HOSPITAL DAS CLÍNICAS OF THE FACULTY OF MEDICINE OF THE UNIVERSITY OF SÃO PAULO - HCFMUSP

INFORMED CONSENT FORM

Efficacy of a Fully Automated Electronic Screening and Brief Intervention to Reduce Harmful Alcohol Consumption: A Randomized Clinical Trial (PROSA e-SBI)

2022-10-04

HOSPITAL DAS CLÍNICAS OF THE FACULTY OF MEDICINE OF THE UNIVERSITY OF SÃO PAULO - HCFMUSP

INFORMED CONSENT FORM

RESEARCH DATA

Research Title - Integrated Digital Screening and Brief Intervention System for Reducing Harmful Alcohol Consumption - PROSA – eTIB

Principal Investigator - MARTINO MARTINELLI FILHO – Physician - Regional Medical Council No. 27,133

Department/Institute - CLINICAL UNIT OF CARDIAC STIMULATION – InCor-HCFMUSP

In accordance with resolution 466/2012, the following content must be included in the explanations about the research.

Invitation to participate –
We are inviting you to participate in this study, which will be conducted at InCor-HCFMUSP.

Justification and objectives of the study –
We are conducting this study to evaluate whether a digital system can identify the risk you are exposed to due to alcohol consumption and, after classifying the level of consumption risk, carry out an action to raise awareness about harmful (high-risk) alcohol consumption. We will compare conducting these activities in person, with the help of a healthcare professional, versus doing them digitally, i.e., using a mobile phone.

Procedures to be performed and methods to be employed –
We will ask you to answer several questionnaires to find out whether you usually drink alcohol and what type. You will be randomly assigned to answer these questionnaires either in person or via mobile phone. After you answer these questionnaires, a risk classification will be made. From that point, we will carry out an awareness action to encourage you to reflect on the type of consumption you engage in. Again, this action may be in person, if you answered the questionnaires in person, or via mobile phone, if you answered the questionnaires via mobile phone. It is estimated that answering all questionnaires will take a maximum of 15 minutes.

Explanation of possible discomforts and risks arising from participation in the research –

The main discomfort for you will be the extra time spent at the hospital to answer the questions we ask, if done in person, or dedicating time to the same process using a mobile phone.

Expected benefits for the participant –
No direct benefit is expected for you from participating in this study. The intention of this study is to help people in the future, because once the study is completed, we will be able to better understand whether the use of a mobile phone can be used to measure the risk of people who usually consume alcoholic beverages and whether it is possible to carry out an action to encourage reflection on the consumption of such beverages. If using a mobile phone proves feasible, it could be used for the entire population of Brazil and help many people.
If it is identified that you consume alcoholic beverages excessively, you will be advised to seek help at appropriate locations near your residence.

Clarification on the form of follow-up and assistance to which research participants are entitled –
It is important to inform you that no participant in this study will have any type of treatment they are undergoing altered, even after the study ends.

Guarantees of full freedom for the participant to refuse to participate or withdraw their consent at any stage of the research without any penalty, as well as guarantees of confidentiality and privacy –
Since we will not modify your treatment, there are no more advantageous alternatives if you do not wish to participate.
You may withdraw from our study at any time, without any harm to the continuity of your treatment at InCor (if you are a patient).

Your information will be analyzed together with that of the other research participants, without revealing your name or the name of any other study participant.

You may learn about the results of our study whenever we have such data, even before the study ends or after its conclusion.

You will not incur any additional expenses for participating in our study. There is also no financial compensation for participation.

We will only use your information for the purpose of conducting this study.

Guarantee that the participant will receive a copy of the consent form –
If you agree to participate in our study, we will ask you to sign this consent form in two copies, one for you and one for us.

Explanation of guarantees for reimbursement of expenses arising from the research and explanation of the guarantee of compensation for any damages resulting from the research –
We do not anticipate that you will experience any problems from participating in our study, but should this happen, you have the right to request reimbursement for any expenses you may incur.

At any stage of the study, you will have access to the professionals responsible for the research to clarify any questions. The principal investigator is Dr. Martino Martinelli Filho, who can be reached at Av. Dr. Enéas de Carvalho Aguiar, 44. Phone number(s): (11) 2661-5321, email: martino@incor.usp.br. For 24-hour contact at the emergency room, call (11) 2661-5299. If you have any concerns or questions about the ethics of the research, please contact the Research Ethics Committee (CEP) – Rua Ovídio Pires de Campos, 225 – 5th floor – phone: (11) 2661-7585, (11) 2661-1548, (11) 2661-1549; from 7 am to 4 pm, Monday through Friday, or by email: cappesq.adm@hc.fm.usp.br.

I have been sufficiently informed about the study "Integrated Digital Screening and Brief Intervention System for Reducing Harmful Alcohol Consumption - PROSA – eTIB".

I have discussed the above information with the Principal Investigator Martino Martinelli Filho or the person(s) delegated by him, Raphael Coutinho or Caio Vitale, regarding my decision to participate in this study. The objectives, procedures, potential discomforts and risks, and the guarantees have been made clear to me. I voluntarily agree to participate in this study, sign this consent form, and receive a copy initialed by the researcher.

---------- Date **/**/_____

Signature of participant / legal representative

---------- Date **/**/_____

Name of participant / legal representative

---------- Date **//**___

Signature of the person responsible for the study