the wrist, known as the carpal tunnel. Swelling can narrow this tunnel so that the median nerve is compressed (nerve entrapment), causing CTS. Carpal tunnel decompression, also known as carpel tunnel release surgery, is a simple operation that that is recommended if the symptoms of carpal tunnel are particularly severe. During the surgery, a ligament in the wrist is cut, which relieves pressure on the median nerve.

Who can participate?
Adults who have had carpal tunnel decompression surgery at least four months ago, who report numbness or difficulty doing up buttons.

What does the study involve?
Participants undergo four sensory tests, to determine whether there are any problems with the way the can feel. They are then randomly allocated into one of two groups. Those in the first group receive “sensory re-learning”, which involves practising a set of exercises every day for four weeks. Those in the second group are not given “sensory re-learning” exercises to practise for the four week study period. At the end of the study period, and after another four weeks, the sensory assessments are repeated.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
February 2011 to May 2011

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

Who is the main contact?
Dr Christina Jerosch-Herold

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
10263

Study information

Scientific Title
A pilot randomised controlled trial to evaluate the feasibility and acceptability of a sensory re-learning intervention after carpal tunnel decompression

Acronym
SeRCaT

Study objectives
This study is looking at the effect of a home based sensory relearning programme in patients who continue to have sensory impairment after carpal tunnel decompression. Surgical decompression for moderate or severe carpal tunnel syndrome (CTS) is the most longterm effective treatment for symptom relief and return to function. However recovery of functional sensibility and muscle strength is not always complete especially in patients with a long duration of symptoms and more severe presurgical impairment. Rehabilitative interventions such as sensory relearning programmes have been shown to improve sensibility in the hand after peripheral nerve trauma and stroke but there are no trials to date which have explored whether this treatment works in patients after carpal tunnel decompression. This preliminary trial aims to evaluate what effect sensory relearning has on sensibility and hand function and to assess the acceptability and feasibility of conducting a larger scale trial in the future. Patients who have undergone carpal tunnel decompression at least four months earlier will be invited to respond to a screening questionnaire which asks them about the severity of any numbness and difficulty

in using their hand. Those who report numbness and difficulty with handling small objects will be invited to attend the clinical trials unit to have a full assessment of their hand sensibility. Validated tests of sensory function will be used to objectively assess the extent of any sensory impairment. Those with impairment will then be invited to participate in the trial, whereby patients will be randomly (by the toss of coin) allocated to either receive sensory relearning for 4 weeks or no intervention. All patients will be reassessed at 4 and 8 weeks after the initial assessment and the results between the two groups compared.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norfolk Research Ethics Committee, 24th November 2010, ref: 10/H0310/57

Primary study design
Interventional

Study design
Randomised interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal impairment associated with Carpal tunnel syndrome

Interventions
1. Sensory relearning programme - a home programme involving 4 weeks of daily exercises in which through vision, attention and learning discrimination of textures and objects is practised and integrated in everyday activities
2. Follow Up Length: 2 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Sensory function at 4 weeks and 8 weeks

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/05/2011

Eligibility

Key inclusion criteria

1. Patients who have had carpal tunnel decompression and are at least 4 months post surgery
2. Aged 18 years old or older
3. Respond as having at least mild numbness or mild difficulty with doing up buttons, this will be assessed via 2 screening questions taken from the Boston Carpal Tunnel Questionnaire (FS 6 and 11)
4. An abnormal result in at least 2 tests from a battery of 4 sensory assessments

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Those whose scores on all 4 sensibility tests are within a normal range

Date of first enrolment
04/02/2011

Date of final enrolment
31/05/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Allied Health Professions
Faculty of Medicine and Health Sciences
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Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	01/12/2012		Yes	No