Impact of a tele-physical rehabilitation program on people with Multiple Sclerosis: Multicenter randomized clinical study.

Version 2. 15/1/2025

Patient Information Sheet for Participation in a Research Project

(This document will be signed in duplicate, with one copy retained by the researcher and the other by the patient.)

Introduction

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by a Research Ethics Committee for medicinal products.

Our intention is to provide you with accurate and sufficient information so that you can decide whether or not to participate in this study. To this end, please read this information sheet carefully and we will clarify any questions you may have.

You may also consult with anyone you deem appropriate.

Voluntary participation and right to withdraw consent:

You should know that your participation in this study is voluntary and that you may decide not to participate or change your mind and withdraw your consent at any time, without this affecting your relationship with your doctor or causing any harm to your treatment.

Objectives:

We are asking for your participation in this research project, the main objective of which is to assess the safety and occurrence of adverse effects during telerehabilitation. The aim is to bring rehabilitation treatment to people who, for various reasons, are unable to attend in person, observing its usefulness and safety.

Benefits:

You may not obtain a direct benefit from your participation in this study. However, the identification of possible factors related to multiple sclerosis could benefit other patients who suffer from this disease in the future and contribute to a better understanding and treatment of this disease.

Study procedures:

This study aims to compare two procedures. Assignment to one of them will be determined by chance. Your doctor will not be involved in this process. If you decide to participate, you will have a 50% chance of being in the intervention group or the control group.

The study has a set duration of 4 months. If you are assigned to the intervention group, you will be required to complete a tele-rehabilitation program at home for 2 months. After this time, you will be invited to continue with your daily life for another 2 months. On the other hand, if you are assigned to the control group, you will be offered educational information on physical activity and leading an active life, which you can incorporate into your daily activities for 4 months and fill out a series of documents.

Whether you are in the intervention group or the control group, you will be asked to come to the center for three check-ups: one before the study starts, one after two months, and the last one at the end of the four months.

Discomfort and possible risks from taking part in the study:

We do not expect any negative effects from your participation in this study. You may experience fatigue, muscle soreness, or other discomforts related to the therapeutic activity.

Personal data protection:

Both the sponsor and the center will ensure that the confidentiality of your personal data collected during the study is maintained, in compliance with both national data protection laws and European data protection laws.

For more information on confidentiality and personal data protection, please refer to Appendix 1.

The study is being conducted by the FUNDACIÓ PRIVADA PER A LA LLUITA CONTRA L ESCLEROSI MÚLTIPLE (PRIVATE FOUNDATION FOR THE FIGHT AGAINST MULTIPLE SCLEROSIS), with Tax ID No.:

G59165100 and registered office at C MARE DE DEU DEL REMEI, 31-37 (08004) BARCELONA - Barcelona, has

taken out a Professional Health Liability Insurance policy through this entity and under the Right of Establishment

No. 021S00367RCS, effective from February 8, 2024, to February 7,

2025, with a limit per claim of €2,000,000.00 and an annual insurance premium of €2,000,000.00. If you would like more information about this section, please consult the principal investigator of the study at your center.

We inform you that your participation in this study may modify the general and specific conditions (coverage) of your insurance policies (life, health, accident, etc.). Therefore, we recommend that you contact your insurer to determine whether participation in this study will affect your current insurance policy.

Contact in case of questions

If you need more information about this study, you can contact the principal investigator, Dr. Edwin Roger Meza Murillo of the Cemcat Neuroimmunology Service, Tel. 931756176 Extension 3

Study title: Impact of a tele-physical rehabilitation program on people with Multiple Sclerosis: Multicenter randomized clinical study.

I _____ (name and surname of the patient) _____
I have read the information sheet that has been given to me.
I have been able to ask questions about the study.
I have spoken with: Sergio Aguilar Alegre.
I understand that my participation is voluntary.
I understand that I can withdraw from the study:
1. Whenever you want
2. Without having to explain
3. Without this affecting my medical care.

I freely give my consent to participate in the study, I confirm that I have read **Appendix 1** and I agree with its content.
I agree that the doctors responsible for this study may contact me in the future if it is deemed appropriate to add new data to those collected: Yes__ No__

Signature of participant Signature of researcher
Date: ____/____/____ Date: ____/____/____

Signature of family member/representative (if applicable)
Date: ____/____/____

I want you to communicate to me the information derived from the research that may be relevant to my health or that of my family members: Yes__ No__
Telephone or contact email: …….
Signature of participant Signature of researcher
Date: ____/____/____ Date: ____/____/____

Signature of family member/representative (if applicable)
Date: ____/____/____

I wish to be informed of the information derived from the genetic tests carried out (Explanatory note: only for those studies that include this type of tests, as long as they are validated and may have relevance to the health of the participant). If they are part of the objective of the study, they must be reported on the information sheet: Yes__ No__

Signature of participant Signature of researcher
Date: ____/____/____ Date: ____/____/____

Signature of family member/representative (if applicable)
Date: ____/____/____

I accept the future use of my data in unrelated research: Yes__ No__
(Explanatory note: only for those studies that include the reuse of the data obtained for this study in future research not related to the research object of this study, unless anonymized data is used, it is required to request explicit informed consent at the time of granting consent to participate in the study, previously explaining the safeguards and guarantees that will apply).

Signature of participant Signature of researcher
Date: ____/____/____ Date: ____/____/____

Signature of family member/representative (if applicable)
Date: ____/____/____

Appendix 1: Protection of personal data relating to the patient information sheet and informed consent form for the study

Who is responsible for data processing?

The Vall d'Hebron University Hospital Foundation-Research Institute (VHIR) is the promoter of this study and is based at Paseo de la Vall d'Hebron 119-129. Both the Center and the Sponsor are responsible for processing your data. The Center is responsible for all data contained in your medical record that could identify you, and the Sponsor is responsible for the data collected in this study in coded form. The role of the data controller is to ensure that your information is used correctly. The Sponsor and the Center will comply with data protection regulations:

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

- Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights.

What data will be collected and used, and what is the legal basis for the processing of your personal data?

The Promoter will not collect more data than is necessary to carry out this study (related to your pathology, the tests performed and the treatment received).

What will this data be used for?

The Promoter will use this data to answer the study question(s) and related research, which are explained in the information sheet provided to you.

The Sponsor and the researcher could reuse this data for other research projects related to the disease under study (or specify a related area of interest), respecting confidentiality at all times and guaranteeing compliance with current legislation. Your information will only be used in research that has received a favorable report from a Research Ethics Committee, and in a way that does not contradict the preferences expressed by you in the signed consent. In those countries where the law does not require approval by a REC, a favorable report from the data protection officer or an expert will be required under the terms established in the applicable regulations.

What about confidentiality?

At all times, the confidentiality of your data will be maintained. During your participation in the study you will be identified by a code and neither the researcher nor the Hospital will transfer any information that could directly identify you to the Sponsor. The list that

relates the identification code to the data that identifies you (name, surname, medical record number,...) is kept confidentially in your Health Center, and will not leave it.

Access to your identified personal information will be restricted to the principal investigator of the study/collaborators, health authorities, the Research Ethics Committee and personnel authorized by the Sponsor (study monitors, auditors), when they need it to verify the data, study procedures, and compliance with standards of good clinical practice; but always maintaining their confidentiality. Your identity may be revealed in exceptional cases, such as medical emergencies for your health or legal requirements. The processing, communication and transfer of personal data of all participants will comply with the provisions of the applicable regulations.

How long will your data be saved?

All the information that we request from you is necessary to be able to participate in this study and it is mandatory that it be provided, in order to guarantee its correct development. The Center and the Promoter are obliged to keep the data collected for the study, according to the legal deadlines established in the regulations: the Promoter, for at least the time necessary to carry out the study, and the Center, for the time necessary to provide adequate assistance.

What rights do I have?

With respect to your data, you have the following rights:

You can ask at any time what data is being stored (right of access), who is using it and for what purpose; You may request a copy of your personal data for your own use. You can request to receive a copy of the personal data provided by you in order to transmit it to other people (portability). You can correct the personal data provided by you (right of rectification) and limit the use of data that is incorrect (right of rectification and deletion). You can object to or restrict the use of your personal data (right to object).
In relation to the rights over your personal data, we remind you that there are some limitations in order to guarantee the validity of the research and comply with the legal duties of the Promoter and the drug authorization requirements: the data collected up to that point cannot be deleted even if you stop participating in the study or even if you withdraw your consent to the data processing. Likewise, you may have limited access to the data (for example, until the study ends). Likewise, you will have the right to withdraw consent regarding data processing, however, such withdrawal could determine your cessation of participation in the study. For the same reason, if you withdraw from the study, we will save the information about you that has already been collected so far. To protect your rights, we will use as little information as possible.
Likewise, we inform you of your right to file a claim with the Data Protection Agency regarding any action by the Promoter or the Center that you consider violates your data protection rights. If you wish, you can contact the data protection officer of your Hospital for the study, or contact the data protection officer of the Promoter (next section).

Who do I contact?

Principal investigator/collaborator of the study: Edwin Roger Meza Murillo / Sergio Aguilar Alegre Telephone
931756176, extension: 3
Contact information for the Center's DPD: (individualize the information for each center; at the Vall d'Hebron University Hospital: dpd@ticsalutsocial.cat)
Contact information for the Promoter's DPD: (individualize the information; if the promoter is the VHIR: dpd@ticsalutsocial.cat)
Contact details of the promoter by postal mail: (individualize the information; if the promoter is the VHIR: Paseo Vall d'Hebron 119-129, Edificio Mediterránea, 2nd Floor, -08035 Barcelona-).

How will the results be communicated?

The Promoter will publish the results of the study, preferably in scientific journals, conferences... The anonymity of the study participants will be maintained at all times.

I freely give my consent to the processing of my personal data as detailed in this Appendix, I am aware that failure to give my consent will prevent me from participating in the study. YES ___ NO ___

I freely give my consent to the transfer of my personal data contemplated in this Appendix and for the purposes established therein. YES ___ NO ___

I freely give my consent to the Transfer of my personal data contemplated in this Appendix and for the purposes established therein. YES ___ NO ___