

# **HOSPITAL DAS CLINICAS OF THE FACULTY OF MEDICINE OF THE UNIVERSITY OF SÃO PAULO - HCFMUSP**

## **TERM OF FREE AND INFORMED CONSENT**

---

### RESEARCH DATA

Research Title: Effect of Tele-rehabilitation on Nonspecific Chronic Low Back Pain in the Black Population: A Randomized Controlled Trial

Principal Investigator: Amélia Pasqual Marques

Department/Institute: Department of Physical Therapy, Speech and Language Pathology, and Occupational Therapy, Faculty of Medicine, University of São Paulo

Data: March 15, 2023.

We emphasize that we follow Brazilian Resolution [466/2012](#), and the following contents are part of the explanations about the

research:

### **Invitation to Participate**

We invite you to participate in the research "Effect of Tele-rehabilitation on Nonspecific Chronic Low Back Pain in the Black Population: A Randomized Controlled Trial," which aims to evaluate the effect of tele-rehabilitation in the treatment of nonspecific chronic low back pain (without specific cause) using graded activity in the black population.

Your participation in the research is voluntary. You may choose not to answer any question or withdraw from the treatment, and you may stop your participation at any time. Your non-participation will not result in any harm to the researchers. The researchers guarantee that the information collected will only be used for the purposes outlined in the research objectives, and there is no possibility that the information collected may incriminate participants directly or indirectly.

**Justification and Objectives of the Study** - Low back pain affects many individuals and is responsible for significant absenteeism from work and compromises the ability to perform daily tasks and quality of life. With this study, we aim to better understand how tele-rehabilitation (remote care) can assist in managing low back pain, improving social impacts, and daily life for black individuals living in Brazil. As a proposed treatment approach, we are suggesting a program of exercises and education on how to deal with pain called Gradual Activity, which has been used as a treatment for low back pain, aiming to improve pain by addressing negative beliefs and attitudes (fear of exercising and understanding how one's body functions).

**Procedures to be Conducted and Methods to be Employed** - You may participate in the group that will receive Gradual Activity (low-intensity exercises, strengthening of the muscles of the spine, and education about the lumbar spine), while the other group will be the Educational Group (topics will be discussed to gain knowledge about low back pain, such as performing daily activities, in the workplace, and self-care). We will also make weekly calls to check on your low back pain and whether you are performing the activities proposed by the researcher. You will have

Short Project Title: Telerehabilitation for Chronic Low Back Pain in the Black Population.	Confidential	
Informed Consent Form Version 1.0 dated March 16, 2023		
Researcher's Name: Doctor. Amélia Pasqual Marques Faculty of Medicine, University of São Paulo		
	Participant's/ Legal Representative's Signature	Principal Investigator's Signature

Updated March 2023

access to an online platform and will be taught step by step how to navigate the platform and perform all proposed activities.

We will conduct an assessment before the treatments, after they are completed, and after 3 and 6 months, during which you will be followed by the research team. A questionnaire will be administered with questions about pain, functional capacity, quality of life, your level of physical activity (whether you exercise or not and how often), nutritional status (weight and height), your beliefs about possible fears related to work and physical activity due to low back pain, and whether you show signs of anxiety or depression.

**Explanation of Possible Discomforts and Risks Arising from Participation in the Research** - The risks of your participation are minimal; you may experience some discomfort or uneasiness during the performance of certain activities proposed in the Gradual Activity group and the educational program, such as performing a physical exercise or a relaxation technique.

If there is any harm resulting from the research, you have the right to request compensation through legal and/or extrajudicial means as provided for in Brazilian legislation (Civil Code, Law 10.406/2002, Articles 927 to 954; among others; and National Health Council Resolution No. 510 of 2016, Article 19).

**Expected Benefits for the Participant** - At the end of your participation in this research, you may be better equipped to manage low back pain. Additionally, we believe that the benefits will be significant and may also assist other rehabilitation professionals in improving care and treatment for low back pain. You should carry out the proposed activities following all the information provided by the researcher, such as finding a quiet place to perform the activities, concentrating on all stages of the exercises, and always following the step-by-step instructions of the entire research.

If we find results that favor the Gradual Activity group, participants randomized to the educational group will receive the GAG intervention free of charge after the study is completed.

**Assistance to Research Participants** - You will be accompanied by the physiotherapists responsible for this project during and after the study. You may immediately inform them of any doubts or situations that may arise during your participation in the study.

At any stage of the study, you will have access to the professionals responsible for the research. The principal investigator is Doctor. Amelia Pasqual Marques, who can be found at Rua Cipotanea, 51, Cidade Universitaria, ZIP code: 05360-000 - Sao Paulo – SP, second floor, room 10, Phone (11) 30918423, office hours 08:00 to 12:00 / 14:00 to 17:00. The executing researcher is Ingred Merllin Batista de Souza, who can be found at Cipotanea, 51, Cidade Universitaria, ZIP code: 05360-000 - Sao Paulo – SP, second floor, room 10, (11) 30918423 or (11) 953921279, office hours 08:00 to 12:00 / 14:00 to 17:00.

**Participants will receive a copy of the informed consent form** - You will receive a copy of this research's informed consent form, and the principal investigator will sign all copies.

**Confidentiality and Privacy** - You have full freedom to refuse to participate or continue in this research. By refusing, you will not be subject to any punishment or consequence. We guarantee that you will not be identified, and your responses will remain confidential.

Short Project Title: Telerehabilitation for Chronic Low Back Pain in the Black Population.	Confidential	
Informed Consent Form Version 1.0 dated March 16, 2023		
Researcher's Name: Doctor. Amélia Pasqual Marques Faculty of Medicine, University of Sao Paulo		
	Participant's/ Legal Representative's Signature	Principal Investigator's Signature

Updated March 2023

Given the sensitivity of the subject matter and any potential discomfort related to the topic, the researchers will take all necessary measures to ensure total confidentiality and anonymity of the data. The research platform used (RedCap) ensures data security and anonymity of participants.

**Remuneration** - There will be no personal expenses incurred as a result of the research, nor financial compensation related to your participation.

At any stage of the study, you will have access to the professionals responsible for the research to clarify doubts. The principal investigator is Doctor Amélia Pasqual Marques, who can be found at the address Rua Cipotânea, 51, Cidade Universitária, CEP: 05360-000 - São Paulo – SP, second floor, room 10, Phone (11) 30918423, operating hours 08:00 to 12:00 / 14:00 to 17:00. Email: pasqual@usp.br. If you have any considerations or doubts about the research ethics, please contact the Research Ethics Committee (CEP) – Rua Ovídio Pires de Campos, 225 – 5th floor – tel: (11) 2661-7585, (11) 2661-1548, from 7 am to 4 pm from Monday to Friday or by email: cappesq.adm@hc.fm.usp.br.

I declare that I have been sufficiently informed about the study "Effect of tele-rehabilitation on nonspecific chronic low back pain in the black population: a randomized controlled trial".

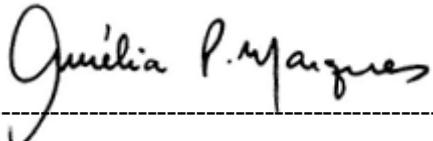
The objectives, procedures, potential discomforts and risks, and guarantees were clear to me. I voluntarily agree to participate in this study. I discussed the information above with the Responsible Researcher (Amélia Pasqual Marques) or person(s) delegated by her about my decision to participate in the study. It is important that you keep a version of this document in your files, which can be obtained by downloading the file at the link at the bottom of the page. If you are unable to download it, you may request the responsible researcher to send the document via another digital means.

----- Data \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Signature of the participant / legal representative

-----

Participant's name / legal representative



----- Data \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Signature of the study's responsible

Short Project Title: Telerehabilitation for Chronic Low Back Pain in the Black Population.	Confidential	
Informed Consent Form Version 1.0 dated March 16, 2023		
Researcher's Name: Doctor. Amélia Pasqual Marques Faculty of Medicine, University of São Paulo		
	Participant's/ Legal Representative's Signature	Principal Investigator's Signature

Updated March 2023