

UNIVERSITY OF SAO PAULO - FACULTY OF MEDICINE
INFORMED CONSENT FORM

IDENTIFICATION DATA – PATIENT OR LEGAL REPRESENTATIVE

1. NAME: :.....
ID : GENDER : .M F
DATE OF BIRTH:/...../.....
ADDRESS
CITY:.....
POSTAL CODE:.....
PHONE NUMBER: (.....)

2.LEGAL REPRESENTATIVE.....
DEGREE OF RELATEDNESS
ID : GENDER : .M F
DATE OF BIRTH:/...../.....
ADDRESS
CITY:.....
POSTAL CODE:.....
PHONE NUMBER: (.....)

STUDY INFORMATION

1. TITLE: COMPARISON OF EFFECTS OF TRAINING IN A VIRTUAL ENVIRONMENT WITH AND WITHOUT PHYSIOTHERAPEUTIC INTERVENTION IN CHRONIC STROKE PATIENTS.

RESEARCHER: Maria Elisa Pimentel Piemonte

POSITION: Professor. Regional Council Registration 12863-F

SECTION: Department of Physiotherapy, Communication Science & Disorders And Occupational Therapy

3. RISK OF THE STUDY:

MINIMAL x MEDIUM
LOW HIGH

4.DURATION OF RESEARCH: Two years

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We invite you to participate in this study that aims to compare the effects of a balance training program using video game, to improve balance and gait in stroke patients.

If you agree to participate, you will be assessed by an experienced physiotherapist with questions and tests to evaluate your balance and your walk. This assessment will be repeated in the end of the treatment and two months after the end of the treatment.

After an evaluation, you will go through a random drawing to determine which group you will participate (training group with the supervision of a physiotherapist, or training group with manual and verbal help from a physiotherapist during the game). Both trainings will be conducted using video game twice a week, at the same location, and will last 60 minutes.

The first stage of the two trainings is identical and consists of global warming exercises for mobility and elasticity of the legs. In the second stage, the training sessions will be conducted with eight Nintendo Wii Fit games, four in each session. If you are randomly selected for treatment with supervision of the physiotherapist, you will play the games with the physiotherapist explaining how to perform the game; if you are selected for treatment with manual help from the physiotherapist, you will play games with the physiotherapist helping to guide the movements - but both groups will be trained using the video game.

The risk of participating in this study is minimal but, as you are not used to exercise, you may experience minor discomfort, such as muscle fatigue. The physiotherapist will always be around to avoid the risk of falling.

Although the aim of this study is to improve balance and gait of patients who have had a Stroke, it is not possible to ensure that you notice any of these improvements, whereas it is an experimental study.

We are available to answer any questions or clarify any doubts about the study. The lead researcher is the physiotherapist Maria Elisa Pimentel Piemonte and the researchers are physiotherapists Mariana Armando Lourenço, Camila Souza Miranda and Tatiana de Paula Oliveira, which can be found at the address Cipotânea Street, 51 - Cidade Universitária, or by the phone +55 11 3091-8427. If you have any question about ethical issues, you can contact the Research Ethics Committee – Dr. Arnaldo Avenue, 251; phone +55 11 3893-4401/4407 – E-mail: cep.fm@usp.br.

You are free to withdraw your consent at any time and cancel your participation in this study, without any loss of your activities at this center.

You will not have your identification or your data revealed. All information about the progress of the study will be revealed to you, even if they are not favorable.

There will be no personal expenses for you at any stage of the study, as there will be no financial compensation related to your participation.

In case of any damages resulting from your participation in this study, you will be entitled to indemnification in compliance with the current laws of this country.

We commit ourselves to use the data collected only for this study.

"I believe I have been sufficiently informed about the information I read or have read to me describing the study 'COMPARISON OF EFFECTS OF TRAINING IN A VIRTUAL ENVIRONMENT WITH AND WITHOUT PHYSIOTHERAPEUTIC INTERVENTION IN CHRONIC STROKE PATIENTS'.

I discussed with the lead researcher or other researchers about my decision to participate in this study.

It was clear to me the purposes and procedures of the study, the discomforts and risks, the guarantees of confidentiality and permanent clarification. It is also clear that my participation is free of expenses and that I have guaranteed access to hospital treatment when necessary.

I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during it, without loss of any benefit at this service.

I declare that I have received and understood sufficient information about the study procedures and the researcher's assurance that any questions will be promptly clarified.

I agree that the evaluations will be recorded and the data will be published for academic and scientific purposes, provided that the confidentiality of my participation and identification is maintained."

Patient or legal representative signature / /

(Valid for researcher only)

I declare that I have obtained in an appropriate and voluntary manner the Informed Consent Form of this patient or legal representative for participation in this study.

Researcher signature / /