

Plan Overview

A Data Management Plan created using DMPTool

DMP ID: <https://doi.org/10.48321/D1MW8J>

Title: Photobiomodulation in Chronic Knee Pain in Patients Who Are in PreRehabilitation for Bariatric Surgery: Double Blind, Randomized, Controlled Placebo Clinical Trial

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Funder: Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (capes.gov.br)

Template: Digital Curation Centre

Project abstract:

Chronic pain is a global public health problem, which intensifies even more in the obese population, reaching about 33% of these patients. Among the topography, chronic knee pain affects 80%, constituting an important cause of disability and decreased quality of life. In addition, in grade 3 obesity, also called morbid obesity, in which bariatric surgery is already indicated, knee pain makes it difficult or prevents participation in the pre-habilitation program that includes physical therapy through therapeutic exercises with the aim of reducing postoperative complications. In this sense, a double-blind, randomized, placebo-controlled clinical trial will be conducted with the objective of evaluating the effect of photobiomodulation (PBM) on pain and functionality of obese patients with chronic knee pain who are in a preRehabilitation program for bariatric surgery, discussing its role as an analgesic therapy and modifier of peripheral and central sensitization mechanisms of the pain pathway. PBM is a safe treatment option, with no undesirable effects and low cost. The primary outcomes will be pain intensity, through visual analogue scale, 6-minute walk test, knee range of motion, SF-36 quality

of life questionnaire and Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire, validated version for Portuguese - Brazil. Secondary outcomes will be pressure pain threshold and rolling pinch maneuver measured by digital algometer. There will be 2 groups: an intervention group (photobiomodulation associated with standard physiotherapy treatment) and another placebo group (device turned off associated with the same standard physiotherapy treatment). The application sites will be knees and lumbar paravertebral 2 times a week for 12 weeks. The dosimetric standards will be 4J/point in the knees and 3J/point in the lumbar. The results obtained will be statistically analyzed and later published in a scientific journal.

Start date: 12-01-2023

End date: 12-31-2024

Last modified: 09-04-2023

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Photobiomodulation in Chronic Knee Pain in Patients Who Are in PreRehabilitation for Bariatric Surgery: Double Blind, Randomized, Controlled Placebo Clinical Trial

Data Collection

What data will you collect or create?

Clinical safety and tolerability parameters plus clinical data referring to pain, quality of life and functionality assessments by clinical measures:

Visual Analog Scale Change Data

6 minute walk test Change

SF-36 Scale Change Scale that assesses quality of life

Knee injury and Osteoarthritis Outcome Score (KOOS) Change

Knee joint range of motion Change

Pressure pain thresholds will be assessed in the muscles related to knee Change Pressure pain thresholds will be evaluated with algometer in the muscles: vastus medialis, adductor longus, rectus femoris, vastus lateralis, tibialis anterior, peroneus longus, popliteus, sartorius, gracilis, quadratus lumborum, supraspinatus ligaments (Lumbar) between L1-L2, L2- L3, L3-L4, L4-L5 and L5-S1 and sacral (S) S1-S2, as previously described in the literature

The dermatomes pinching and rolling maneuver Change The pinching and rolling maneuver in the L1, L2, L3, L4, L5, S1 and S2 dermatomes will also be performed to assess signs of subcutaneous hyperalgesia and the pain threshold will be measured with an algometer.

How will the data be collected or created?

Regarding the time of collection: at the initial assessment (baseline in the same day of first PBM therapy) and at the end of the intervention (after 14 weeks from baseline).

Regarding the form of collection, all data will be collected in face-to-face medical evaluations

Documentation and Metadata

What documentation and metadata will accompany the data?

The original data referring to knee pain, quality of life and functionality assessments will be saved in spreadsheets without data that can identify the participants, preserving the anonymity of the cases. These worksheets contain captions identifying which outcome and evaluation methods the results belong to each other. The data will be accompanied by the relevant metadata, according to Dublin Core Standards, and will include: data title, unique identifier, creation date, modification date, corresponding unit.

Ethics and Legal Compliance

How will you manage any ethical issues?

The project was approved by the Research Ethics Committee of Hospital das Clínicas da Universidade Federal de Goiás with the Approval Number: 66250922200005078

The study will be conducted in accordance with Resolution 466/2012, Good Practices for Clinical Research and the protocol are registered on the Clinical Trials platform. Participants will only be included after properly obtaining consent and signing the Free and Informed Consent term. All data published or made available will preserve the anonymity of the participants, and will not contain sensitive data or data that identify the participants.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

We will adopt the regulations of Law nº 9.610/1998 on copyright. In this way, the research team will own the copyright, which, however, may be transferred to the publisher at the time of publication, depending on the editorial policies.

Storage and Backup

How will the data be stored and backed up during the research?

All research data will be collected directly in electronic data and stored on the research team institutional servers with automatic internal backups and backups in the institutional drive, in addition to firewall protection. All access to research team members' drives is done with passwords only.

How will you manage access and security?

The system has authentication tools, access control and activity recording, ensuring security and traceability of data and access. Only the principal investigator and the study manager have access to data and passwords.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

The registered protocol will be submitted to publication in a scientific journal making the protocol public before the collected data. Upon completion of the study, the original non-identifiable data collected and stored in the spreadsheets drives will be exported to an Open Science repository such as Mendeley Data, Figshare or similar with your metadata. The results after the statistical analysis will also be sent for publication in indexed scientific journals.

What is the long-term preservation plan for the dataset?

Non-identifiable data will be preserved in accordance with the policies of these data platforms and scientific journals.

Data Sharing

How will you share the data?

The registered protocol will be submitted to publication in a scientific journal making the protocol public before the collected data. Upon completion of the study, the original non-identifiable data collected and stored in the spreadsheets drives will be exported to an Open Science repository with your metadata. The results after the statistical analysis will also be sent for publication in indexed scientific journals with the purpose of collaborating with the scientific community and auditing the results data

Are any restrictions on data sharing required?

Sensitive data or any data that allow identification of research participants will not be made public, will not be published nor exported to the data repositories, in accordance with the General Law for the Protection of Personal Data, Law No. 13,709/2018.

Responsibilities and Resources

Who will be responsible for data management?

The research team

What resources will you require to deliver your plan?

The resources made available by the Nove de Julho University are sufficient for data management.
