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## Visceral Manipulation Treatment to Patients With Non-specific Neck Pain With Functional Dyspepsia

**This study has been completed.**

### Sponsor:

University of Nove de Julho

### Collaborators:

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### Information provided by (Responsible Party):

Fabiano Politti, University of Nove de Julho

### ClinicalTrials.gov Identifier:

NCT03043625

First received: February 1, 2017

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[History of Changes](#)

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### Purpose

**Background:** Non-specific neck pain (NS-NP) is characterized by pain in structures located in the region between the superior nuchal line and the spinal process of the first thoracic vertebra, without association with any specific systemic disease provided by multifactorial and/or little known causes.

**Objective:** The objective of the present study will be to verify the clinical effects of MV through visceral nociceptive inhibition in NS-NP patients with functional dyspepsia.

**Methods:** In this study sixty NS-NP patients with functional dyspepsia (age: 18 and 50 years) will be randomized in into two groups: visceral manipulation group (VMG) (n =30) and control group (CG) (n =30). The VMG will be treated with visceral manipulation to the stomach and liver while CG received placebo treatment. The immediate effects and 7 days after treatment will be evaluated through pain, cervical range, and electromyographic activity of the upper trapezius.

Condition	Intervention
Neck Pain	Other: Visceral manipulation
Functional Dyspepsia	Other: Control group (CG)

Study Type: Interventional  
Study Design: Allocation: Randomized  
Intervention Model: Parallel Assignment  
Intervention Model Description:  
randomized, double-blinded, sham-controlled, study  
Masking: Participant, Outcomes Assessor  
Primary Purpose: Treatment

Official Title: Effect of Visceral Manipulation on Electromyographic Activity of the Upper Trapezius Muscle, Cervical Range and Pain in Patients With Non-specific Neck Pain With Functional Dyspepsia: A Randomized, Double-blinded, Sham-controlled, Study

**Resource links provided by NLM:**

MedlinePlus related topics: [Indigestion](#) [Neck Injuries and Disorders](#)

[U.S. FDA Resources](#)

**Further study details as provided by Fabiano Politti, University of Nove de Julho:**

Primary Outcome Measures:

- Pain intensity assessed with Numerical Rating Scale [ Time Frame: 12 months ]  
Numerical rating scale (NRS) (11 point; 0: no pain, 10: the worst possible pain imaginable) translated and cross-culturally adapted for the Brazilian population
- Pain area documented on a body chart [ Time Frame: 12 months ]  
Pain area will documented on a body chart. The drawings will be subsequently digitized and pain areas will be measured using open source software named ImageJ (version 1.43, National Institutes of Health, Bethesda, Maryland).

Secondary Outcome Measures:

- Electromyography [ Time Frame: 12 months ]  
The sEMG signal of the upper trapezius muscle will be recorded on the side with the greatest self-reported pain.
- Cervical range of motion [ Time Frame: 12 months ]  
A flexometer (Sami ®) will be used to verify cervical range of motion (ROM) of the flexion/extension, right and left lateral flexion and rotation.

Enrollment: 60  
Actual Study Start Date: October 1, 2016  
Study Completion Date: February 1, 2017  
Primary Completion Date: January 30, 2017 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
<p>Experimental: Visceral manipulation Group (VMG) The VMG will be treated with visceral manipulation to the stomach and liver</p>	<p>Other: Visceral manipulation Participants will be instructed to lie down comfortably on a stretcher in the supine position, with lower limbs flexed and abdomen exposed, and the physiotherapist positioned to the right side of the patient. The therapeutic intervention will be began with the left hand of the physiotherapist in contact with the lower region of the stomach, to which a force will be applied so that the organ was moved in an upper and lateral left direction while the right hand controlled and directed the knees of the patient to the right side until the moment when the physiotherapist notice an increase in tension in the stomach region. For the liver manipulation, the same procedures will be followed, however, with contact in the right epigastric region and the knees directed to the left side. The same position will be maintained for each organ treated until the physiotherapist could feel, through touch, a decrease in the tension of the viscera. The mean treatment time will 5 minutes.</p>
<p>Placebo Comparator: Control group (CG) The CG will be received placebo treatment. In the placebo treatment, the therapist should place the hands over the navel region without exerting any local tension for 1 minute.</p>	<p>Other: Control group (CG) The CG will be received placebo treatment. In the placebo treatment, the therapist should place the hands over the navel region without exerting any local tension for 1 minute.</p>

## Eligibility

Ages Eligible for Study: 18 Years to 50 Years (Adult)  
 Sexes Eligible for Study: All  
 Accepts Healthy Volunteers: No

### Criteria

#### Inclusion Criteria:

- history of neck pain for a minimal period of the three months;
- neck with restricted movement (active or passive) in at least one direction;
- Neck Disability Index considering score range of 11-24 (score out of a 50) ;
- numerical rating scale (NRS) for perceived pain intensity considering 3-7 points on an 11-point;
- Presence of symptoms related to functional dyspepsia, according to the Rome III diagnostic criteria: uncomfortable postprandial fullness, early satiety, epigastric pain and epigastric burning, accompanied by

no evidence of structural disease capable of explaining the symptoms .

#### Exclusion Criteria:

- Individuals with history of neurological disorders (i.e., irradiated pain) or neck surgery; systemic disease; connective tissue disorder and herniated disc;
- current pregnancy;
- medical diagnosis of fibromyalgia;
- physical therapy treatment with, massage, or acupuncture in the previous two weeks;
- use of analgesic, muscle relaxant, psychotropic agent, or anti-inflammatory agent in the previous three days;
- chronic neck pain resulting from a traumatic incident; chronic musculoskeletal condition (e.g., muscular disorder, polyarthritis).

### **Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

No Contacts or Locations Provided

### **More Information**

#### Publications:

Barral JP, Mercier P. Visceral Manipulation. Eastland Press; 2005.

[Binder A. The diagnosis and treatment of nonspecific neck pain and whiplash. Eura Medicophys. 2007 Mar;43\(1\):79-89. Review.](#)

Responsible Party: Fabiano Politti, Principal Investigator, University of Nove de Julho  
ClinicalTrials.gov Identifier: [NCT03043625](#) [History of Changes](#)  
Other Study ID Numbers: VM-2016  
Study First Received: February 1, 2017  
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#### Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Plan Description: The data will not be shared with other researchers. The results of the study will be published as a manuscript in a scientific journal.

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Fabiano Politti, University of Nove de Julho:

Neck pain  
visceral manipulation  
functional dyspepsia  
electromyography  
pain

Additional relevant MeSH terms:

Neck Pain	Signs and Symptoms
Dyspepsia	Signs and Symptoms, Digestive
Gastritis	Gastroenteritis
Pain	Gastrointestinal Diseases
Neurologic Manifestations	Digestive System Diseases
Nervous System Diseases	Stomach Diseases

ClinicalTrials.gov processed this record on July 31, 2017