HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO-HCFMUSP

INFORMED CONSENT FORM

Research title - Efficacy and safety of auricular acupuncture in depression: a multicenter randomized clinical trial

Principal investigator - Dr. Alexandre Faisal Cury - CRM-SP 51045

Department/Institute - Department of Preventive Medicine - Faculty of Medicine of the University of São Paulo

RESEARCH RISK ASSESSMENT:

(X) Minimal Risk ( ) Medium Risk

( ) Low Risk ( ) High RiskDADOS DA PESQUISA

RESEARCH DURATION: 6 months

PRESENTATION AND INVITATION:

We invite you to participate in a scientific research entitled "Efficacy and safety of auricular acupuncture in depression: a multicenter randomized clinical trial", coordinated by Professor Dr. Alexandre Faisal Cury.

Research is a set of procedures that seeks to create or increase knowledge about a subject. Although these findings often do not bring direct benefits to the research participant, they may be useful to many people in the future. To decide whether or not to participate in this research, you need to understand enough about the risks and benefits so that you can make an informed judgment.

Initially, we will explain the reasons for the research. Then, we will provide an informed consent form (ICF), a document that contains information about the research, for you to read and discuss with family members or other people you trust. Once you have understood the purpose of the research and

are interested in participating, you will be asked to sign the last page. A signed copy of this form will be sent to your email, and a copy will be kept on file by the responsible researchers.

JUSTIFICATION, OBJECTIVES, AND PROCEDURES:

The objective of this study is to evaluate the efficacy of auricular acupuncture in reducing depressive symptoms. This study is justified because it is a therapy used for millennia with few scientific studies, considered easy to apply, low-cost, with few side effects, and could help people with depressive symptoms.

If you agree to participate, you will have two sessions of auricular acupuncture lasting thirty minutes, twice a week for six weeks, totaling twelve sessions. At the beginning of the study, during the auricular acupuncture applications, after three and six months, you will answer six questionnaires, lasting twenty to thirty minutes, to evaluate the evolution over time.

A smaller sample of the study will be invited to undergo blood collection at two points in the study, in the first and last week of auricular acupuncture sessions. This subsample will be selected by a computer-generated lottery. This collection will be performed by a qualified professional in the School Clinic, who will collect approximately 10 ml of blood from the brachial vein. This collection will be important to evaluate the possible mechanisms of action of auricular acupuncture. This blood will be used only for this research, and after analysis, it will be discarded respecting biosafety standards. All data collection procedures will be carried out in an individualized office in the School Clinic or in a specific room at the University to avoid exposing the participants.

DISCOMFORTS, RISKS AND BENEFITS:

By participating in this research, you will be exposed to minimal risks, such as some physical discomfort with the application of auricular acupuncture or with the nature of the questionnaire questions that may induce some emotional feeling. If they occur, the following measures will be taken: you can contact the study team, who will take the necessary actions (removal of the ear needle or referral to a psychologist, naturopath or psychiatrist from the study in case of emotional discomfort), under the responsibility of the responsible researchers.

Inclusion in the study does not define a medical diagnosis of depression; it is only indicated that you have depressive symptoms. Inclusion in the study will occur if you reach a minimum score evaluated by the PHQ-9 instrument. From screening to any of the follow-up contacts, the researchers may encounter severely depressed individuals with suicidal ideation or suffering from some other serious mental disorder. These participants will be referred to a psychiatrist who will take the necessary measures according to each case and will not receive auricular acupuncture intervention.

Some participants may be concerned about the confidentiality of their data and, above all, about aspects related to possible exposure of opinions that may be a source of eventual embarrassment by peers. Care for maintaining confidentiality and anonymity in this research aims to minimize the above-mentioned risks.

If you are selected to participate in the blood analysis, you will undergo a venous puncture for collection of 10 mL (about 1 tablespoon) of blood. Side effects of blood collection may include pain, bleeding, and hematoma. Although the researchers may not be able to identify other risks, if identifiable, these will be controlled.

In terms of benefits, the research procedures in the recruitment phase will identify patients with depression and possibly at risk of suicide who would not have been otherwise identified, ensuring specialized care for severe depression or suicidal ideation. In addition to monitoring throughout the research of routine care and referral to specialized services if necessary.

This study will test a simple, inexpensive, non-pharmacological, and easy-to-apply intervention for depression. Therefore, it has the potential to generate significant gains in public health in terms of improving access to complementary treatments and reducing the treatment gap for depressive disorders. The knowledge gained may be critical in influencing the agenda for collective and mental health policies in Brazil.

Furthermore, the study results will be made available to participants by indicated email or in the way the participant decides, after the conclusion of the study. After the study's conclusion, if one group demonstrates superior effects to the other, at the end of the research, participants will have access to the protocol. Therefore, this research is justified in its risk-benefit balance, as the potential benefits outweigh

the potential risks. Since auricular acupuncture is widely used worldwide, considered a technique of easy application, low cost, and minimal side effects.

METHOD OF MONITORING AND ASSISTANCE:

You will be accompanied by the study team during and after the research. At any stage of the study, you will have access to the professionals responsible for the research. The principal investigator is Dr. Alexandre Faisal Cury, who can be found at Rua Pedro Fioretti, 454, Osasco, SP, Telephone (15)98107-3571, business hours from 08:00 a.m to 6:00 p.m. The executing investigators are Daniel Maurício de Oliveira Rodrigues, Ana Elise Machado Ribeiro Silotto, and Artur Heps. Avenida Pedra Branca, 25, Pedra Branca, Palhoça, SC, CEP 88117-700, Telephone (48) 3279-1143, business hours from 08:00 a.m. to 06:00 p.m.

If you experience any adverse event, please contact the investigators at the following email addresses: danielrodrigues@usp.br, ana.silotto@usp.br, arturheps@usp.br, or call (48) 99677-6240 (24-hour telephone).

If you have any concerns or questions about the research ethics, please contact the Research Ethics Committee of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo (CEP-FMUSP): - Rua Ovídio Pires de Campos, 225 - 5th floor - tel: (11) 2661-7585, (11) 2661-1548, from 7:00 a.m. to 4:00 p.m. from Monday to Friday or by email: cappesq.adm@hc.fm.usp.br

FREEDOM TO REFUSE AND WITHDRAW FROM THE STUDY:

The choice to participate in the study is yours. You may also withdraw from the research at any time without any prejudice to you. Assistance is provided throughout the research, and free access to all information and additional clarifications about the study and its consequences is guaranteed. If it is detected that you have a condition that requires treatment during your participation in the research, you will receive guidance from the research team to receive specialized care. You may also contact the investigators at any stage of the research by email or telephone, using the contact information provided in this document

CONFIDENTIALITY AND PRIVACY MAINTENANCE:

The material and information obtained may be published in classes, conferences, scientific events, lectures, or scientific journals, without identification. The researchers are responsible for the safekeeping and confidentiality of the data, as well as for not exposing individualized research data. Your participation is voluntary, and you have the freedom to refuse to answer any questions that may cause you any kind of embarrassment. Your data will be analyzed together with other participants, and the identification of any participant will not be disclosed under any circumstances. You will receive a copy of this Informed Consent Form.

REIMBURSEMENT GUARANTEE:

You will not have any costs since the cost of this research will be the responsibility of the research budget. You are entitled to reimbursement for expenses arising from your participation in the research.

COMPENSATION GUARANTEE:

You are entitled to compensation for any damages resulting from the research.

I believe I have been sufficiently informed about the information I have read or that has been read to me, describing the study Efficacy and safety of auricular acupuncture in depression: a multicenter randomized clinical trial. I have discussed with _____ my decision to participate in this study. The study's purposes, procedures to be performed, discomforts and risks, guarantees of confidentiality, and permanent clarifications have been made clear to me. It was also clear that my participation is free of charge, and I am guaranteed access to treatment when necessary. I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during the study, without penalties or loss of any benefits that I may have acquired, or in my care in this Service.

---------- Date____/__/____

Participant/ legal representative signature

for illiterate, semi-literate patients, or those with hearing or visual impairments.

---------- Date____/__/____

Witness signature

(Only for the project responsible)

I declare that I have appropriately and voluntarily obtained the Informed Consent of this patient or legal representative for participation in this study.

---------- Date____/__/____

Study's responsible signature