

# Radial nerve mobilization decreases pain sensitivity and improves motor performance in patients with thumb carpometacarpal osteoarthritis

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|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>15/05/2011   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>26/05/2011 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>30/06/2017       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input checked="" type="checkbox"/> Results          |
|                                        |                                                       | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

Osteoarthritis is a condition that causes joints to become painful and stiff, such as the carpometacarpal (CMC) joint of the thumb. Thumb CMC osteoarthritis is a major cause of disability in Europe and the United States. In fact, 30-40% of postmenopausal women and 40-50 year-old men suffer from this condition. The main cause of thumb CMC osteoarthritis is deterioration of the surfaces of the joint and abnormal bone growth. This condition can be treated using surgery, but the results are usually only partially successful. Neurodynamic techniques are a form of manual therapy directed to the neural (nerve) structures through positioning and movement of multiple joints. Although there is only limited evidence to support its use in treatment, researchers have found small advantages in patients treated by this method; for example, certain neuropathic conditions and musculoskeletal pain disorders. There are two general methods used to apply neurodynamic techniques: sliding and tensioning. Sliding techniques, the focus of this current study, consist of alternating combinations of movement of least two joints in which one movement loads the nerve thus increasing tension in the nerve while the other movement simultaneously unloads the nerve which decreases the tension of the nerve. The aim of this study is to assess the effects of a manual therapy technique on pain and function in patients with thumb CMC osteoarthritis.

### Who can participate?

Patients aged 70 to 90 with thumb CMC osteoarthritis

### What does the study involve?

Participants are randomly allocated to either the treatment or the placebo (sham treatment) group. Treatment consists of mobilization of the radial nerve with an experimental sliding technique. Pain and pinch strength are measured before treatment and after one and two weeks. Participants in the placebo group attend the same number of sessions as those in the treatment group, but they receive ultrasound treatment for 10 minutes on the dominant hand (sham treatment).

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

Where is the study run from?  
Azienda Sanitaria Locale 3 (Italy)

When is the study starting and how long is it expected to run for?  
September 2010 to May 2011

Who is funding the study?  
Investigator initiated and funded (Italy)

Who is the main contact?  
Dr Jorge Villafañe

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jorge Hugo Villafañe

**Contact details**  
via c. Colombo 2/9  
Piosasco  
Italy  
10045

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

### Scientific Title

Radial nerve mobilization decreases pain sensitivity and improves motor performance in patients with thumb carpometacarpal osteoarthritis: a randomized controlled trial

### Study objectives

Thumb carpometacarpal osteoarthritis (TCOA) constitutes a major cause of upper limb related-disability in Europe and the United States. In fact, 30-40% of postmenopausal women and 40-50 year-old men suffer from this condition. TCOA contributes to the largest number of osteoarthritis-related surgical procedures conducted in United States. The main cause of TCOA is the degenerative alteration of the trapeziometacarpal (TM) joint. This includes chronic deterioration of superficial surfaces of the joint and ectopic bone regeneration. These characteristics of TCOA result in increased pain at the base of the thumb.

The primary intent in this study is to confirm that neurophysiological changes occur in response to this intervention and extend these findings to a different peripheral musculoskeletal pain condition.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Local Health Authority, Collegno, Italy (Residenze Sanitarie Assistenziali Azienda Sanitaria Locale 3 (A.S.L 3), Collegno Italy), ref: 93571/c

### **Study design**

Randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Thumb carpometacarpal osteoarthritis

### **Interventions**

Radial nerve mobilization (treatment group):

1. Treatment was performed in six sessions over four weeks and was applied to the dominant hand three times during a four-minute period with one-minute pauses between periods
2. The technique consisted of a sliding mobilization of the proximal-distal radial nerve
3. To begin the technique, the patient was positioned in supine and the physiotherapist was seated
4. The physiotherapist depressed the patients' shoulder girdle, extended the patients elbow and then internally rotated the arm
5. The patients' wrist, thumb and all the fingers were flexed. Finally ulnar deviation of the hand was added.
6. This combination of movements is hypothesized to cause stress the radial nerve
7. Once the upper extremity was positioned two movements were done as follows:
  - 7.1. Shoulder depression was applied simultaneously with elbow flexion and wrist extension
  - 7.2. Shoulder elevation is performed with elbow extension and wrist flexion and ulnar deviation
8. These motions are alternated at a rate of approximately 2 seconds per cycle (1 second into extension and 1 second into flexion)

Placebo technique (control):

1. Participants in the placebo group attended the same number of sessions as those in the treatment group, but they received intermittent ultrasound therapy for 10 minutes with an intensity of 0 watts/cm<sup>2</sup> to on the hypothenar area of the dominant hand
2. Gel was used as required

### **Intervention Type**

Other

## Phase

Not Applicable

## Primary outcome(s)

### 1. Mechanical pain sensitivity:

1.1. Pain sensitivity was determined by measuring pressure pain threshold (PPT)

1.2. Measurements were performed with a Mechanical Pressure Algometer (Wagner Instruments, Greenwich, Connecticut, USA) with a 1cm<sup>2</sup> rubber-tipped plunger mounted on a force transducer was used for measuring PPT

1.3. Pressure was applied at a rate of 30 kPa/s

1.4. The mean of three measurements was calculated and used for the main analysis

1.5. Previous papers have reported an intraexaminer reliability of this procedure ranging from 0.6 to 0.97, while the interexaminer reliability ranged from 0.4 to 0.98

1.6. The following points were evaluated:

1.6.1. TM joint at the bottom of the anatomical snuffbox, tubercle of the scaphoid bone and unciform apophysis of the hamate bone

1.6.2. Three measurements were made with a one-minute pause between them

1.6.3. Although pain from deep tissue is difficult to assess precisely, PPT have been found useful in assessing pain reactions in OA patients

### 2. Motor performance:

#### 2.1. Pinch strength

2.1.1. The pinch strength was evaluated with a mechanical pinch gauge (Baseline, NY, USA) in the sitting position with the shoulder adducted and neutrally rotated and the elbow flexed at 90°

2.1.2. Two different measurements were taken. First we measured the tip pinch between index and thumb fingers. Then we measured tripod pinch, between index and, middle fingers and the thumb.

2.1.3. The reliability of pinch strength has been found to be high (Intra-class correlation coefficient [ICC]= 0.93) (34)

3. Measurements were taken before intervention, after 1 month, 1st Follow-up and 2 months, 2nd follow up

## Key secondary outcome(s)

### 1. The Beck Depression Inventory (BDI)

1.1. Review of internal consistency for the BDI ranges from 0.73 to 0.92, with a mean of 0.86, with alpha coefficients of 0.86 and 0.81 for psychiatric and non-psychiatric populations, respectively

1.2. The BDI observed showed high discrimination of depressive symptoms (75-100%)

### 2. State-Trait Anxiety Inventory (STAI)

2.1. This is a self rated questionnaire divided in two parts: anxiety-trait (referring to personality aspects) and anxiety-state (referring to systemic aspects of the context)

2.2. Responses are in a 1-4 scale

2.3. Anxiety-state refers to how individuals feel at the moment and anxiety-trait to how they generally feel

2.4. Each part varies from 20 to 80 points, and the scores indicate low (0-30), medium (31-49) or high (50 or more) anxiety levels

3. Measurements were taken before intervention, after 1 month (1st follow-up) and 2 months (2nd follow up)

## Completion date

30/05/2011

# Eligibility

## Key inclusion criteria

Patients who used the dominant hand systematically such as ex-factory workers and home workers, and were diagnosed with secondary thumb carpometacarpal osteoarthritis (TCOA) in the dominant hand by X-ray detection of stage III and IV according to the Eaton-Littler-Burton Classification.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

1. Patients if they scored more than 4 on the Becks Depression Inventory and/or more than 30 on the State Trait Anxiety Inventory (STAI)
2. Patients with a medical history of carpal tunnel syndrome, arthritis, surgical interventions on trapeziometacarpal (TM) joint, or DQuervains tenosynovitis
3. Patients presenting degenerative or non-degenerative neurological conditions in which pain perception was altered

## Date of first enrolment

20/09/2010

## Date of final enrolment

30/05/2011

# Locations

## Countries of recruitment

Italy

## Study participating centre

via c. Colombo 2/9

Piossasco

Italy

10045

# Sponsor information

## Organisation

Azienda Sanitaria Locale 3 (Italy)

## Organisation

Rey Juan Carlos University (Universidad Rey Juan Carlos)

## Organisation

Azienda Sanitaria Locale

## ROR

<https://ror.org/05xcney74>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded (Italy)

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/03/2012   |            | Yes            | No              |