# VA RESEARCH CONSENT FORM

**Subject Name:** _____ **Date:** _____

**Subject Initials:** _____

**Principal Investigator:** SARVARI YELLAPRAGADA **VAMC:** _____

H-50009 - FEASIBILITY OF A TELE-GAME-BASED EXERCISE (TELE-EXERGAME) PROGRAM TO PREVENT DECONDITIONING IN HOSPITALIZED COVID-19 VETERAN PATIENTS

**Consent Form-SPIRE COVID-19**

**Concise and Focused Presentation**

You have been invited to participate in a research study. Please read this information and feel free to ask any questions before agreeing to participate in the study.

Regular physical activity during hospitalization is critical to prevent the loss of muscles in the legs. However, the current hospital physical activity program is often not practical for COVID-19 patients and for those who required prolonged bed rest. Some limitations of the traditional physical activity programs include associated risks (e.g., risk of spreading infection and risk of falls) and are time-consuming. We propose our novel game-based foot and ankle exercises, called Tele-Exergame, as an alternative and practical option to address this problem. This study will help us test how practical, acceptable, and functional is the Tele- Exergame program in COVID-19 patients and hospitalized patients. This research will help in the improvement of exercise programs in hospitals and telemedicine.

**Background**

Prolonged bed rest and immobilization during hospitalization may lead to complications such as loss of muscle strength and loss of foot sensation, called hospital-acquired weakness. Recent studies suggested that the in-hospital mobility programs effectively reduce the consequences of low physical activity in elderly hospital patients.

However, the traditional physical activity program is not practical, particularly among hospitalized COVID-19 patients and those suspected of having COVID-19 because of the associated risk of infection spreading. These programs are also ineffective for hospitalized non-COVID-19 patients, especially those at high risk of falling because they demand more staff and time.
To address the problem, we propose a novel game-based foot and ankle exercise called Tele-Exergame, as an alternative and practical option.
Exergames are digital games that use body movement to promote physical activity and involve foot strength, balance, and foot flexibility exercises. Tele-exergame also helps interaction between patient and staff via telemedicine.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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**Purpose**

The main goal of this study is to give people the TeleExergame program and see: 1) If it is safe and easy to do, 2) If patients can do it and like it, 3) If it improves the patient's ability to move.
We will be giving the program to hospitalized COVID-19 patients, hospitalized Veterans, or other PUI (person under investigation for COVID-19 infection). Our hypothesis is that people who need prolonged bed rest while hospitalized will be less likely to lose muscle while in hospital and gain their mobility back more quickly after being discharged than if they didn't have the TeleExergame program.
If we successfully achieved our study objectives, we intend to use it for hospitalized COVID-19 patients and those who need to have prolonged bed rest.

**Procedures**

The research will be conducted at the following location(s):
Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center.
This study has three complete visits, and the daily exercise program will last until 4 weeks after leaving the hospital. Therefore, please read the description of the study visits carefully.

We will loan you a tablet for telemedicine purposes. You may have access to the Tele-Exergame program on the tablet for the entire hospitalization period (minimum hospitalization >= 3 days). Exercise sessions will be from 3-10 minutes, twice daily, based on your ability. The Tele-Exergame device will document your performance during exercise tasks and coaches you on how to do foot and ankle exercises. Our research team can guide you to do the exercises using the telemedicine tablet, provide instructions for sensor attachment, and encourage daily practice. In addition, clinical staff who deliver your regular care will be able to use the tablet for remote interactions with you for clinical purposes.

You will be asked to play a series of games by moving your foot and ankle. Using a sensor strapped on your foot will act like a joystick to play the game. The program provides step-by-step interactive instruction to help you to complete the exercises. In addition, the sensor on foot will quantify your performance during the activity and report it to our research staff.
You will undergo screening at your first visit and clinical assessments at the time of discharging from the hospital and at about four weeks after leaving the hospital.
The clinical assessments will let us know about your weakness, mental health, and recovery. These clinical assessments will be done using questionnaires and by the sensor attached to your foot.

Immediately after obtaining your consent, the research assistant will proceed with the clinical assessments and introduce a tele-exergame device. The assessments include specific questionnaires to evaluate your sleep quality, physical activity, mental health, and weakness. We will also collect your health information from your electronic health record. However, suppose you cannot finish all these questionnaires at one time. In that case, we will request you to complete the remaining assessments

later and provide you the tele-exergame device now.
We will answer any of your questions and provide time for education and adaptation in using the Tele-Exergame device before leaving the hospital. In addition, before leaving, we will collect clinical questionnaires and medical activity orders noted.
You will be given the tablet for another four weeks after you leave the hospital and will be able to continue exercising at home. You will also use the tablet for the above-mentioned weekly telemedicine consultation and the completion of clinical assessments.

**Clinically Relevant Research Results**

The results generated from this research study are not expected to have any clinical relevance to you.

**Sharing and Future Research Studies with Identifiable Private Information**

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

**Confidentiality**

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Other: Patient contact information Admission/Discharge dates

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**

We believe that there are no significant psychological, legal, or social risks. Your participation is voluntary, and you can stop or leave the study at any time. We will complete the proposed tele-exergame via telemedicine. You will do all exercises while sitting or lying down on a bed to

minimize the associated risks, such as falls. There is a potential risk of infection for research staff. To reduce the risk, all staff, who need to interact with patients, will use approved PPE and all established precautions and requirements at MEDVAMC.
The foot sensors used for tele-exergame as well as tablets are battery-powered, self-contained units. Each sensor weighs less than 0.25 kg. The sensor will be attached to your foot using a comfortable strap that can be disinfected. One patient will keep the same sensor/tablet during the study and will not share it with any other participant to prevent spreading infection. Fatigue and muscle soreness may occur due to physical effort from exercise, but this is a normal and temporary response. We will recommend sufficient rest to minimize discomfort.

Since we will obtain personal information, there is a possibility for invasion of privacy. However, these risks are considered minimal as they have a low likelihood of occurrence. Confidentiality will be maintained by storing the data for analysis without names attached, using a numerical code. A master list will be kept separately to facilitate data collection. Subject identifiers will not be included in any computer files. Only staff with the permission of the principal investigator (Dr. Yellapragada) will have access to the master list.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**
The benefits of participating in this study may be: The main benefit is the positive feeling that you will have by participating in a study that will potentially help other people develop new technology that could improve the care of COVID survivors and hospitalized older adults. This also could assist in improving mobility, preserve mental health, and accelerate recovery after leaving the hospital. You might eventually benefit from this technology if the device became validated and available for clinical use in the future.

You will be compensated for your time to collect the questionnaire at 4-weeks after leaving the hospital ($50 per patient). At the end of the study, a research investigator will collect the tele-exergame device from you. . However, you may receive no benefit from participating.

**Alternatives**
You may choose to not participate in this study.

**Investigator Withdrawal of Subject from a Study**
The investigator or sponsor may decide to stop you from taking part in this study at any time. We may remove you from the study for entirely personal reasons (e.g., if you move to another city) or because the research has been stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

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**Subject Costs and Payments**

You will not be asked to pay any costs related to this research.

You will be compensated for your time to collect the questionnaire at 4-weeks after leaving the hospital ($50 per patient).

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, SARVARI YELLAPRAGADA, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: DR. YELLAPRAGADA 713-794-7303 during the day and MARIA NOUN at (713)798-7537

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

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**You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at 713-794-7918 or 713-794-7566.**

Department of Veterans Affairs

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

| | |
|---|---|
| Subject | Date |
| Investigator or Designee Obtaining Consent | Date |
| Witness | Date |

Subject ID:_____