Istituti Clinici Scientifici Maugeri

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Study Title: Auto-calibrating System for Upper Limb Disability Assessment, Neurological and Occupational Rehabilitation (AS-ULDAR)

Date:04.15.2023

INFORMATION SHEET AND CONSENT DECLARATION

for an adult patient capable of personally providing consent

INFORMATION SHEET

Dear Madam/Sir,

The Operational Unit of Istituti Clinici Maugeri, IRCCS Montescano, invites you to participate in a low-intervention clinical study entitled: "Self-Calibration System for Upper Limb Disability Assessment, Neurological and Occupational Rehabilitation."

This research is a national multicenter study. You are being asked to participate in this study because you are affected by one of the following neurological conditions: stroke sequelae, Parkinson's disease, amyotrophic lateral sclerosis, or mild cognitive impairment.

To carry out this research, we require the cooperation and availability of individuals who, like you, meet the scientific eligibility criteria for the assessment that will be performed.

Before deciding whether or not to give your consent to participate, please read these pages carefully, taking all the time you need, and ask for clarification if you do not fully understand the information provided or if you require further details. Furthermore, if you wish, before making your decision you may seek advice from your family members or from a physician you trust.

Please note that signing the consent form is voluntary, but it is necessary in order to participate in the study.

PURPOSE OF THE STUDY (OBJECTIVE)

The study, defined as a low-intervention clinical study, refers to a study that aims to collect data beyond normal clinical practice without altering a patient's usual diagnostic and therapeutic pathway.

The study aims to evaluate the usability and feasibility of a robotic system for occupational therapy intended for patients with neuromuscular diseases. Using an anthropomorphic robotic arm, wearable inertial sensors, and an assistive glove, the study will assess the impact on patients' motor performance, cognitive function, and quality of life.

The protocol includes traditional and rehabilitative therapy sessions, with and without the use of the device, and the final evaluation will be based on various assessment measures, including usability, psychosocial impact, and the incidence of adverse events.

The study design is interventional and multicenter and provides for the enrollment of 30 patients divided into two treatment groups.

LOW-INTERVENTION CLINICAL STUDIES

Low-intervention clinical studies are studies that involve interventions or treatments with a limited impact on the health or well-being of participants. These studies may include low-complexity interventions, such as minor lifestyle changes, the use of dietary supplements, participation in educational programs, or other minimal modifications to clinical practice.
These studies may be used to examine the effectiveness or feasibility of simpler or less invasive interventions, or to explore the acceptability of new treatments. Since they involve low-risk interventions and generally do not have significant implications for participants' health, they often require less stringent monitoring and assessment procedures than clinical studies involving more intensive or invasive interventions.

WHAT PARTICIPATION IN THE STUDY INVOLVES

If you agree to participate in this study, you will undergo an assessment visit to verify that your condition meets the required eligibility criteria.
If you participate, you may be randomly assigned to one of the two treatment arms.

- **Arm A:** you will receive 12 sessions using the robotic arm in addition to your regular traditional physiotherapy sessions.
- **Arm B:** you will undergo your therapy sessions as provided for in your treatment plan.

At the first and the last treatment session, you will undergo a series of assessments using rating scales and questionnaires to evaluate your motor and cognitive conditions, as well as your level of satisfaction with the use of the device.
The study will last a total of 18 months. The first 12 months will be devoted to patient recruitment.
The analysis of the collected data will last 6 months, and a total of 30 participants are expected to be enrolled.

RESULTS OF THE STUDY AND CONFIDENTIALITY OF THE COLLECTED INFORMATION

All your data will be coded and recorded in computerized format. You will be assigned a personal numerical or alphanumeric code that will not allow you to be identified outside the research center (pseudonymization).

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY?

By participating in the study, the potential benefits include improvements in strength and quality of life through the use of a dynamic robotic arm. This innovative approach may offer a personalized

and engaging treatment for individuals with upper limb impairments. However, there are also risks associated with participation, such as discomfort during the use of the device and possible side effects, including a feeling of malaise caused by movement. It is important to consider these risks before participating in the study and to discuss them with the medical staff.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY?

You are free not to participate in the study. In this case, you will still receive all the standard therapies/treatments provided for your condition. You will not be penalized in any way for choosing not to participate, you will not be required to explain your decision, and the physicians will continue to care for you with due attention, using the best conventional therapeutic approaches available for your condition.

WITHDRAWAL FROM THE STUDY

Your participation in this research is entirely voluntary, and you may withdraw from the study at any time without providing any explanation for your decision. Should you decide to leave the study, however, please inform the study physician so that he or she can explain how to proceed safely. If you withdraw from the study, you will continue to receive the best available care and treatment.

By signing this consent form, you explicitly agree that, should you decide to withdraw from the study, the medical data collected before your withdrawal may still be processed, always in pseudonymized form, together with the other data collected within the framework of the study.

The sponsor may terminate the study prematurely at any time, informing both you and the relevant Ethics Committee of the reasons for doing so.

WHAT HAPPENS IF YOU SUFFER HARM AS A RESULT OF PARTICIPATING IN THE CLINICAL STUDY?

Insurance Coverage

Participation in a clinical study may involve inconveniences and risks that cannot be determined in advance. For this reason, clinical studies provide insurance coverage to protect participants.

In compliance with current legislation, the sponsor, **the Department of Industrial and Information Engineering of the University of Pavia**, has taken out insurance policy no. …….. with the insurance company …….. to cover damages arising directly from the clinical study.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you request it, at the end of the study you will be informed of the data and results concerning you and, more generally, of the overall results of the study.

IS IT USEFUL TO INFORM YOUR GENERAL PRACTITIONER?

If you decide to participate, it is important that your general practitioner be informed. For this purpose, we have prepared a letter that you may give to your physician, explaining the study procedures.

FURTHER INFORMATION

The study protocol proposed to you has been drafted in accordance with the European Union Good Clinical Practice Guidelines and the current revision of the Declaration of Helsinki, and has been approved by the Ethics Committee of this institution.

You may report any matter that you consider appropriate regarding the research in which you are involved to the Ethics Committee of this institution (**Territorial Ethics Committee Lombardia 6, c/o Fondazione I.R.C.C.S. Policlinico San Matteo, Viale Golgi 19, 27100 Pavia**).

If you agree to participate in the project, you may request additional information about the research and the progress achieved at any time. You will also be promptly informed should any new information become available that could influence your willingness to continue participating in the project.

You may also access the documentation relating to the research in question and the opinion expressed by the Ethics Committee regarding it.

For further information and communications during the study, you may contact the following medical staff:

Dr. _____ tel. _____ mail _____

Dr. _____ tel. _____ mail _____

WHO ORGANIZES AND SPONSORS THIS STUDY?
The study is coordinated by ICS Maugeri – IRCCS Montescano and sponsored by the Department of Industrial and Information Engineering of the University of Pavia within the framework of the Fit4Med Rob Project.

CONSENT DECLARATION
This declaration must be personally signed and dated by the patient and by the physician who conducted the informed consent discussion ONLY IF THE PATIENT HAS DECIDED TO PARTICIPATE IN THE STUDY.

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I, the undersigned, ...
declare that I have received from Dr. .....
comprehensive explanations regarding the request to participate in the above-mentioned study, in accordance with the information sheet attached hereto, a copy of which was provided to me sufficiently in advance.
I also declare that I have had the opportunity to discuss these explanations, to ask all the questions I considered necessary, and to receive satisfactory answers, as well as to consult a person of my trust regarding the details of the study.
I therefore freely agree to participate in the study, having understood the meaning of the request and having comprehended the risks and benefits involved. I am aware of my right to withdraw from participation at any time.
I have also been informed of my right to have free access to the documentation relating to the study (clinical-scientific and therapeutic) and to the opinion expressed by the Ethics Committee.
I am also aware that, during the study, a representative of the Sponsor or its delegate, the Ethics Committee, or national or international Regulatory Authorities may monitor the conduct of the study and verify the accuracy of the data recorded in the medical records/data collection forms.

□ **I agree** □ **I do not agree**

to inform my general practitioner about my participation in this study
Date …… Patient's signature ……..
Date …… Signature of the physician who informed the patient
……
……..
(If the patient is unable to read or sign, an independent witness not involved in the Investigator team and not affiliated with the Sponsor must be present throughout the informed consent discussion. The witness must personally sign and date the informed consent statement after the form and any other written information have been read and explained to the subject, and the subject has given verbal consent to participate in the study.)
In this case: I, the undersigned ……., certify that Dr.
…… has thoroughly explained to Mr./Mrs.
……
the characteristics of the study in question, according to the information sheet attached hereto, and that the participant, having had the opportunity to ask all necessary questions, has freely agreed to participate in the study.
Date ……. Signature of the independent witness ……..
Date ……. Signature of the physician who provided information to the patient
……

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