Consent Form

This is an invitation for you to participate in the research: "Project RevELA: Effects of a home-based exercise protocol with remote and face-to-face monitoring of individuals with Amyotrophic Lateral Sclerosis: randomized clinical trial", which has physiotherapist Aline Alves de Souza as the responsible researcher .

This research aims to compare the forms of monitoring, in person and remotely, of the home exercise protocol and the impact of these exercises on the levels of functional physical capacity, fatigue and pain in people with Amyotrophic Lateral Sclerosis (ALS).

The reason that leads us to carry out this study is the need for continuous care for people with ALS, especially with regard to the maintenance of physical capacity, strength and functionality, in addition to health education for their caregivers and family members.

If you decide to participate, the Consent Form will be signed and then you will undergo a physical therapy evaluation, with non-invasive tests to observe the functional physical capacity, the level of fatigue, the occurrence of pain and also the cognitive level.

Participants will be randomly allocated into two groups: the control group (CG) and the experimental group (EG). EG participants and their caregivers will receive a guideline with type, frequency, and duration of exercises. In addition, they will have weekly remote monitoring (1 time a week), via telephone contact, by the study therapists. Those in the CG will also receive the guideline, and will have weekly follow-up (once a week) in person, with home visits from the study therapists.

The revaluation will be carried out every 2 months with the application of specific questionnaires remotely, through video calling platforms. Risk prediction is related to possible constraints when answering questions that reinforce awareness of restricted and disabling physical conditions; you may also experience dyspnea (respiratory discomfort) from answering questions over a period of time. To minimize the risks, researchers will, at the beginning of each assessment, make you aware of answering questions calmly, without haste; you will not be required to answer questions that make you uncomfortable and/or uncomfortable; you can take breaks anytime you feel tired and we will also ask the caregiver/companion for assistance in answering questions if necessary. We will also use secure platforms in the case of questionnaires and we will follow the provisions of the General Law for the Protection of Personal Data (No. 13.709) to protect your personal data.

The possible benefits will be included in the assessment and physical therapy guidelines that will be given to each case in a specific way, in addition to helping health professionals and the scientific community to clarify the process of motor evolution of the condition; give support

to physiotherapists in the development of motor and treatment plans; as a result, assist in research and technologies related to physical therapy assistance in ALS. You are free to opt out of the survey at any time without any prejudice or coercion, and the assistance provided by the multi-professional team is guaranteed .

If you have any problem related to the research, you will be entitled to free assistance that will be provided through physical therapy care by the responsible researchers.

During the entire period of the research, you can clear up your doubts by calling physiotherapist Aline Alves de Souza through contact: (84) 99819-8935 or at the Federal University of Rio Grande do Norte: Avenida Senador Salgado Filho, number 3000.

The data you provide us will be confidential and will only be disclosed at conferences or scientific publications, with no data that might identify you being disclosed.

These data will be kept by the responsible researcher in a safe place and for a period of 5 years. If there is any expense for your participation in this research, it will be borne by the researcher and reimbursed to you. If you suffer any proven damage as a result of this research, you will be indemnified.

If you have any questions about the ethics of this research, you should contact the Research Ethics Committee of the Onofre Lopes University Hospital, telephone: (84) 3342-5027, address: Av. Nilo Peçanha, 620, Petrópolis – Teaching and Education Management. Survey – Administrative Building – 3rd floor, Natal/RN. gep_huol@outlook.com.

This document was printed in two copies. One will stay with you and the other with the responsible researchers.

Patient Consent Form

After having been clarified about the objectives, importance and how the data will be collected in this research, in addition to knowing the risks, discomforts and benefits it will bring to me and having been aware of all my rights, I agree to participate in the research “Project RevELA: Effects of a home-based exercise protocol with remote and face-to-face monitoring of individuals with Amyotrophic Lateral Sclerosis: randomized clinical trial", and I authorize the disclosure of information provided by me in conferences and/or scientific publications as long as no data can identify me.

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Signature of research participant

Statement by the responsible researcher

As the researcher responsible for the study "Project RevELA: Effects of a home-based exercise protocol with remote and face-to-face monitoring of individuals with Amyotrophic Lateral Sclerosis: randomized clinical trial ", I declare that I assume full responsibility for faithfully complying with the methodological procedures that have been clarified and guaranteed to the participant of this study, as well as to keep the identity of the same confidential.

I also declare that I am aware that, if I fail to comply with the commitment hereby assumed, I will be violating the norms and guidelines proposed by Resolution 466/12 of the National Health Council - CNS, which regulates research involving human beings.

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Signature of the Researcher