HOSPITAL DAS CLÍNICAS

DA

FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO

Free and informed consent term for intervention group

Title - Impact of technological innovation on virtual care, monitoring and engagement of patients with uncontrolled hypertension: Hyper2.

Principal researcher - Prof. Dr. Luiz A. Bortolotto

Department/Institute - Hypertension Clinical Unit

Duration of the study - 12 months

Invitation to participate - The investigators invite participants to participate in this research as a volunteer. Your participation will help us to improve the quality of care the investigators provide to our patients.

1. Justification and objectives of the research: The most important cause of uncontrolled blood pressure is low access to healthy lifestyle and drug treatment. New technologies have provided tools for better patient follow-up and improved treatment adhering for educational and motivational issues. For this reason, our goal is to evaluate the effectiveness of an artificial intelligence application developed for home monitoring compared to institutional standard follow-up in patients with uncontrolled hypertension.
2. Procedures that will be used and purposes: When selected (a) and have agreed to participate in the study, participants will make an appointment in the hospital with the multidisciplinary team. In this consultation, clinical data will be collected as blood pressure office, weight, height and abdominal circumference. Also, blood samples will be collected to evaluate total cholesterol and fractions, triglycerides, fasting glycemia, potassium, serum creatinine and 24-hour urine for

urinary sodium. In addition, participants will answer questionnaires to assess quality of life, anxiety, sleep quality and food intake.

After that, in the same consultation, the team will deliver on loan an automatic device to measure blood pressure at home and it will be installing the Avatr app in your mobile phone and will explain how to perform these measurements at home. Participants will have a period of 15 days to adapt to the use of the application, where participants will receive virtual guidance by the multidisciplinary team. The team will also explain that they will contact participants when blood pressure values are higher or lower to guide procedures. After this period, the lord will use the application for 12 months.

The visits of the study after inclusion will occur every 12 weeks (visits 2, 3, 4 and 5), totaling 4 visits after the start of study, the final after 12 months. Patients will perform 24-hour ambulatory blood pressure monitoring at visits 2, 3 and 5. In visits 2 to 5, will be collected information such as the measurement of blood pressure office, weight and abdominal circumference, and data on symptoms and events that occurred (hospitalizations, emergency room visits, symptoms). In the last visit of 12 months, in addition to these measures, the questionnaires performed on the first visit and laboratory dosages will be repeated and the team will catch the mobile phone and blood pressure device that were lent to them.

3. Discomfort and expected risks: The risk of this research is minimal. The investigators can highlight how low risk to lose data collected by the application or problems in updating the software. In addition, the multidisciplinary team may not receive the alerts for changes of the blood pressure, once they have no internet network. The measurement of blood pressure, heart rate, and abdominal circumference presents no risks or discomfort for patients.
4. Benefits that can be obtained: The use of the application will provide important information for participants to take better care of your health and better control your blood pressure, thus avoiding the complications of the disease.
5. Clarification given by the researcher on the guarantees of the research subject:

a) Participants will have access at any time to information about the procedures

and examinations performed, as well as the risks and benefits related to the exams used in the research. All doubts arising during the study may be clarified at any time by the researcher responsible for this study.

b) Participants may, at any time, withdraw your consent to participate in the study and stop participating in it, without prejudice to your treatment and follow-up at the Heart Institute (InCor).

c) All information obtained in this study will be of complete confidentiality, confidentiality and privacy.

d) If participants suffer any physical damage as a direct result of the procedures performed, participants will receive all medical care provided by the Heart Institute (InCor). If the hospital is unable to provide such medical care, participants will be reimbursed for the party causing the damage and it will be done in accordance with the common and reasonable medical expenses incurred in the treatment of such physical damage. By participating participants agree to cooperate with any medical insurance available to participants in relation with this medical care

e) If participants suffer physical damage as a result of the procedures required by the study, participants will be reimbursed for the actual and reasonable medical expenses actually spent on the treatment of this damage and not covered by hospital insurance or other third-party coverage, provided that the damages are not due to your failure to follow the instructions contained in the informed consent form or communicated by those responsible for the study. This medical care should be obtained by participants in the same way that participants normally get other medical treatments. No other form of provision was made for financial repayment or other forms of compensation (such as loss of wages, loss of working days or discomfort) in relation to such damages; however, when signing this form, participants will not be giving up any of your legal rights.

6. <u>Contact in case of clinical emergencies or adverse effects of medicines:</u>

There is no use of medications to perform these procedures. Any doubt regarding the results obtained may be requested later from the principal investigator. It is

worth remembering that the complete results of the methods performed will only be obtained after the completion of the study in all patients. Dr. Luiz A Bortolotto: 44 Dr. Enéas de Carvalho Aguiar Avenue, São Paulo, SP, Brazil; phones 2661-5084 and 2661-5334.

7. Post-informed consent: This study and corresponding procedures were satisfactorily explained to me and I understood them. I read and understood the above information. I had the opportunity to ask questions and all were answered satisfactorily. I am signing this form voluntarily and agree to participate in the study until otherwise deciding. I understand that I will receive a copy of this consent form to participate in this study.

Date:

_____

Signature of the subject of the research or legal representative

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Researcher signature (stamp or legible name)

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urinary sodium. In addition, participants will answer questionnaires to assess quality of life, anxiety, sleep quality and food intake. The participants will be part of the study for 12 months. The visits of the study after inclusion will occur every 12 weeks (visits 2, 3, 4 and 5), totaling 4 visits after the start of study, the final after 12 months. Patients will perform 24-hour ambulatory blood pressure monitoring at visits 2, 3 and 5. In visits 2 to 5, will be collected information such as the measurement of blood pressure office, weight and abdominal circumference, and data on symptoms and events that occurred (hospitalizations, emergency room visits, symptoms). In the last visit of 12 months, in addition to these measures, the questionnaires performed on the first visit and laboratory dosages will be repeated and the team will catch the mobile phone and blood pressure device that were lent to them.

3. Discomfort and expected risks: The risk of this research is minimal and inherent to the risks commonly observed in an outpatient unit. Patient data will be allocated in our electronic medical records, which is in full accordance with the guidelines governed by the General Law for the Protection of Personal Data, Law No. 13,709/201. Blood pressure, heart rate, and abdominal circumference are not at risk or discomfort for patients.
4. Benefits that can be obtained: The study may provide important information for participants to take better care of your health and better control your blood pressure, thus avoiding the complications of the disease.
5. Clarification given by the researcher on the guarantees of the research subject:
    a) Participants will have access at any time to information about the procedures and examinations performed, as well as the risks and benefits related to the exams used in the research. All doubts arising during the study may be clarified at any time by the researcher responsible for this study.
    b) Participants may, at any time, withdraw your consent to participate in the study and stop participating in it, without prejudice to your treatment and follow-up at the Heart Institute (InCor).

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Researcher signature (stamp or legible name)