INFORMED CONSENT

Official Title: Effects of Control of Joint Degrees of Freedom in the Early Rehabilitation Post-stroke for the Recovery of Normal Movement (Non-ompensatory) of the Upper Limb

Secondary IDs: 11181337, [Grantor or Funder: Fondecyt ANID]

NCT number: not yet assigned

date of the document:

INFORMED CONSENT PROTOCOL 1

PROJECT TITLE

Effects of control of joint degrees of freedom in the early rehabilitation post-stroke for the recovery of normal movement (non-compensatory) of the upper limb.

SPONSOR: CONICYT, INITIATION PROJECT FONDECYT 2018, N°11181337
Name of principal investigator: Pablo Burgos Concha National
ID number: 15563965-2
Institution: Department of Physical Therapy, University of Chile Telephones: +56229786513, +56226120753,+56979782534.

Invitation to participate: We are inviting you to be part of a research project titled "Effects of control of joint degrees of freedom in the early rehabilitation post-stroke for the recovery of normal movement (noncompensatory) of the upper limb" because you are in the initial rehabilitation process of stroke that compromised the movement of one of your arms.

Objectives: The objective of this research is to know the effects that specific training has on the way of moving the affected arm of people who have had a stroke.

Procedures: If you agree to participate, we will perform the following procedures during 4 weeks: 1 to 2 daily training sessions for the mobility of your arm of 40 minutes during the first 2 weeks and sessions of 80 minutes, 3 times a week during the last 2 weeks.

Evaluations will be carried out before and after the training received, these will consist of: tests to evaluate the ability to move your arm, resistance of your arm opposed to passive movement, pain evaluation, scale of independence in activities of daily living, questionnaire about quality of life. These evaluations will be repeated once the training finishes, in week 12th and 24th following the study entry.

The evaluation of the ability to move the arm will be done in conjunction with a test called electroencephalography (EEG), in which small metal discs are placed on your head called "electrodes" to observe the electrical activity of the brain while arm movement. We will also use sensors located on your arm, these will help us to record more accurately the movements of your arm.

Protocol 1:

During the training session you will be sitting with your arm positioned on a

structure called "exoskeleton", this structure will help us to fix some articulation movements, to work specifically on a certain movement. A video game will be used to show various challenges in which you should move your arm in the "exoskeleton", being able to visualize your own movement on the screen of the video game, receiving support from the therapist in charge to work with certain movements including the entire range of motion.

In the event that you cannot perform the requested movement, you will work with mental practice (imagine a movement) and the observation of different movements.

Risks: Your participation in this study is risk free. The equipment used such as inertial sensors and EEG have been used for many years now and are considered safe procedures and they do not cause discomfort. The electrodes that record the activity do not produce any sensation. Also, there is no risk of receiving an electric shock.

Costs: The participation in the mentioned research will be at no cost for you. All tests performed for this study will be paid by the research team with funding from FONDECYT. As well as the expenses related to transfer from your home to the training location and vice versa once discharge from the hospital.

As a participant in this study, you or your welfare system must finance hospitalizations, fees, tests and routine treatments for the study and treatment of disease that is not related to this research.

Benefits: In addition to the benefit that this study will mean for the progress of knowledge and the best treatment of future patients, your involvement in this study will directly benefit your rehabilitation process since you will access a longer training time in a period that is considered critical for rehabilitation, as it is the phase in which more progress can be observed. This is because, in addition to this training, you will continue receiving your usual therapy.

Alternatives: If you decide not to participate in this research, you will only continue with the treatment that is usually applied.

Compensation: You will not receive any monetary compensation for your participation in the study. The general expenses of your participation will be covered, considering transfer and food.

Confidentiality: All the information derived from your participation in this investigation shall be maintained in strict confidence, which includes access to researchers or research supervising agencies, by assigning a role of participant, keeping your personal information anonymous.

Any publication or scientific announcement of the results of this investigation will be completely anonymous. (Guarantee of protection of privacy and respect for

confidentiality during processing of personal data, mentioning the methodology to be used).

You or your treating physician will be informed if during the development of this research, new knowledge or complications arise that may affect your willingness to continue your participation in the research.

Voluntariness: Your participation in this research is completely voluntary and you can withdraw at any time by notifying the researcher and your treating physician, this without implying changes in the routine study and treatment of your disease. Likewise, your physician or the researcher may determine your withdrawal from the research if they consider that this decision is in your best interest.

Complications: In the unlikely event that you present complications directly dependent on the treatment applied, you will receive the complete medical treatment of the mentioned above, financed by the research team and at no cost to you or your welfare system. This does not include complications of your disease and its natural course.

Patient rights: You will receive a full copy of this signed document. If you require any other information about your participation in this research or to know the results, you can contact with:

Researcher: Pablo Ignacio Burgos Concha, +56979782534, +56229786513.

Authority of the institution: Homero Puppo Gallardo, +56229786513.

Other patient rights: In case of doubt about your rights, you should contact the President of the "Ethics Committee for Research in Human Beings", Dr. Manuel Oyarzún G. Telephone: 2-9789536, Email: comiteceish@med.uchile.cl, whose office is located next to the Central Library of the Faculty of Medicine, University of Chile, Independencia Avenue 1027, commune of Independencia.

Conclusion: After having received and understood the information in this document and having been able to clarify all my doubts, I give my consent to participate in the project "Effects of control of joint degrees of freedom in the early rehabilitation post-stroke for the recovery of normal movement (noncompensatory) of the upper limb."

_____	_____
Name of participant	Signature
_____	_____
Date	ID number
_____	_____
Name of director of institution or delegate 11 Law 20120	Signature Art.
_____	_____
Date	ID number
_____	_____
Name of researcher	Signature
_____	_____
Date	ID number

INFORMED CONSENT PROTOCOL 2

PROJECT TITLE

Effects of control of joint degrees of freedom in the early rehabilitation post-stroke for the recovery of normal movement (non-compensatory) of the upper limb.

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Procedures: If you agree to participate, we will perform the following procedures during 4 weeks: 1 to 2 daily training sessions for the mobility of your arm of 40 minutes during the first 2 weeks and sessions of 80 minutes, 3 times a week during the last 2 weeks.

Evaluations will be carried out before and after the training received, these will consist of: tests to evaluate the ability to move your arm, resistance of your arm opposed to passive movement, pain evaluation, scale of independence in activities of daily living, questionnaire about quality of life. These evaluations will be repeated once the training finishes, in week 12th and 24th following the study entry.

The evaluation of the ability to move the arm will be done in conjunction with a test called electroencephalography (EEG), in which small metal discs are placed on your head called "electrodes" to observe the electrical activity of the brain while arm movement. We will also use sensors located on your arm, these will help us to

record more accurately the movements of your arm.

Protocol 2:

During the training session you will be seated with your arm placed on a table. A video game will be used to show various challenges in which you must move your arm, being able to visualize your own movement on the video game screen, through a sensor that will be placed in your hand. You will also execute daily movements such as taking glasses, spoons, combs, among others. Receiving support from the therapist in charge to work with certain movements including the entire range of motion. In the event that you cannot perform the requested movements, you will work through imagination and observation of various movements.

Risks: Your participation in this study is risk free. The equipment used such as inertial sensors and EEG have been used for many years now and are considered safe procedures and they do not cause discomfort. The electrodes that record the activity do not produce any sensation. Also, there is no risk of receiving an electric shock.

Costs: The participation in the mentioned research will be at no cost for you. All tests performed for this study will be paid by the research team with funding from FONDECYT. As well as the expenses related to transfer from your home to the training location and vice versa once discharge from the hospital.

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Benefits: In addition to the benefit that this study will mean for the progress of knowledge and the best treatment of future patients, your involvement in this study will directly benefit your rehabilitation process since you will access a longer training time in a period that is considered critical for rehabilitation, as it is the phase in which more progress can be observed. This is because, in addition to this training, you will continue receiving your usual therapy.

Alternatives: If you decide not to participate in this research, you will only continue with the treatment that is usually applied.

Compensation: You will not receive any monetary compensation for your participation in the study. The general expenses of your participation will be covered, considering transfer and food.

Confidentiality: All the information derived from your participation in this investigation shall be maintained in strict confidence, which includes access to researchers or research supervising agencies, by assigning a role of participant, keeping your personal information anonymous.

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Name of participant Signature

_____ _____

Date ID number

_____ _____

Name of director of institution or delegate Signature Art. 11 Law 20120

_____ _____

Date ID number

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_____ _____

Name of researcher Signature

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INFORMED CONSENT PROTOCOL 3

PROJECT TITLE

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Protocol 3:

During the training session, together with the therapist, you will perform exercises for reaching and grabbing objects throughout the range of motion, using weight support from the arm if necessary. You will perform muscle strength exercises for the affected arm. You will train as well transitions and transfers focused on balance and gait.

Risks: Your participation in this study is risk free. The equipment used such as inertial sensors and EEG have been used for many years now and are considered safe procedures and they do not cause discomfort. The electrodes that record the activity do not produce any sensation. Also, there is no risk of receiving an electric shock.

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