

Title: Effect of scapula-focused treatment with additional motor control exercises on pain and disability in patients with subacromial pain syndrome: A Randomized Controlled Trial

Trial registration number. [ClinicalTrials.gov \(NCT02695524\)](https://clinicaltrials.gov/ct2/show/study/NCT02695524)

Date: 06/08/2019

**AMENDMENT AND INFORMED CONSENT FORM APPROVED BY A HUMAN
SUBJECTS PROTECTION REVIEW BOARD**



**FACULDADE DE MEDICINA DE RIBEIRÃO PRETO
UNIVERSIDADE DE SÃO PAULO**

COMITÊ DE ÉTICA EM PESQUISA

OF. 009/2016- REP/CSE-FMRP-USP

Ribeirão Preto, August 06th 2019.

Dear Researcher,

We come to announce that the research project specified below has been reviewed and Approved by the Research Ethics Committee (REC) of the School Health Center of the Ribeirão Preto Medical School of the University of São Paulo, in an ordinary meeting on March 1st, 2016.

CAAE: 52563216.0.0000.5414

Research Project: " Effect of Scapula-focused Treatment with Additional Motor Control Exercises on Pain and Disability in Patients with Subacromial Pain Syndrome: A randomized Controlled Trial ".

Researcher: Gisele Harumi Hotta

In compliance with Resolution 466/12, should be sent to this REC the final report of the research and the publication of the results for a follow-up, as well as any complication or interruption.

Kind regards,

A handwritten signature in blue ink, appearing to read 'Laercio Joel Franco'.

Prof. Dr. Laercio Joel Franco

Coordinator of REC/CSE-FMRP-USP

Prof.Dr. Anamaria Siriani de Oliveira (supervisor)

Department of Health Sciences, Ribeirão Preto Medical School, University of São Paulo

INFORMED CONSENT FORM

We invite you to participate in the study entitled "Effect of Scapula-focused Treatment with Additional Motor Control Exercises on Pain and Disability in Patients with Subacromial Pain Syndrome: A Randomized Controlled Trial" to be conducted in Ribeirão Preto - Brazil. SP, having as responsible researcher for Prof. Dr. Anamaria Siriani de Oliveira, Professor of Medicine of Ribeirão Preto Ribeirão Preto Medical School - USP and PhD student Gisele Harumi Hotta of the Ribeirão Preto Medical School o - USP.

General clarification and purpose of the study:

The aim of this study is to apply a few exercises to improve shoulder movements and to strengthen muscles. This research is important because it will bring greater scientific support for the use of these exercises in the rehabilitation programs of individuals with shoulder pain.

Procedure Explanation:

Four evaluations of your shoulder will be performed, one before the first treatment session, one after four weeks and one after eight weeks of exercise and one after four months of treatment initiation. For all assessments, equipment that measures muscle strength, equipment to measure arm movements, and questionnaires with questions regarding your pain, difficulty and fear of performing some movements will be used. You will be asked in the evaluation to push yourself hard during some movements. You will still be asked to perform some movements such as trying to put your hand on the floor or raising your arms to assess your spine and shoulder. After the evaluation the subjects will randomly be chosen to either to the control group or treatment group. Regardless of which group you belong to, you will perform shoulder strengthening exercises. If you belong to the treatment group, you will perform six more exercises than the control group. The treatment will last 8 weeks, which will be performed 3 times a week, but not in a row, and each exercise will be performed initially without weight and later with additional weight

Possible benefits:

You should be aware that, except for the benefits expected as a result of muscle strengthening, there are no direct benefits to you due to participation in this research and that the data obtained by the researchers will help with better knowledge about the disease. You should also be aware that you can leave the search at any time without causing any harm to you and undertake only to report to at least one of those responsible for the search. In addition, you have the right to claim compensation if participation in this study harm you in any way.

Discomfort and risk:

You have been informed that this experiment may present minimal risk to your health due to the presence of symptoms of pain and discomfort after the sessions and that these symptoms will gradually disappear. If there is no reduction in symptoms, the researcher is willing to solve the problem with physical therapy resources for pain relief (electrotherapy and thermotherapy), monitoring and guidance in relation to daily activities and suspension of the exercises applied. Your identity will be kept strictly confidential.

Health or life insurance:

You were also informed that there is no type of health or life insurance that could benefit you due to your participation in this study.

Freedom of Participation:

Your participation in this study is voluntary. It is your right to discontinue your participation at any time without causing any harm to you.

Identity Secrecy:

The information obtained in this research will in no way be associated with your identity and may not be consulted by lay people without your official authorization. This information may be used for statistical or scientific purposes, provided that your identity and anonymity are maintained.

Those responsible for the study explained all the risks involved, the need for the research and offered to answer all their questions about the experiment. It is your duty to keep a copy of this consent.

I, _____ document number _____

Resident at _____ district _____

City _____ declare that I am ___ years old and agree to participate voluntarily in the research conducted by the responsible students and their respective supervisor.

Volunteer's name: _____ Date: _____

Signing of volunteer: _____

Researcher's name: _____ Date: _____

Signing of researcher: _____

For questions related to this study, contact:

CSE-Cuiabá Ethics Committee: +55 (16) 33150009

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