OSTEOPATHIC CARE COMBINED WITH PHYSIOTHERAPY AND PAIN EDUCATION FOR CERVICOGENIC HEADACHE: STUDY PROTOCOL FOR A THREE-ARM PRAGMATIC RANDOMIZED CONTROLLED TRIAL

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Participant or Legal Representative *Person Obtaining Consent*

Research Ethics Committee: Rua Dona Isabel 94, Bonsucesso, Rio de Janeiro, RJ, (+5521) 3882-9797 extension 2015, e-mail: comitedeetica@unisuam.edu.br

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Appendix 1 – Informed Consent Form

Osteopathic Care Combined With Physiotherapy and Pain Education for Cervicogenic Headache: Study Protocol for a Three-arm Pragmatic Randomized Controlled Trial

Prepared based on Resolution No. 466 of December-10-2012, of the National Health Council

Presentation: You are being invited to participate in a research study whose objective is to assess the effectiveness of Osteopathic Care (OC) in individuals with cervicogenic headache (neck-related headache).

Procedures: Participants will be randomly assigned to one of three groups. You may be selected for the group that will receive Physiotherapy (exercises + Mulligan); for the group that will receive Physiotherapy combined with Osteopathic Care (OC + exercises + Mulligan); or for the group that will receive Physiotherapy combined with sham Osteopathic Care (sham OC). If OC is shown to be effective, all participants may, at the end of the study, be referred for free Osteopathic Care at the Osteopathy Outpatient Clinic.

Below is information related to the assessments that will be conducted in this project:
1. Data such as name, age, weight, and medical history will be collected.
2. Using a numerical scale, you will be asked to rate your pain intensity from 0 to 10, and you will be asked to complete three questionnaires.
3. An assessment will be performed by the Physiotherapist and, after the assessment, you will receive Physiotherapy consisting of neck exercises and a manual technique for the neck. The Physiotherapist will determine the type of intervention and the frequency required for your case. Participants assigned to the intervention group will also receive OC in addition to the treatment mentioned above. OC is a person-centered healthcare approach. It consists of a variety of manipulative manual techniques applied after an Osteopathic examination to identify patterns of dysfunction. The Osteopath will determine the necessary intervention based on the examination. All participants in the three groups will receive treatment for 6 weeks. After 6 weeks of treatment, the assessments will be performed again to evaluate the results obtained, and 24 weeks after the end of treatment, the assessments will be performed again to assess the durability of the results. Our study will help improve the understanding of the effects of OC, with the aim of potentially recommending it in the future for people who suffer from neck-related headache. Follow-up and care will be provided by osteopaths and physiotherapists.

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Benefits: The potential benefits of your participation include improvement in the impact of your headache, improvement in the intensity of musculoskeletal pain, and a perceived sense of improvement.

Risks: All procedures to be performed are noninvasive, thereby reducing the risk of adverse events. Adverse effects may include mild and transient pain, discomfort, and movement stiffness occurring immediately after the application of both OC and Physiotherapy. If necessary, the participant may be referred for care by the physician within the Brazilian Unified Health System who referred them to this research study.

Guarantee of confidentiality, privacy, anonymity, and access: Your privacy will be respected; that is, your name or any other data or element that could in any way identify you will be kept confidential. Anonymity and privacy will be guaranteed. If interested, you will have access to the results.

Guarantee of information and clarification: Assistance throughout the entire research study is assured, as well as your free access to all information and any additional clarification regarding the study and its consequences.

Guarantee of responsibility and disclosure: The results of the examinations and research data will be the responsibility of the researcher, and these results will be disclosed in scientific settings without citing any information that could identify you.

Guarantee of reimbursement of expenses: You will not incur any personal expenses at any stage of the study, nor will you receive financial compensation related to your participation. In the event of personal injury directly caused by the procedures proposed in this study, you will be entitled to medical treatment as well as legally established compensation. However, should you incur any expenses resulting from participation in the research, you will be reimbursed by bank deposit, check, or cash. Likewise, should any harm result from your participation in the study, you will be duly compensated, as provided by law.

Responsibility of the researcher and institution: The researcher and the sponsoring institution will be responsible for any personal or moral harm related to physical and ethical integrity that may result from the research.

Criteria for suspending or terminating the research: The study will be suspended in the event of any methodological or technical failure identified by the researcher, who will be responsible for informing all participants of the reason for the suspension. The study will also be suspended if any risk or harm to the health of the participating subjects resulting from the research is identified that was not anticipated in this form. Once the necessary data collection has been completed, the research will be concluded.

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Infrastructure statement: The institution where the study will be conducted has the infrastructure necessary to carry out the research in an appropriate environment.

Ownership of the information generated: There is no restrictive clause regarding the disclosure of the research results, and the data collected will be used solely and exclusively to substantiate the experiment. The results will be submitted for publication, whether or not they support the study hypotheses.

Regarding refusal to participate: If you wish, you may refuse to participate in the study or withdraw your consent at any time, without having to provide a reason and without any prejudice to the care you receive.

Contact information for the principal investigator and ethics committees: At any stage of the study, you may contact the responsible professional, PAULA OLIVEIRA ESTEVES, who can be reached by telephone at (+5521) 99225-5928. If you have any comments or questions regarding the ethics of the research, you may contact the UNISUAM Research Ethics Committee (contact information in the footer) and the Rio de Janeiro State Department of Health Research Ethics Committee, located at Barão de Itapagipe, 225 - Rio Comprido, Rio de Janeiro - RJ, 20261-005 – 4th Floor. Telephone: (+5521) 3385-9952, e-mail: cep.sesrj@saude.rj.gov.br. Service for the general public and researchers: Tuesday and Friday from 9:00 a.m. to 12:00 p.m. and Monday and Thursday from 2:00 p.m. to 4:00 p.m.

If this form is sufficiently clear to provide you with all the information about the study and if you understand its purposes, the procedures to be performed, its discomforts and risks, and the guarantees of confidentiality and ongoing clarification, you may declare your free consent to participate, being fully aware of the study proposal.

Rio de Janeiro, _____ , _____ , _____

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