Universidade Federal de São Paulo
Campus São Paulo
Unidade Universitária – Escola Paulista de Medicina
Departamento de Medicina (Cardiologia)

Free and Informed Consent Term for Participation in Clinical Research - Approved on January 18th, 2019

You are being invited to participate in this research with the title **" EFFECT OF ACUPUNCTURE ON HEART RATE VARIABILITY IN INDIVIDUALS WITH MULTIPLE SCLEROSIS"** and which aims to analyze the variability of heart rate in individuals with Multiple Sclerosis (MS) during Acupuncture and investigate the effects of Acupuncture on it.

DATA IDENTIFYING THE RESEARCH PARTICIPANT:

Full name of research participant: _____

ID number: _____

Sex:_____ Date of Birth: _____

Address: _____

District:_____ City: _____ Post code: _____

Contact phone: _____

E-mail: _____

The information contained in this record was provided by researchers Prof. Dr. Celso Ferreira, Prof. Dr. Talita Dias da Silva, and Luciana Nagato, aiming to sign a written agreement by which, the participant authorizes their participation with full knowledge of the nature of the procedures and risks to which they will submit, with the capacity of free will and without any intimidation.

Title of the Experimental Work: "**EFFECT OF ACUPUNCTURE ON HEART RATE VARIABILITY IN INDIVIDUALS WITH MULTIPLE SCLEROSIS**".

Objective: The objective of this study is to analyze the autonomic cardiac modulation in individuals with MS and to investigate the effects of acupuncture on it.

Researcher Luciana Nagato: _____

Participant: _____

3. Procedures: For data collection, the following instrument will be used: Visual Analogue Scale of Pain. This scale is a quantitative pain questionnaire that will be applied at the beginning and end of the data collection. In sequence, the participants will perform the Thermography protocol, which comprises capturing images in various postures in the orthostatic position. Afterwards, the participants will remain in the supine dorsal position on a stretcher at rest for 10 minutes to start the SNA analysis with the Ryodoraku (device that measures the electroconductivity of certain points on the skin) by the digital reading of the 24 points called ryodos (SCILIPOTI, 2007). Continuing the procedure, immediately after

CAMPUS SÃO PAULO – DEPARTAMENTO DE MEDICINA (CARDIOLOGIA)
Rua Napoleão de Barros, 715, 10º andar - Vila Clementino - São Paulo – SP
Telefone: (11) 5576-4848

Rubrica do Pesquisador Principal	Rubrica do(a) Participante da Pesquisa

the placement of the Polar V800, an instrument for analyzing heart rate variability, the placing of needles at the points carefully selected for this research begins. The needling will proceed for the experimental group using specific Traditional Chinese Acupuncture points: E36, BP6, F3, IG4, for 20 minutes while the control group will receive needling in sham points (points not recognized as Acupuncture points), with the duration of 20 minutes. Final phase, new reading with Ryodoraku and Thermography.

4. Information: The research participant is guaranteed to receive answers to any question or clarification of any doubt regarding the procedures, risks, benefits, and other issues related to the research. The above-mentioned researchers are also committed to providing up to-date information obtained during the study, although this may affect the individual's willingness to continue participating.

Research participants will have indirect benefits. They will benefit from future information that may improve the quality of life of participants. Therefore, there is no immediate benefit to the participants of this research, only after the conclusions of this work that can contribute in a significant way to the adequate, organized, and effective elaboration of the diagnostic methods and treatment in Acupuncture.

Corroborating, we hope that this study will contribute significantly to rehabilitation programs, so that the knowledge observed and acquired from this research can contribute to the advancement of science and health of these patients. The researcher is committed to disseminate the results obtained.

5. Withdrawal of Consent: The participant is free to withdraw his or her consent, i.e., at any time he or she may cease to participate in the trial if he or she so wishes.

Researcher Luciana Nagato: _____

Participant: _____

6. Legal Aspect: Elaborated in accordance with the directives and regulated norms of research involving human beings in compliance with Resolution No. 466 of December 12, 2012, of the National Health Council of the Ministry of Health - Brasília - DF. We remind you that if the treatment given to the Experimental Group (effective acupuncture) proves to be effective at the end of the study, the same treatment should be made available to the control group (sham acupuncture) according to Resolution 466/2012:III.3.d, which proposes: "To assure all participants at the end of the study, by the sponsor, access, free of charge and for an indefinite period of time, to the best prophylactic, diagnostic and therapeutic methods that have proven to be effective".

7. Guarantee of Secrecy: Researchers ensure the privacy of participants regarding the confidential data involved in the research.

8. Research site:

CAMPUS SÃO PAULO – DEPARTAMENTO DE MEDICINA (CARDIOLOGIA)
Rua Napoleão de Barros, 715, 10º andar - Vila Clementino - São Paulo – SP
Telefone: (11) 5576-4848

Rubrica do Pesquisador Principal	Rubrica do(a) Participante da Pesquisa

Brazilian Association of Multiple Sclerosis (ABEM), located at Av. Indianópolis, 2752 - Indianópolis, São Paulo - SP, Post code: 04064-003, phone:55876050, with authorization of the Coordinator of the Scientific Department Dr. Ana Maria Canzonieri.

9. Identification of those responsible for the research: In case of questions, you can contact the researchers respectively (Advisor and Student): Prof. Dr. Celso Ferreira, (11) 983795555, resident at Rua Albert Einstein, n°51, Bairro Morumbi, São Paulo, email: doutorcelsoferreira@gmail.com Luciana Nagato, (11) 9-82211303, resident at Rua Arcipreste de Andrade, 510 house 3 - Ipiranga, São Paulo, email: luciananagato@msn.com 10. The possible discomfort is related to the use of acupuncture needles, which are sterile, of single and individual use, discarded at the end of the procedure in a compartment suitable for perforating materials. And as for the use of the Ryodoraku device - model NKL USB, the risks are also minimal, because there may be slight discomfort in relation to the pressure of the tip with wet cotton on the skin applied to the points to be evaluated during the reading. The risks in your participation in the research are minimal. If there is an eventual occurrence with the research participant during the activity he is developing, he will receive full assistance from the researcher during and after the procedures, through monitoring in the appropriate public health

Researcher Luciana Nagato: _____

Participant: _____

network. The researcher will be constantly in telephone contact with the participant to follow him/her daily and to know his/her current needs.

11. Ethics Committee: If you have any questions or concerns about your rights as a participant in this study and/or are dissatisfied with the way the study is being conducted, you may contact the Research Ethics Committee of the Federal University of São Paulo at: Rua Prof. Francisco de Castro, 55, SP - São Paulo, Vila Mariana – Post code: 04020-050, or by phone: (11) 55711062, Mondays, Tuesdays, Thursdays and Fridays from 9:00 a.m. to 1:00 p.m. Email: mag.franco@unifesp.br

12 This term will be elaborated in two copies, one for the person responsible for the participant and the other will be filed by the researcher.

13. participation in this survey will be conducted in 5 days, once a week, with an interval of two weeks. Completed in 84 days.

Researcher Luciana Nagato: _____

Participant: _____

Post-Information Consent:

I, _____, holder of the ID_____ , declare that after having been conveniently clarified by the researcher and having

CAMPUS SÃO PAULO – DEPARTAMENTO DE MEDICINA (CARDIOLOGIA)
Rua Napoleão de Barros, 715, 10º andar - Vila Clementino - São Paulo – SP
Telefone: (11) 5576-4848

Rubrica do Pesquisador Principal	Rubrica do(a) Participante da Pesquisa

understood what was explained to me, I consent to participate in the present Research Project "**EFFECT OF ACUPUNCTURE ON HEART RATE VARIABILITY IN INDIVIDUALS WITH MULTIPLE SCLEROSIS** ". I confirm that I have received this informed consent form and authorize the execution of the research work and the dissemination of the data obtained in this study to the scientific community.

* Don't sign this term if you still have any questions about it.

São Paulo, , 2022.

Research Participant's signature: _____

Researcher Responsible Luciana Nagato Signature: _____

CAMPUS SÃO PAULO – DEPARTAMENTO DE MEDICINA (CARDIOLOGIA)
Rua Napoleão de Barros, 715, 10º andar - Vila Clementino - São Paulo – SP
Telefone: (11) 5576-4848

Rubrica do Pesquisador Principal	Rubrica do(a) Participante da Pesquisa