HEADING OF THE ORGANIZATION HOSTING THE EXPERIMENTATION

INFORMATION SHEET AND INFORMED CONSENT FORM FOR ADULT SUBJECTS AIMED AT ENROLLMENT IN A CLINICAL TRIAL

Official Title of the Trial

Evaluation of the Impact of a Rehabilitation Intervention Based on Cycling with Virtual Park on Motivation to Exercise in Adult Patients

Structure-context in which the experiment will take place *(indicate the local structure of the experiment among those indicated)*

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Coordinating center and promoting center of the experimentation

Promoting center: CNR-STIIMA - Istituto di Sistemi e Tecnologie Industriali Intelligenti per il Manifatturiero Avanzato, sede legale: Via Alfonso Corti, 12, 20133 Milano (MI), P.IVA: 02118311006, C.F.: 80054330586

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Experimental coordinator: Dr. Cira Fundarò. Tel. + 39 0385 2471

Registry in which the trial has been or will be registered (if applicable) and any identification code if available

Identification code_____

Register_____

Principal Investigator *(indicate the local trial manager)*

Name

Affiliation

Sponsor

Ministry of University and Research.

The clinical trial is funded by the Fit4MedRob project (PNC0000007), approved by Ministerial Decree no. 1984 of December 9, 2022, of the Ministry of University and Research.

Ethical Committee

HEADING OF THE ORGANIZATION HOSTING THE EXPERIMENTATION

National Ethics Committee for Public Research Institutions

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Dear Sirs/Madams,

1) You are invited to participate in a research study evaluating a device (called VirtualPark). This device enables rehabilitation by combining physical and cognitive exercises on a bicycle/arm ergometer while viewing a real-world environment. The study involves patients with ischemic stroke, Parkinson's disease, incomplete spinal cord injury, frail elderly patients, multiple sclerosis, amyotrophic lateral sclerosis, and mild cognitive decline. The title of the study is "Evaluation of the impact of a rehabilitation intervention based on cycling with Virtual Park on motivation to exercise in adult patients." This is a pilot study conducted at several centers in Italy. Some patients will participate at this center and others at hospitals or treatment centers in Italy. To conduct this research, we require the cooperation and availability of patients who, like you, meet the necessary criteria. Before deciding whether or not to participate, we invite you to read this information carefully, taking all the time you need. If anything is unclear or you require further clarification, you can ask the study staff. Furthermore, if you wish, you can consult with family members or your doctor before making a decision.

2) The primary purpose of this research is to evaluate how using the VirtualPark device increases patient motivation during rehabilitation exercises. The VirtualPark device allows physical exercises (pedaling with the arms or legs) combined with cognitive exercises through virtual reality games displayed on a screen.

   Specifically, this study aims to understand:

   - Motivation – how much VirtualPark motivates patients to perform the exercises.
   - Usability and user experience – how easy and enjoyable it is to use the device, and their overall opinion of using it.
   - Rehabilitation effects – how using the device can affect: cognitive functions (attention, memory, navigation skills, impulse control), functional and motor skills, and endurance.

3) If you decide to participate, the planned activities are:

   a) An initial assessment (T0) of motor and neuropsychological functions.
   b) A treatment cycle with the Virtual Park device; this will be combined with the standard rehabilitation intervention provided by the center. The frequency is 3 sessions per week, 30 minutes each, for 4 weeks. The sessions will take place at the clinical center, and a healthcare professional will accompany you at all times. During the sessions, the device will offer the following exercises:
      - Motor: pedaling on a cycle ergometer
      - Cognitive: attention, working memory, inhibition, and spatial navigation ability
   c) Assessments during and after treatment:
      - after 2 weeks of training (T1);
      - at the end of 4 weeks (T2)
      - one month after the end of the intervention (T3) – to assess cognitive functions

The study will last a total of 8 months, but each patient will participate in only one evaluation and treatment cycle. Approximately 10 patients will participate in this research at this facility.

Before starting, you will have an initial examination to ensure you meet the study criteria. During this examination, the staff will evaluate your clinical data and medical history; no additional invasive or instrumental tests are required. The study will be conducted during your scheduled clinical check-ups for your condition, so no further cooperation will be required.

4) Once you agree to participate, your **family doctor will be informed** of your participation to avoid interference with other ongoing treatments or research.

5) Participation in the trial will not incur any additional costs.

6) By participating, you will be able to use a multimodal technology that combines physical and cognitive exercises during your rehabilitation process. The results from your participation may help develop useful pathways for other patients with chronic neurological conditions in the future.

7) **Participation in the study does not entail any additional costs** or risks for the participant compared to the usual treatment provided by the Center. No invasive procedures, drug administration, or X-rays/exposure to ionizing radiation are foreseen.

8) Participation in the study does not entail any additional costs or risks for the participant compared to the usual treatment provided by the Center.

9) For any damages that may arise from participation in the trial, we inform you that **adequate insurance coverage** is in place to cover any personal injury resulting from the trial, in accordance with the provisions of the Ministerial Decree on Health of July 14, 2009, Official Journal No. 213 of September 14, 2009. It is important to note that**:**

    i) Insurance coverage cannot exceed the maximum insured amount. This limitation does not, however, affect the injured party's right to obtain compensation from the party responsible for any damages in excess of the maximum insured amount.

    ii) The insurance coverage is active only for damages for which a claim for compensation is submitted within the period established by the policy, which can be consulted upon your request.

10) Participation in the study is completely voluntary. If you choose not to participate, you will continue to receive standard treatments for your condition.

11) Your participation in this research program is completely voluntary; you may withdraw your consent at any time without having to provide a reason.

The study protocol proposed to you has been drawn up in accordance with the European Union's Good Clinical Practice Standards and the current revision of the Declaration of Helsinki and has been approved by the National Ethics Committee for Experiments in Public Research Bodies (EPR) and other national public bodies (CEN).

12) For **further information** and communications during the study, you can contact the following personnel:

(Please complete the form for each center with specific information)

a) Center:
b) Study Contact:
c) Telephone:
d) Email:

CONSENT STATEMENT

[This statement must be signed and dated personally by the patient who conducted the informed consent discussion.]

I, the undersigned

…….

[If Legal Guardian]……
(full name and surname of the patient)

I declare that I have received from the doctor……..

detailed explanations regarding the request to participate in the experimental study in question, as reported in the information sheet attached here, a copy of which was delivered to us sufficiently in advance.

I further declare that I have been able to discuss these explanations, that I have asked all the questions I deemed necessary and have received satisfactory answers, and that I have had the opportunity to inquire about the details of the study from a trusted person.

I therefore freely agree to participate in the trial, having fully understood the meaning of the request and having understood the risks and benefits involved.

I consent (□ yes □ no) to my attending physician being informed of my participation in the study.

I have also been informed of my right to free access to the trial documentation (insurance, clinical-scientific, pharmacotherapeutic) and to the Ethics Committee's evaluation.

Signature of the patient / Guardians, legal representatives of the patient……..

Date…….

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Signature of the doctor who gave the information……

Date……..