Effectiveness of the Home-Based Graded Repetitive Arm Supplementary Program Combined with Occupational Therapy Versus Conventional Occupational Therapy Alone on Quality of Life and Upper Limb Function After Stroke: A Randomized Controlled Trial

NCT ID not yet assigned

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PATIENT INFORMATION SHEET

Study Title:	Effectiveness of the Home-Based Graded Repetitive Arm Supplementary Program Combined with Occupational Therapy Versus Conventional Occupational Therapy Alone on Quality of Life and Upper Limb Function After Stroke: A Randomized Controlled Trial
Principal Investigator:	Eva María Navarrete Muñoz

You are being invited to participate in a research project. This study has been approved by the Ethics Committee for Research with Medicines of the Department of Health of Alicante – Hospital General. The project will be conducted in accordance with Good Clinical Practice (GCP) guidelines and international ethical principles applicable to medical research in humans (Declaration of Helsinki and its latest revision).

To help you decide whether to participate, it is important that you understand the purpose of the research, what your participation involves, how your information will be used, and any potential benefits, risks, or inconveniences. This document provides detailed information about the study. Please take the time to read it carefully. We will answer any questions you may have. Once you fully understand the project, you will be asked to sign the informed consent form if you wish to participate.

Please note that your participation in this study is entirely voluntary. You may withdraw at any time without penalty and without affecting your legal rights or the quality of your medical care.

The project will be conducted at the Hermanas Hospitalarias Center in Valencia.

WHY IS THIS STUDY BEING CONDUCTED?

After a brain injury such as stroke, people may experience a range of impairments depending on the location and severity of the damage. These can include sensorimotor deficits (e.g. reduced mobility), cognitive impairments (e.g. attention or memory problems), perceptual or emotional changes, among others. One of the most frequent and disabling sequelae is the loss of upper limb mobility and function. In fact, around 80% of stroke survivors have some degree of upper limb impairment, and only 15% achieve substantial functional recovery.

In upper limb rehabilitation after stroke, increased treatment intensity leads to better outcomes compared to conventional approaches, which often involve fewer hours per week. However, logistical limitations (e.g. staffing, resources), economic constraints, and delays in referral may prevent access to intensive rehabilitation.

One strategy to increase treatment intensity is through home-based exercise programmes. The HomeGRASP programme (Graded Repetitive Arm Supplementary Program) is a structured set of home exercises for the arm and hand, supervised weekly by an occupational therapist. It includes a wide range of exercises—from strengthening to improving manual dexterity—and adds up to seven extra hours per week of upper limb rehabilitation.

This study aims to translate and culturally adapt the programme (currently available in English), and to evaluate the impact of the HomeGRASP programme on quality of life, autonomy, and upper limb functionality after stroke, when implemented as a complement to conventional occupational therapy, using a randomised controlled trial design.

WHAT IS THE PURPOSE OF THIS PROJECT?

To translate the HomeGRASP programme into Spanish and adapt it to our cultural context, and to assess changes in quality of life and upper limb functionality in stroke survivors following the use of this programme as a complement to conventional occupational therapy.

HOW WILL THE STUDY BE CARRIED OUT?

Your occupational therapy team at the rehabilitation centre will explain the study and ask whether you would like to participate.

If you agree, an initial evaluation will be carried out to assess the mobility and dexterity of your affected arm, as well as your autonomy and quality of life. This will take place over two 1-hour sessions or one 2-hour session before your usual therapy.

After this assessment, you will be randomly assigned to one of two groups:

If you are assigned to the experimental group, you will continue your regular rehabilitation at the centre and also complete a home-based arm and hand exercise programme (HomeGRASP). This programme involves 1 hour of daily exercise, 7 days per week, for 8 weeks.

If you are assigned to the control group, you will continue your usual rehabilitation sessions with no additional intervention.

After 8 weeks, the same evaluations conducted at the beginning will be repeated to assess any changes. This will also take place over two 1-hour sessions or one 2-hour session before your regular therapy.

Participation in this study will not require you to visit the centre more often than usual, and you will not miss any of your scheduled rehabilitation sessions.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATION?

You will receive the same treatment and care whether or not you participate. Therefore, there are no direct benefits to you. However, the information you provide may help us develop more effective tools for upper limb rehabilitation after stroke.

There is no financial compensation for participating in this study.

ARE THERE ANY RISKS?

Shoulder pain is a common issue after stroke, especially in the more affected limb. Although the HomeGRASP programme includes exercises designed to prevent or relieve shoulder pain, incorrect performance may cause or worsen discomfort. For this reason, the programme is supervised weekly by your occupational therapist. Please notify your therapist if you experience any pain so the exercises can be modified accordingly.

No other health risks are anticipated. All assessments and treatments will be supervised by your occupational therapist or another rehabilitation professional.

WHAT DATA WILL BE COLLECTED?

You will be asked to provide demographic information (e.g. age, sex, education, socioeconomic status, marital status, employment history, caregiver support) and clinical data (e.g. diagnosis, date of diagnosis, medications, duration of rehabilitation, treating professionals, weekly therapy hours, pre-stroke hand dominance, sensory/motor impairments, other conditions).

You will also complete evaluations on personal autonomy, quality of life, and upper limb function:

Autonomy and quality of life:

Functional Independence Measure (FIM): Assesses independence in daily living activities.

CAVIDACE scale: Completed by you and someone close to you, to assess perceived quality of life.

Upper limb mobility and dexterity:

Wolf Motor Function Test: 17 tasks using everyday objects.

Purdue Pegboard Test: Manual dexterity and coordination.

Duruöz Hand Index: 18 questions on hand function in daily tasks.

Motor Activity Log-30: Questionnaire on arm use and movement quality in everyday life.

Box and Blocks Test: Measures how many blocks can be moved from one side of a box to the other in one minute.

Additionally, we will collect information on your use of the HomeGRASP programme: completion, missed days or exercises, time spent reviewing exercises in session, adjustments made, and feedback provided.

HOW WILL MY PERSONAL DATA BE USED AND PROTECTED?

All personal data will be collected, processed, and stored in accordance with the Spanish Data Protection Act (Ley Orgánica 3/2018) and the EU General Data Protection Regulation (GDPR, EU Regulation 2016/679).

Access to your personal data will be restricted to study investigators and staff, authorised health authorities, and oversight committees (e.g. ISABIAL). Your data will be processed using codes that do not directly identify you. Only your assigned therapist or clinical collaborator will be able to match this code to your identity.

You have the right to:

Access your data

Object to its use

Request corrections

Request data deletion (with certain exceptions for legal or scientific reasons)

Limit its processing

Request a copy or its transfer to another party (data portability)

If you wish to exercise any of these rights, please contact the principal investigator. Please note that some data may need to be retained even if you withdraw from the study to ensure the integrity of the research and compliance with applicable laws.

Both the research centre and sponsor will act as data controllers and are committed to protecting your data. Data will be kept for a minimum of 25 years after the end of the study. After that, it may be kept for healthcare or future research purposes if legally permitted and with your consent.

If data is transferred outside the EU, it will be protected through legal safeguards such as contracts approved by data protection authorities. You may contact us at enavarrete@umh.es for more information.

WHO CAN I CONTACT IF I HAVE QUESTIONS?

If you have any questions or need further information about the study, you may contact:

Eva María Navarrete Muñoz – enavarrete@umh.es

INFORMED CONSENT FORM

Study ID Number:	Acta 2024-11
Study Title:	Effectiveness of the Home-Based Graded Repetitive Arm Supplementary Program Combined with Occupational Therapy Versus Conventional Occupational Therapy Alone on Quality of Life and Upper Limb Function After Stroke: A Randomized Controlled Trial
Principal Investigator:	Eva María Navarrete Muñoz

I, ...

(Full name handwritten by the participant)

confirm that I have read the information sheet and had sufficient time to consider my decision. I have had the opportunity to ask questions, and all of them have been answered satisfactorily.

I understand that my participation is voluntary. I understand that I can withdraw from the study:

- At any time
- Without giving any reason
- Without this affecting my medical care

After carefully considering the information provided to me, I hereby state my decision:

☐ I give ☐ I do not give

My consent for the access and use of my data under the conditions detailed in the information sheet.

PARTICIPANT'S SIGNATURE:	**INVESTIGATOR'S SIGNATURE:**
NAME:	**NAME:**
DATE:	**DATE:**

WITHDRAWAL OF CONSENT

I …… hereby withdraw the consent previously given on [date] and no longer wish to participate in the study: Effectiveness of the Graded Repetitive Arm Supplementary Program - Home Version Combined with Occupational Therapy Versus Conventional Occupational Therapy Alone on Quality of Life and Upper Limb Functionality After Stroke: a Randomised Controlled Trial.

PARTICIPANT'S SIGNATURE:	**INVESTIGATOR'S SIGNATURE:**
NAME:	**NAME:**
DATE:	**DATE:**