

Effect of a nursing intervention based on health education on functionality, depression symptoms and quality of life in patients with ischemic stroke.

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Summary

This study is entitled "Effect of a nursing intervention based on health education on functionality, depression symptomatology and quality of life in patients with ischemic stroke". The promoter and principal investigator is María del Rosario Marín Arnés.

This is a quasi-experimental, longitudinal and prospective clinical trial, which will be carried out in patients who have suffered an ischemic stroke and who were treated in the neurology unit of the Lucas Augusti University Hospital, where this same study will be carried out.

The main objective of the study is to determine the effect of a nursing intervention based on health education on quality of life and symptoms of depression in people who have suffered an ischemic stroke.

To achieve this objective, variables such as cognitive status, symptoms of depression, autonomy and ability to perform in basic activities of daily living, neurological deficit and quality of life will be assessed.

Regarding the total number of subjects under study, according to the Atlas of Stroke in Galicia published by the Spanish Society of Neurology in 2018, the autonomous community of Galicia had a population of 2,701,819 inhabitants. Applying an incidence rate of 187.4 cases per 100,000 inhabitants, according to the IBERICTUS study, 5,064 new cases of stroke are estimated each year in Galicia per 100,000 inhabitants. The province of Lugo has 324,842 inhabitants on 1 January 2024, according to the INE, which, applying the same incidence rate, estimates 609 new cases of stroke per 100,000 inhabitants per year. Considering the proportion of ischemic strokes compared to other types of strokes 80:20, the estimated cases of the same would be 487 new cases in Lugo. The representative sample size of stroke patients in the province of Lugo would be 70 patients, 35 patients receiving the intervention and 35 controls.

Términos MESH: Ischemic Stroke; Nursing; Depression; Anxiety; Health Education; Quality of Life

Background and justification of the project

Stroke is defined as a syndrome with rapid onset of a focal neurological deficit of vascular origin. Classically, strokes are divided into two large groups: ischemic strokes, which will occur 80-85% of the time, and hemorrhagic strokes, which account for 15-20% of strokes. Specifically, ischemic stroke is defined as an episode of neurological dysfunction caused by focal cerebral infarction delimited by an occluded artery that decreases cerebral blood flow. Its etiology classification can be differentiated into five main subtypes: atherothrombotic stroke of large artery, cardioembolic stroke, lacunar of small vessel, stroke of rare cause and stroke of undetermined origin. In any case, as a consequence there will be an area of ischemia at risk of cell death and an infarcted area already necrotic, causing irreversible damage. The functional evolution of the patient after a stroke is classically established in three periods. An acute period that goes from the onset of symptoms to hospital discharge, a subacute period in which there is a progressive functional improvement, which continues in most cases during the first 3-6 months and finally a chronic phase of functional stabilization. Epidemiologically speaking, stroke is the second cause of death and third cause of disability worldwide and the first in Europe, with its incidence and prevalence being higher in women. While it is true that on the one hand there is a decrease in mortality in developed countries, on the other hand, there is an increase in the incidence associated with aging and an increase in life expectancy. For this last issue, it is estimated that mortality from ischemic stroke will increase in Spain by about 39% between 2015 and 2035. In Spain in 2022, cerebrovascular disease accounted for 48% of total admissions due to a neurological cause. It affects 1.5% of people, increasing to 3% from the age of 65 and to 10% from the age of 80. In Europe, the sex-adjusted

incidence of stroke was 191.9 per 100,000 person-years and the sex-adjusted prevalence was 9.2%. In 2019, the total number of disability-adjusted life years related to stroke exceeded 125 million worldwide.

Economically, ischemic stroke accounts for 3-4% of health expenditure in Western countries and is expected to quadruple in the future.

The main deficits, disabilities and complications observable after a stroke include paralysis, emotional imbalance, speech and language disorders, visual disturbances, cognitive deficits, physical and mental fatigue, epileptic seizures and pain. The greatest risk factor predicting poor prognosis of ischemic stroke is age, which is directly related to epidemiological data.

Ischemic stroke is the leading cause of acquired disability in adults. Two out of three people affected by a stroke associate difficulties in basic tasks such as showering or bathing without help and in household chores. A high percentage of these people perceive their state of health as fair (37.3%), or bad or very bad (36.5%) and a majority suffer pain or discomfort (62.4%) and difficulties in carrying out their daily activities (59.1%).

The mental health of those who have suffered a stroke is also severely affected, with women and those over 65 scoring significantly worse. It is estimated that between 20 and 50% of stroke survivors develop depressive symptoms at some point, which can have a direct impact on the patient's physical and cognitive recovery. The manifestation of post-stroke depression includes everything from persistent sadness to loss of interest in activities that the patient previously enjoyed, changes in appetite or difficulties concentrating or falling asleep. In the same way, dysphagia, a common complication after an ischemic stroke, is also related to the appearance of depressive symptoms. Other risk factors have been described when it comes to developing symptoms of depression in patients who have suffered a stroke, such as low educational level or low economic level. Early identification and treatment of depression in post-ischemized patients is crucial for improving their quality of life and early rehabilitation.

Patient function after stroke is associated with the likelihood of hospital readmission. Patients with poor function at discharge are more likely to need long-term care and intensive rehabilitation plans. Functionality includes the interaction of positive aspects between the 3 main components: body functions and structures; activity and participation; and environmental and personal factors. Post-stroke functionality has not yet been comprehensively assessed. Some authors postulate a progressive functional improvement beyond 12 months when accompanied by rehabilitation treatment and, on the contrary, a progressive functional deterioration in the absence of specific rehabilitation therapy.

The greatest attention to stroke patients has commonly focused on the acute phase, which has managed to reduce morbidity and mortality. However, studies focused on the subacute phase are less frequent and few are those that focus on long-term evolution. Other authors postulate that differences in functional status at three months are associated with significant differences in survival and performance status during a seven-year follow-up.

In relation to the subacute phase, the evaluation of the functional status of ABVD is recorded in only 24.6% of cases at discharge and for six months after the episode.

To assess the autonomy of stroke patients, it is necessary to consider how the physical, cognitive, and psychological impacts of stroke may lead to a wide range of activity limitations and participation restrictions.

Patients who have suffered a stroke are often predisposed to a sedentary lifestyle that affects performance in activities of daily living, thus increasing the risk of relapse. Resuming activities of daily living is therefore of great importance for life satisfaction and is considered as a primary goal for rehabilitation. The first six months after stroke are therefore considered critical for rehabilitation. Rehabilitation plays a fundamental role in this

process since it directly influences the reduction of disability and handicap by reducing the personal, family and social cost, and its usefulness is fully established.

The functional evolution varies with the initial clinical severity. Maximum functionality is reached on average at 2 months in patients with initially mild strokes, at 3 months in patients with moderate strokes, at 4 months in severe strokes and at 5 months in very severe strokes. In addition, several studies have shown that functional outcome after stroke is a potent predictor of long-term mortality, therefore, we need to promote maximum functional independence of stroke survivors living at home through supervised and tailored nursing interventions and physical activities. Results from previous studies indicate that Barthel's delta, i.e. the change in a patient's functional autonomy, is equal to 0 for those interventions performed in routine clinical practice other than treatment with rt-PA or thrombectomy after suffering from an ischemic stroke. Therefore, it can be deduced that they are not having a clear or optimal effect on functional improvement in those patients who have suffered an ischemic stroke.

Experts recommend a series of services and resources for a good functional recovery of patients who have suffered a stroke. Among other issues are training and health education programs. In this way, the nursing profession is trained to formulate personalized comprehensive care plans, promote comprehensive recovery, and strengthen communication with patients and their families. Nurses should perform interventions in accordance with general practice to provide continuity of care for stroke patients throughout the patient's recovery journey. Integrated care is desirable and constitutes a reference model for all situations considered. Planning for teaching and discharge from hospital can help families of patients who have suffered a stroke to make specific long-term arrangements for the expected functional outcome. In addition, post-discharge follow-up and support interventions should be implemented that are individualized to the caregiver's needs. Early rehabilitation intervention and evidence-based nursing interventions showed significant improvements in their scores on tests related to cognitive impairment and neurological deficit, as well as improved disability. However, there are hardly any standardized, approved and scientifically proven health education programs. The application of nursing interventions, through health education, to minimize the levels of depression caused by the disease, to two groups, case and control, will allow us to evaluate the influence of health education on the symptomatology of depression and improve the quality of life in patients who have suffered an ischemic stroke.

Study hypothesis

A nursing intervention based on health education will improve quality of life and reduce the symptoms of depression in patients who have suffered an ischemic stroke.

Objectives

General objective: to determine the effect of a nursing intervention based on health education on quality of life and depression symptoms in people who have suffered an ischemic stroke.

Specific objectives:

1. To assess and compare the level of depression in patients who have suffered an ischemic stroke.
2. To assess and compare the degree of autonomy and level of functional dependence of patients who have suffered an ischemic stroke.
3. To assess and compare the cognitive status of patients who have suffered an ischemic stroke.
4. To assess and compare neurological deficits of patients who have suffered an ischemic stroke.

5. Assess and compare the risk of bronchoaspiration, the presence of pressure ulcers, swallowing, blood pressure, temperature and glucose level and assess the level of pain.
6. To correlate the cognitive state and the level of depression symptomatology with implemented variables.
7. To reduce the psychological impact of depression in patients who have suffered an ischemic stroke who have received health education.
8. To compare the level of depression symptoms in patients who have suffered an ischemic stroke who received health education with those who did not.

Type of study

It is a quasi-experimental, longitudinal and prospective clinical trial.

Material and methods

Scope of study

For the preparation of this study, the target population was patients who have suffered an ischemic stroke for the first time and were treated by physicians from the Neurology and Neurosurgery Service of the Lucas Augusti University Hospital (HULA).

Definition of the subjects to be studied

A representative sample size of patients who have suffered an ischemic stroke for the first time and treated by physicians from the Neurology and Neurosurgery Service of the HULA will be collected. From this sample, 2 groups will be extracted: the group to which a health education program will be applied and the control group to which this program will not be applied.

Subject selection and withdrawal

Inclusion criteria: anterior or posterior cerebral occlusion, age ≥ 18 years.

Exclusion criteria: intracranial hemorrhage, pregnancy, cognitive inability to participate, non-acceptance to participate in the study and administer questionnaires.

Recruitment and recruitment of participants

Prior to the recruitment process, the required informed consent signed by said participant will be obtained. Next, the variables will be collected. The recruitment of participants will be carried out by the principal investigator and collaborating researchers of the study in the neurology and neurosurgery ward:

- Eva Gómez Fernández
- Mercedes Fernández Vázquez
- María Irene Núñez Fernández
- María del Rosario Marín Arnés

The tasks "*Bibliographic Review, Study Design, Documentation Presentation, Database Design*" will be carried out by the collaborating researcher Félix Martínez Eiriz supervised and in collaboration with the collaborating researchers Emilio Rubén Pego Pérez and Emilio Gutiérrez García.

The recruitment of patients and immediate data will be carried out consecutively on the neurology and neurosurgery floor of the HULA by the collaborating researchers Eva Gómez Fernández, Mercedes Fernández Vázquez, María Irene Núñez Fernández and the principal investigator María del Rosario Marín Arnés and by the collaborating researcher in neurology consultation at the HULA María Lourdes Bermello López.

The performance of the sessions is conditioned by the time of diagnosis of the stroke. In this way, it is necessary to recruit a minimum group of patients to carry out the workshops according to the established methodology. Subsequently, these will be carried out by the collaborating researcher Félix Martínez Eiriz. After 3 and 6 months following the workshops, the same researcher together with the collaborating researcher María Lourdes Bermello López will carry out the follow-up and reevaluation in the neurology consultation of the HULA.

Finally, the process of integrating data and statistical analysis together with the final task of writing results, discussion and conclusions and their dissemination will be carried out by the collaborating researcher Félix Martínez Eiriz.

First, the initial evaluation of the patients will be carried out for the collection of variables to be studied in the neurology and neurosurgery floor of the HULA. Subsequently, recruitment will be carried out after delivering a sheet with all the information and the due consent document and they will be scheduled in outpatient clinics where the intervention of this study will be applied.

Assignment/Randomization Procedure

The procedure for assigning the members of each group will be random and the EPIDAT program will be used to make this selection.

Justification of the sample size

According to the Atlas of Stroke in Galicia published by the Spanish Society of Neurology in 2018, the autonomous community of Galicia had a population of 2,701,819 inhabitants. Applying an incidence rate of 187.4 cases per 100,000 inhabitants, according to the IBERICTUS study, 5,064 new cases of stroke are estimated each year in Galicia per 100,000 inhabitants. The province of Lugo has 324,842 inhabitants on 1 January 2024, according to the INE, which, applying the same incidence rate, estimates 609 new cases of stroke per 100,000 inhabitants per year. Considering the proportion of ischemic strokes compared to other types of strokes 80:20, the estimated cases of the same would be 487 new cases in Lugo.

In relation to the calculation of the sample size, the following formula is applied.

$$n = \frac{\left[Z_{1-\frac{\alpha}{2}} \sqrt{2p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)} \right]^2}{(p_1 - p_2)^2}$$

Where:

- P2 (frequency of exposure between controls) = 0.4
- OR=4
- Assuming a 1:1 ratio of controls per case
- n = participants as the minimum sample size.

Assuming the calculations, the representative sample size of stroke patients in the province of Lugo would be 70 patients, 35 patients receiving the intervention and 35 controls.

Primary and secondary variables

Independent variables:

- Socioepidemiological: sex, age (< 65 years, 65-80 years, >80 years), date of ischemic event.
- Clinical Signs: type of stroke, treatment modality (received rt-PA or mechanical thrombectomy according to the candidates' protocol), number of falls, degree of pain, presence of pressure ulcers, genesis of new pressure ulcers, episodes of bronchoaspiration, presence of pneumonia, presence of dysphagia, vital signs (blood pressure, glycemia, temperature).
- You receive health education after a stroke or do not receive health education after a stroke.

Dependent variables:

- Assessment of cognitive status by scoring the Mini Mental State Examination (MMSE) questionnaire.
- Assessment of depression symptomatology by scoring on the Beck questionnaire (BDI) or also called depression self-report inventory.
- Assessment of autonomy and ability to perform in basic activities of daily living by means of a score from the Barthel Index.
- Neurological deficit using the NIHSS scale.
- Assessment of quality of life by scoring on the European Quality of Life Scale.

Instruments

This section lists the instruments that will be used to measure the variables under study. They are described in a more extensive manner in Annex I.

1. Mini mental status examination (MMSE).
2. Beck Questionnaire (BDI).
3. Barthel index.
4. National institute of Health Stroke Scale (NIHSS).
5. Visual Analog Scale (VAS)
6. European Quality of Life Scale (EQLS).

Description of the intervention

The initial evaluation of the patients will be carried out for the collection of the variables to be studied upon admission. Subsequently, 2 groups will be established: the group to which a health education program will be applied (intervention of this study that will be specified below) and the control group. Finally, a follow-up is proposed at 3 and 6 months after the health education intervention to collect data related to the chronic/stabilization phase in post-stroke recovery.

Nursing intervention: Health education for post-stroke patients

Objectives

- Learn to identify and recognize prodromal symptoms of a new ischemic event.

- Identify what changes have occurred or may occur in patients after the sequelae of the ischemic event and how they may impact their daily lives.
- Describe the recommended care that patients can incorporate into their daily lives to reduce the impact of sequelae and improve their quality of life.
- Learn to recognize and manage early signs and symptoms of low mood and depressive symptoms.

Methodology

The sessions taught are based on meaningful learning, also supported by constructivist, cognitivist and behavioural learning.

The program consists of 3 fundamental pillars: session 1. *Early symptoms of stroke and recognition*, session 2. *Living with stroke: the day-to-day care*, session 3. *Mood management*. In addition, a workshop (session 4) will be designed for intervention in depression based on the development of coping tools through full breathing techniques, relaxation techniques, psychotherapy and mindfulness. All sessions will preferably be group. The contents of these sessions are detailed in Annex II.

Taking into account that 35 patients will receive the health education program, it is estimated that 3-4 groups of 8-12 people distributed independently in the sessions taught by the same instructor.

Materials

- Classroom for health education at HULA.
- Physical and digital support to support the sessions.

Time scheduling

The sessions will be divided into two different days.

Day 1 (40 minutes)

- Session 1: Early symptoms of stroke and recognition of these.
- Session 2: Living with stroke: the day-to-day care.

Day 2 (40 minutes)

- Session 3: Mood management and depression.
- Session 4: relaxation workshop with guided meditation (mindfulness)

Timeline and expected completion date.

Once the Santiago-Lugo Research Ethics Committee issues this research plan as favorable, the study will begin following the following schedule:

Task	July and August 2025	September 2025 to November 2025	November 2025 to May 2026	June to August 2026	September 2026 to January 2027	February to December 2027	January 2028 to September 2028
Literature review							
Study design							
Submission of documentation							

Database design							
Patient recruitment and immediate data							
Conducting the workshops							
Follow-up 3 months							
Follow-up 6 months							
Data integration and statistical analysis							
Results, discussion, conclusions							
Scientific dissemination							

The tasks "*Bibliographic Review, Study Design, Presentation of Documentation, Database Design*" will be carried out by the collaborating researcher Félix Martínez Eiriz.

The recruitment of patients and immediate data will be carried out consecutively on the neurology and neurosurgery floor of the HULA by the collaborating researchers Eva Gómez Fernández, Mercedes Fernández Vázquez, María Irene Núñez Fernández and the principal investigator María del Rosario Marín Arnés and by the collaborating researcher in consultation of the neurology of the HULA María Lourdes Bermello López.

The performance of the sessions is conditioned by the time of diagnosis of the stroke. In this way, it is necessary to recruit a minimum group of patients to carry out the workshops according to the established methodology. Subsequently, these will be carried out by the collaborating researcher Félix Martínez Eiriz. After 3 and 6 months following the workshops, the same researcher together with the collaborating researcher María Lourdes Bermello López will carry out the follow-up and reevaluation in the neurology consultation of the HULA.

Finally, the process of integrating data and statistical analysis together with the final task of writing results, discussion and conclusions and their dissemination will be carried out by the collaborating researcher Félix Martínez Eiriz.

The collaborating researchers Emilio Rubén Pego Pérez and Emilio Gutiérrez García will be in charge throughout the research process of the work surrounding it with respect to the contribution to the conception and design of the work, acquisition and analysis of the study data, critical review with important intellectual input, responsibility for the accuracy and completeness of the research, supervision, final approval, and project management.

Statistical analysis plan

A descriptive analysis will be carried out using measures of central tendency, such as mean (M), and dispersion, using standard deviation (SD), to examine quantitative variables. In the case of qualitative variables, absolute frequencies and percentages will be used. To determine the correlation between groups, the Chi-square test (χ^2) will be applied to the qualitative variables. Regarding the quantitative variables, the Kolmogorov-Smirnov test will begin to evaluate the normality of the distribution ($n=70$). If the quantitative variables show a non-parametric distribution, the Kruskal-Wallis test will be used to compare more than two groups, while the differences between pairs will be analyzed using the Mann-Whitney U test. If they are parametric, it will be appropriate to resort to ANOVA, Tuckey and Bonferroti. The association between the variables will be evaluated in terms of strength and direction using Spearman's correlation coefficient. Distracting factors (age and sex) that usually tend to normal will be tested with ANOVA and Levene. The effect of the intervention will be determined using relative risk (RR) Statistical analyses will be performed using PASW Statistics software (version 23.0; SPSS Inc., Chicago, Illinois), establishing a bilateral significance level of $p<0.05$.

Ethical-legal aspects

Compliance with Good Clinical Practice Standards, Declaration of Helsinki, Oviedo

Convention, as well as data protection regulations, management of medical records and other applicable regulations depending on the type of study.

The review and approval of the research plan by the Santiago-Lugo Research Ethics Committee is requested, following local and international regulations in the field of medical research and the standards established by the Declaration of Helsinki. The development of this thesis will be carried out respecting the Declaration of Helsinki of the World Medical Association of 1964 and ratifications of the following assemblies on ethical principles for medical research on human beings, and the Convention on Human Rights and Biomedicine, signed in Oviedo on April 4, 1997 and successive actions. The researchers participating in this study undertake that all clinical data collected from the study subjects will be separated from the personally identifiable data, so that the anonymity of the patients is ensured; respecting the Law on the Protection of Personal Data and Guarantee of Digital Rights (Organic Law 3/2018, of 5 December), Law 41/2002, of 14 November (basic regulation of patient autonomy and rights and obligations in terms of clinical information and documentation), as well as Law 3/2001, of 28 May (regulating informed consent and clinical documentation), as well as Law 3/2005, of 7 March, amending Law 3/2001 and Decree 29/2009 of 5 February, which regulates access to electronic medical records. The patient's data will be collected by the investigator in the study-specific data collection notebook (CRD). Each CRD will be encrypted, protecting the patient's identity. Only the research team and the health authorities, who have a duty to maintain confidentiality, will have access to all the data collected for the study. The data controller will be the HULA. Information may only be transmitted to third parties that cannot be identified. Once the study is completed and the thesis is finished, the data collected will be destroyed or kept anonymous for use in future research according to what each participant chooses in the signing of the consent. An Information Sheet will be provided to the participants and informed consent. Information regarding the identity of patients will be and is considered confidential for all purposes. In order to properly maintain confidentiality with respect to patient information, an appropriate coding and identification dissociation will be carried out in the database, so that only the researcher may associate such data with an

identified or identifiable person. The database that will generate the study will not contain any identification of the patient. Once the study is complete, the database will be deleted. With regard to the data of the study, the provisions of the Organic Law on "Protection of Personal Data" in force will be followed.

Informed consent models.

The informed consent forms have been drafted, to be delivered individually to the participants.

Confidentiality of the information collected in the context of the study.

In order to properly maintain confidentiality with respect to patient information, an appropriate coding and identification dissociation will be carried out in the database, so that only the researcher may associate such data with an identified or identifiable person. Once the study is completed, the data will be deleted or kept pseudonymized as selected by the patient in the Consent.

Commitment to publish results

The researcher undertakes to disseminate the results of his or her research, whether positive or negative.

Economic report and source of funding

Not applicable.

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Data collection notebook

The data collection notebook is detailed in Annex III.

Annexes

Annex I. Description of the instruments

Mini Mental State Examination (MMSE): created in 1975 by Marshal Folstein and later in 1979 adapted to the Spanish version by Lobo: the Mini-Cognitive Exam (MEC). This test is used to assess cognitive impairment, allowing the detection of cognitive problems such as dementia. It covers several areas: temporal and spatial orientation, fixation or immediate memory, calculation and concentration, delayed memory, language (naming, repetition, comprehension, reading and writing) and finally graphic constructive praxis. The maximum score is 30 points, which is interpreted as the absence of cognitive impairment. The cut-off point for suspecting cognitive impairment is a value <23 points. Its application lasts approximately 5 minutes. Its categories are: 30-27 points no cognitive impairment, 26 and 25 points doubtful cognitive status, 24-10 points mild-moderate cognitive impairment, 9-6 points moderate-severe cognitive impairment, 6 points: severe cognitive impairment.

Beck Depression Inventory (BDI): The BDI allows the severity of depressive symptoms to be measured. It was originally published in 1996 by Beck et al. and later adapted to Spain. It consists of 21 items that cover questions about the depressive symptoms experienced in the last few weeks. Each question is assigned a score of 0-3, with 0 being less severe and 3 being greater. The maximum score that can be obtained is 0. According to the score obtained, we find four groups from least to most severe, from 14 points is when it is considered that there is a clinically significant depression. The application of this scale takes approximately 10 minutes. Categorization: Minimum range: 0-13; Mild depression: 14-19; Moderate depression: 20-28; Severe depression: 29-63 points.

Barthel Index: The Barthel Index or Maryland Disability Index was created in 1965 by Mahoney and Barthel. It is one of the most widely used instruments to determine functional capacity. It is a scale that assesses patients' independence in basic activities of daily living (ABVD). Its application takes between 2-5 minutes as a self-report and up to 20 minutes if it is carried out by direct observation. It assesses 10 ABVD, seven of which are activities related to personal care (eating, washing, dressing, grooming, bowel movements, urination, toilet use) and the other three have to do with mobility (ambulation, transferring, and going up/down stairs). Each activity is scored according to the degree of independence, with values ranging from 0 (total dependence) to 15 (total independence). The maximum score is 100, which would indicate that it is totally independent, while the minimum score is 0 and would indicate that the patient has total dependence. Its interpretation is as follows: 100 points independence, ≤ 60 mild dependence, 40-55 moderate dependence, 20-35 severe dependence and 5-20 total dependence.

Visual Analogue Scale (VAS): on the Visual Analogue Scale EVA, the intensity of pain is represented on a 10 cm line. At one end is the phrase "no pain" and at the opposite end "the worst pain imaginable". The distance in centimeters from the point of "no pain" to the one marked by the patient represents the intensity of the pain. It may or may not have marks every centimetre, although for some authors the presence of these marks decreases their accuracy. The way in which the patient is presented, whether horizontal or vertical, does not affect the outcome. It is the most widely used scale, even in critically ill patients. For some authors it has

advantages over others. The patient needs to have good motor and visual coordination, so it has limitations in the elderly patient and in the sedated patient. A value below 4 in VAS means mild or mild-moderate pain, a value between 4 and 6 implies the presence of moderate-severe pain, and a value greater than 6 implies the presence of very severe pain.

NIHSS Scale: This scale is a tool used to assess the severity of a stroke and its neurological effects. It was developed in 1989. It is used both for the initial assessment of the patient and for follow-up. It is widely used in clinical practice and in research related to cerebrovascular diseases. It is made up of 11 items which assess: the level of consciousness, sensory-motor impairment, language and vision, giving scores to each one according to the degree of impairment. Therefore, the scores will vary between 0 (normal function) and 4 (deterioration). The individual scores for each item are added together to calculate a patient's total NIHSS score. The maximum possible score is 42, with the minimum score being 0. Based on the categorization of the scale, a score of 0 points is considered asymptomatic, a minimum deficit a score of 1; mild deficit a score between 2-5, moderate deficit a score between 6-15, significant deficit values between 16-20 points and severe deficit > 20 points.

European Quality of Life Scale (EQ-5D-5L): is a generic questionnaire on health-related quality of life, developed by the EuroQol Group. It assesses five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each with five levels of severity (no problems, mild problems, moderate problems, severe problems, and extreme problems or unable to) that describe 3,125 possible health conditions. If in a particular dimension, there are no problems this is represented as level 1, while extreme problems are represented as level 5. Hence, each state of health on the EQ-5D-5L can be described using a five-digit number, where 11111 indicates perfect health and 55555 indicates the worst possible state of health. It also features a visual analog scale (EQ-VAS) where the patient rates their overall health on a vertical scale from 0 (worst imagined health) to 100 (best health imaginable).

Annex II. Development of interventions.

Early symptoms of stroke and recognition of these (10 minutes).

A stroke is a neurological disease that occurs when blood flow to the brain is interrupted. This prevents blood from flowing, which means parts of the brain are damaged and may stop working. A Transient Ischemic Attack is a type of stroke that is also caused by the interruption of blood flow, but temporarily, with symptoms usually lasting a few minutes and the person recovering completely in less than 24 hours.

Some of the most common symptoms of stroke are described below:

- Sudden loss of movement or weakness of the arm, leg, or face, especially when it occurs on one side of the body.
- Sudden vision problems.
- Sudden headache, with no apparent cause.
- Slurred speech: Drooping lip, babbling, inability to find the right words, or not being able to understand what other people are saying.
- Sudden problems walking or loss of balance or coordination.
- Sudden sensation of corking or tingling in the face, arm and/or leg on one side of the body.

Living with stroke: the day-to-day care (30 minutes).

Stroke can leave behind sequelae that affect different spheres of personal performance. Therefore, the essential objective is for the affected person to achieve the maximum autonomy to develop. In general, it is interesting to let them do everything they can on their own and if they can't, involve them in some way in the tasks and daily life. Most recovery is experienced in the first three months after the stroke. Recovery continues more slowly until at least six months, and some people continue to recover slightly into a year. In addition, the pharmacological treatment prescribed in each case must be followed. To prevent another stroke it is very important to continue with all these measures for the rest of life.

The most common difficulties and uses when dealing with them are described below.

Slowing down to process information:

- It is "normal" that everything goes slower.
- There is a change of new rhythms and they are not on a whim, so everyone should be aware of the change.
- Simplify the information you want to convey in a simple and concise way.
- Decrease the amount of information to be transmitted at any given time.
- When doing an activity or action, it is useful to establish or think about an outline of how it is going to be carried out.
- Avoid distractions and noise.
- Maintain a more or less constant level of activation, that is, do not do tasks until exhaustion or rest for long periods.

Concentration difficulties:

- Take many breaks of a few minutes during an activity.
- Choose certain times to carry out more difficult activities.
- Vary the activities to maintain interest in them.

Cognitive impairment:

- Have pre-established routines and time dynamics.
- Have routines with personal utensils, that is, always leave the same belongings in the same place.
- External aid: diaries, blackboards, reminder notes, alarms, reminders.
- Personalized daily, weekly or monthly calendars with schedules of activities, appointments...
- Reduce the amount of information that needs to be remembered.
- Put into practice what has been learned as soon as possible.
- Modify the environment to facilitate recall: write down information, choose a fixed place to, put labels...

A language disorder may also occur. An inability to understand and/or utter any type of adequate language or a speech alteration may occur:

- Simplify the conversation.
- Avoid noise.
- Speak slowly and vocalize.
- Position yourself where you can maintain eye contact.
- Turn your face toward the person.
- Look the person in the eye.
- Do not shout.
- Repeat what you have said if the person does not understand you.

- Use short sentences.

Behaviour:

- Understand that the brain injury may have changed the way you react.
- Reinforce positive behaviors.
- Correct an inappropriate response with tact.
- Do not react to strange and incorrect behavior.

Domestic sphere: daily activities such as dressing, hygiene, elimination or eating will be affected to a greater or lesser extent.

Dress:

- Start by undressing, because it is easier.
- Dress seated.
- Wear loose, loose clothing
- Do not wear clothes that are difficult to close.
- Leave enough time to get dressed.
- Break the task down into smaller steps and help only where you need to.
- Always undress the strong side first and always dress the weak side first.
- Whenever possible do without buttons and/or zippers, wear T-shirts, sweaters, sweatshirts...
- Wear comfortable clothes, loose garments and elastic at the waist.
- Replace lace-up shoes with Velcro shoes.
- Wear shoehorns.

Personal hygiene

- Place grab bars next to the toilet and inside the shower.
- Replace the bathtub with a shower.
- Have a shower seat handy.
- Use soap dispensers instead of bottles.
- Use sponge with handle.
- Put everything you need for the shower within easy reach.
- Use electric shaving machines.
- Use electric toothbrushes.
- Use or manufacture a larger and/or longer handle for the toothbrush.

Feeding:

- Sit up for all meals.
- Stand very straight.
- Keep your head slightly forward.
- Look at food.
- Take small bites and sips.
- Avoid foods with different textures, preferably with homogeneous consistencies.
- Avoid carbonated drinks.
- Stay upright for at least 20-30 minutes after eating to digest food.
- Place food between the teeth, on the stronger side of the person's mouth
- Give him thick liquids and foods with a homogeneous texture.

- The weak arm should rest on the table.
- Use deep plates.
- Use barriers around the plates.
- Make the handle of the cutlery larger if the person has trouble holding it.

Hydration:

- When using a straw, always place it on the strong side of your mouth against your cheek.
- If the person cannot drink from a glass or use a straw, use a syringe.

Elimination:

- Do not drink anything at least an hour before bedtime.
- Protect the mattress with an underpad or similar.
- Go to the bathroom regularly and at scheduled times.
- The color of your urine should be only slightly darker than water, so it can help to know if you need to increase or decrease your water intake.
- Avoid constipation.

People who have suffered a stroke are more likely to fall, so muscle-strengthening and balance exercises are important. It is also important to identify and modify as much as possible those aspects of the home that may pose a greater risk of falls, such as removing carpets, putting plastic chairs in the bathtub or shower, as well as handholds, and wearing shoes with non-slip soles.

Visual disturbances: looking towards the affected side, since with a little training the loss of vision of half of a visual field is compensated by turning the head to look to that same side.

Sensitivity disorder (tingling, unpleasant sensations, or lack of sensitivity to touch): Being especially careful about forming wounds or burns without the person noticing.

Mood management and depression (15 minutes).

It is common for mood alterations, anxiety, emotional lability, apathy, irritability or lack of awareness of the sequelae of the stroke to occur, as well as emotional "ups and downs", which must be understood and managed. Post-stroke depression can manifest itself through a variety of symptoms, including persistent sadness, loss of interest in previously enjoyed activities, changes in appetite and sleep, or even difficulty concentrating. As can be seen, there are depressive symptoms that can be related to other functional spheres and therefore can be easily confused with other types of symptoms.

In the face of these difficulties, it is advisable to:

- Identify and manage early symptoms of depression.
- Understand that mood swings are usually not directed against anything or anyone.
- Identify and avoid situations that systematically cause an altered state. Help identify in which situations you "shoot".
- Leave their own space for the affected person, as they can be overwhelmed with so much protection.
- The patient should not be treated as a sick person.
- It's normal for stroke survivors to cry more easily.

- Minimize frustration when facing a task, intervening as little as possible to ensure the achievement of the objective.
- Look for activities that are rewarding, occupy their time, promote their independence and self-sufficiency as much as possible, sometimes simply with that you can avoid other unwanted behaviors.
- Perform structured exercise programs to relieve symptoms of depression.

It is considered valuable to provide documentary support to the sessions as a summary and future information.

Complete breathing, relaxation, guided meditation and mindfulness workshop (25 minutes)

The workshop will be guided by the primary structure of mindfulness:

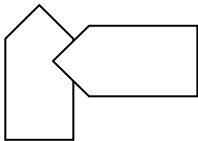
1. Home - Posture Relaxation
2. Mindfulness - inhale and exhale.
3. Open observation – observing emotions while promoting a curious, non-judgmental attitude
4. Closing - brief reflection.

Annex III. Data collection notebook

Participant ID	Sex	Idade	Windy weather	Date of ischemic event	Event Type	BDI to the inductor	BDI after rt-PA	BDI to high	MMSE to the inductor	MMSE tras rt-PA	MMSE to the high
Participant ID	Barthel	NIHSS	Temperature	TA	Glycemia	Swallowing assessment	Breathing	UPP	Pain (EVA Scale)		

MMSE

Orientation	
What year are we in?	1
What season are we in?	1
What date are we on?	1
What day are we on?	1
What month are we in?	1

Where are we?	1
Province?	1
Province?	1
Nation?	1
City?	1
¿Hospital?	1
Plant?	1
Fixation	
Name three objects at one-second intervals. Then ask the patient all three. Score one point for each correct answer. Repeat the objects until the patient learns all three.	3
Attention and calculation	
Series of seven. Score one point for each correct answer. Stop after five answers. Alternatives: Spell "world" backwards.	5
Memory	
Recall of the three previously learned objects	3
Point to a pencil and clock. Have the patient name them when you point to 2	2
Have the patient repeat, "No yes, no no, no ifs and buts."	1
Have the patient follow three types of command: "Take the paper in your right hand, fold it in half, put it on the floor."	3
Have the patient read and obey the following: "Close your eyes" (written in large print)	1
Have the patient write a sentence of their own choice (the sentence must have a subject and an object to make sense, ignore spelling mistakes when punctuating)	1
Enlarge the drawing below up to 1-5 centimeters per side and have the patient copy it (note a point if all sides and angles hold and if the intersecting sides form a quadrangle)	
	
Total score	30

BDI

Pessimism	
I'm not discouraged about my future	0
I feel more discouraged about my future than I used to be	1
I don't expect things to work out for me	2
I feel like there's no hope for my future and it can only get worse	3
Sadness	
I don't feel sad	0
I feel sad a lot of the time	1

I feel sad all the time	2
I feel so sad or so unhappy that I can't stand it	3
Failure	
I don't feel like a failure.	0
I've failed more than I should have	1
When I look back, I see a lot of failures	2
I feel that as a person I am a total failure	3
Loss of pleasure	
I get as much pleasure as ever from the things I enjoy	0
I don't enjoy things as much as I used to	1
I get very little pleasure from things I used to enjoy	2
I can't get any pleasure from the things I used to enjoy	3
Feelings of guilt	
I don't feel particularly guilty	0
I feel guilty about several things I have done or should have done	1
I feel pretty guilty most of the time.	2
I feel guilty all the time	3
Feelings of punishment	
I don't feel like I'm being punished	0
I feel like maybe I can be punished	1
I hope to be punished.	2
I feel like I'm being punished	3
Dissatisfaction with oneself	
I feel about myself the same as I always do	0
I've lost confidence in myself	1
I'm disappointed in myself	2
I don't like myself	3
Self-criticism	
I don't criticize or blame myself more than usual	0
I'm more critical of myself than I used to be	1
I criticize myself for all my mistakes	2
I blame myself for everything bad that happens	3
Suicidal Thoughts or Desires	
I have no thought of killing myself	0
I've had thoughts of killing myself, but I wouldn't	1
I'd like to kill myself	2
I would kill myself if I had the chance to do it.	3
Crying	
I don't cry any more than I used to	0
I cry more than I used to.	1
I cry for any little thing	2
I feel like crying, but I can't	3

Agitation	
I'm no more restless or tense than usual	0
I feel more restless or tense than usual	1
I'm so restless or agitated that it's hard for me to sit still	2
I'm so restless or agitated that I have to always be on the move or doing something	3
Loss of Interest	
I haven't lost interest in other activities or people	0
I'm less interested in other people or things than before	1
I've lost almost all interest in other people or things	2
It's hard for me to care about anything	3
Indecision	
I make my own decisions as well as ever	0
I find it more difficult than usual to make decisions	1
I find it much more difficult than before to make decisions	2
I'm having trouble making any decisions	3
Devaluation	
I don't feel like I'm not valuable	0
I don't consider myself as valuable and useful as I used to consider myself	1
I feel less valuable when I compare myself to others	2
I feel like I'm worthless	3
Loss of energy	
I have as much energy as ever	0
I have less energy than I used to have	1
I don't have enough energy to do too much	2
I don't have enough energy to do anything.	3
Changes in sleep habits	
I have not experienced any change in my sleep habits	0
I sleep a little more than usual	1
I sleep a little less than usual	
I sleep much more than usual	
I sleep much less than usual	2
I sleep most of the day	3
I wake up 1-2 hours earlier and can't go back to sleep	
Irritability	
I'm not as irritable as usual	0
I'm more irritable than usual	1
I'm much more irritable than usual	2
I'm irritable all the time.	3
Changes in appetite	

I have not experienced any change in my appetite	0
My appetite is a little less than usual	
My appetite is a little bigger than usual	1
My appetite is much lower than before	
My appetite is much higher than usual	2
I have no appetite at all.	
I want to eat all day.	3
Difficulty Concentrating	
I can concentrate as well as ever	0
I can't concentrate as well as usual	1
It's hard for me to keep my mind on something for long	2
I find that I can't focus on anything	3
Tiredness or Fatigue	
I'm no more tired or fatigued than usual	0
I get tired or tired more easily than usual	1
I'm too fatigued or tired to do many of the things I used to do	2
I'm too fatigued or tired to do most of the things I used to do	3
Loss of interest in sex	
I haven't noticed any recent changes in my interest in sex	0
I'm less interested in sex than I used to be	1
I'm much less interested in sex	2
I've completely lost interest in sex	3

BARTHEL'S INDEX

Grooming	1. Dependent 2. Independent for washing face, hands and teeth, combing and shaving	0 5
Bathing or Showering	1. Dependent 2. Independent for bathing or showering	05
Eat	1. Dependent 2. You need help cutting, spreading butter, using seasonings, etc. 3. Standalone (able to use any instrument)	0510
Stool control	1. Incontinent (or need to be given an enema) 2. Exceptional accident (one/week) 3. Continent	0510
Urine control	1. Incontinent, or probed unable to change the purse 2. Exceptional accident (maximum one/24 hours) 3. Continent, for at least 7 days	0510

Scroll	<ol style="list-style-type: none"> 1. Motionless 2. Independent in wheelchair at 50 m 3. Walk with a little help from a person (physical or verbal) 4. Independent at least 50 m, with any type of crutch, except walker 	051015
Going up and down stairs	<ol style="list-style-type: none"> 1. dependent 2. Needs physical or verbal help, can carry any type of crutch 3. Independent to get on and off 	0510
Moving between the chair and the bed	<ol style="list-style-type: none"> 1. Dependent, not sitting still 2. Needs important help (1 trained person or 2 people), may be sitting 3. Needs some help (a little physical help or verbal help) 4. Independent 	051015
Using the toilet	<ol style="list-style-type: none"> 1. Dependent 2. You need some help, but you can do something on your own 3. Independent (coming in and out, cleaning and dressing) 	0510
Dressing and undressing	<ol style="list-style-type: none"> 1. Dependent 2. You need help, but you can do about half, without help 3. Freestanding, including buttons, zippers, laces, etc. 	0510

NIHSS

Level of consciousness	Alert	0
	Not alert (minimal verbal stimuli)	1 2
	Non-alert (repeated stimuli)	3
	Reflex responses	
1.b. Questions	Both correct answers	0
	A correct answer	1
	No correct answer	2
What month are we in?		
How old is he?		
1.b. Motor commands	Both correct answers	0
	A correct order	1
	No Correct Order	2
Eye Closure		

Open and close your hand s

Conjugate look	Normal	0
	Partial paralysis of the gaze	1
	Forced Gaze Deviation	2
Field of view	Normal	0
	Partial Hemianopia	1
	Complete hemianopia	2
	Blindness	3
Paresia facial	Normal mobility	0
	Minor paresis	1
	Partial paresis	2
	Complete paralysis of the hemiface	3
Left Upper Limb/Right Upper Limb	No limb drop	0/0
	Drop in less than 10 seconds	1/1 2/2
	Stress against gravity	3/3
	Movement in the horizontal plane	4/4
	No movement	
Left Lower Limb/Right Lower Limb	No limb drop	0/0
	Drop in less than 5 seconds	1/1
	Stress against gravity	2/2
	Movement in the horizontal plane	3/3 4/4
	No movement	
Limb ataxia	Absent	0
	Present in 1 limb	1
	On 2 or more limbs	2
Sensory Scan	Normal	0
	Slight/moderate loss	1
	Severe/Total Loss	2
Language	Normal	0
	Mild/moderate aphasia	1
	Severe aphasia	2
	Global aphasia	3
Dysarthria	Normal	0
	Light to moderate	1
	Grave	2
Extinction and Inattention	Normal	0
	Partial extinction	1
	Complete extinction	2
Total (Maximum 42)		

EUROPEAN QUALITY OF LIFE SCALE

Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐