STUDY PROTOCOL WITH SAP

Early occupational therapy intervention in the hospital discharge process after suffering a stroke

P García-Pérez[1,2], JP Lara[1], C de la Cruz-Cosme[3], MC Rodríguez-Martínez[2]

[1]Brain Health Unit CIMES-IBIMA-University of Malaga; [2]Health Sciences School-University of Málaga; [3]Neurology Department, Virgen de la Victoria University Hospital of Málaga

ClinicalTrials.gov ID NCT04835363
Information provided by Patricia García-Perez, University of Malaga (Responsible Party)
Document date 2021-02-01
Last Update Posted 2023-05-06

Research background

We call a stroke or cerebrovascular accident (CVA) those sudden episodes of the circulatory system that compromise the stability of an affected brain area, whether permanently or temporarily. In this way, we will use the defined terms to refer to cerebral infarction, as well as intracerebral and subarachnoid hemorrhages (1). Stroke is a cerebrovascular disease that has a great health and social impact due to its high incidence and prevalence, and is the leading cause of acquired disability in adults in developed countries. Its incidence in Spain is 187.4/100,000 inhabitants/year. It represents a great burden, not only from a health point of view, but also from a personal and family point of view, due to its impact on the lives of people who suffer from it and their caregivers (2, 3).

It is also one of the main causes of hospital stay and death in our country. The relevance of stroke is given by its mortality data, as well as the dependency of survivors. In the acute phase of stroke, mortality rises to 25% of cases, appearing more frequently in hemorrhagic strokes (up to 50% of deaths) than ischemic strokes (25%). Studies show that in the first six months after the circulatory event, many of these deaths are caused by cardiopulmonary complications; however, after this stage, significant clinical and functional stabilization is achieved. Of the total survivors, 30-40% will present some serious sequelae, up to 60% of users will present minor sequelae or no sequelae, and only 6% of cases with severe initial paralysis will completely recover mobility. These data demonstrate the importance of rehabilitation to facilitate the relearning of these patients, having been shown in previous studies to be useful in the user's recovery in terms of functional autonomy, also increasing the frequency of return home and reducing hospital stay. Similarly, a caregiver-mediated program has been shown to have the potential to improve bodily function, activity, and participation outcomes for these individuals with stroke.

In addition, caregivers participate more actively in the rehabilitation process, which can increase feelings of empowerment, reducing caregiver burden levels and easing the transition from hospital to home (4).

Generally, initial assistance in stroke begins with a call to the 061 or 112 services and arrival at the Emergency Department. Subsequently, the user is admitted to the Stroke Unit and once stabilized, they are transferred to the neurology ward. The importance of rehabilitation in the acute phase is given by the existence of a therapeutic window during which interventions can truly modify the course of the disease and achieve neuronal reactivation. This improvement may be due to the existence of an area of penumbra in the periphery of the ischemic zone, whose damage is potentially reversible, although it can only be achieved for a short and variable time of up to 24 hours if reperfusion of said tissue is achieved, as well as the resolution of diaschisis (transsynaptic failure of neurons connected to the damaged area). However, there is a brain reorganization that can be modulated by rehabilitation techniques through the phenomenon of neuronal plasticity, which determines the importance of an efficient interdisciplinary intervention (4, 5).

The role of the occupational therapist has its place at all levels of stroke intervention, both in direct action with the user, as well as in counseling and family or social support. Occupational intervention is initially directed at sensorimotor and perceptual-cognitive performance skills, as well as re-education and training in basic and instrumental activities of daily living (ADL); Subsequently, an intervention more oriented towards the social and labor integration of the person is proposed (6). Occupational Therapy (OT) intervenes on function, using specific procedures and activities to develop, maintain, improve and/or recover the performance of functions and activities necessary in daily life, compensate for dysfunctions and/or promote health and well-being. Based on the framework for occupational therapy practice, we classify this function into areas of occupation (basic and instrumental ADLs, rest and sleep, education, work, play, leisure, and social participation) and performance skills (motor skills and praxis, sensory-perceptual skills, emotional regulation skills, cognitive skills, and social and communication skills). Therefore, the initial objective of an intervention plan carried out from OT is to improve the user's independence in carrying out ADLs, achieving the highest possible level of autonomy and promoting their well-being and quality of life (6, 7).

According to a study published in 2015, the prognosis of stroke in Spain has changed in recent years. Both survival and functional outcome have improved as a result of the introduction of a new model of care. This new model, based on stroke units, early reperfusion therapies, physiotherapy and secondary prevention, has been promoted by the stroke strategy of the Spanish National Health Service in coordination with regional health authorities and healthcare professionals. health. However, this model does not take into account the intervention of OT in the discharge process, as other countries with positive results in functional independence do, among others (8).

Finally, it should be remembered that this pathology also has a relevant economic impact on the direct national health cost, plus those derived from its work and socio- family repercussions. According to a recently published study, the cost of patients admitted to stroke units in Spain is €27,711 per patient/year. More than two- thirds are social costs, mainly informal care (9).

Foundation

The early supported discharge (ESD) model for rehabilitation was introduced in the late 1990s and includes a well- resourced interdisciplinary team that coordinates discharge and plans, monitors, and continues rehabilitation in the hospital setting. home (10).

Based on randomized controlled trials conducted, there is evidence that early discharge with hospital follow-up (ESD) and with continued rehabilitation at home has beneficial effects in stroke users; However, the effects of the ESD service in routine clinical practice in Spain have not been investigated (11, 12). Likewise, there is a lack of published data regarding the impact of Occupational Therapy in the hospital discharge process along with conventional care and rehabilitation in terms of patient functional outcomes, caregiver burden, and health care costs. during the first six months after the stroke (13).

It is important to take into account the involvement of the family in the rehabilitation process, as well as their knowledge regarding the patient's illness and care to provide a stimulating and safe environment at home that reduces the risk of ulcers, muscle or tissue shortening. soft joints, dislocations, etc., in patients with sequelae motor deficit. The treatment provided in current public healthcare is insufficient, which may be worrying due to the limited recovery after stroke and the difficulty in community reintegration. This is why certain variables are of special interest when trying to assess the effectiveness of this type of action, such as motor improvement and the importance of functional mobility of the upper extremities, which can contribute to a better quality of life for patients. stroke survivors (13, 14).

There are at least three important perspectives to take into account in any project to assess actions on the consequences of stroke: the personal, the social and public health. From a personal perspective, returning home after a hospital stay for stroke and being able to participate in rehabilitation planning, as well as deciding goals, results in patient empowerment and greater satisfaction, improving mood and promoting well-being. From a social perspective, it helps the family feel less distressed when support is provided at home, it reduces the risk of readmission and stress-induced symptoms in family members, which is also an opportunity to improve the caregiver quality of life and reduce their risk of illness, as family members often report feeling a great burden as caregivers. From a public health perspective, making it safe to discharge with occupational therapy support means decreased costs. There are no studies in our environment that demonstrate whether discharge with OT support is effective and profitable, whether it increases the safety of patients and families, or whether patients perceive less anxiety and depression, higher levels of functional independence and a better quality of life. (5).

Research objectives

General Objective

The general objective of the present study is to determine if the early intervention of occupational therapy (OT) together with usual care in the hospital discharge process after stroke has a positive effect on the quality of functional independence of the patient, comparing it with the control group that will have the assistance regular care and rehabilitation.

We designed a four-week early OT intervention program for patients who have suffered a stroke with the aim of improving quality of life and facilitating their return home by providing them and their caregiver with knowledge about specific care and neurorehabilitation.

Specific Objectives

Primary outcome: Quality of life. Secondary results: Functional independence and support needs in activities of daily living, sensory-motor skills, perceptual-cognitive skills, communication skills, anxiety and depression levels.

Methods

Type and general design of the study

This is a prospective, randomized, controlled clinical trial. The population to be represented is that of patients who are discharged from the neurology service of the Virgen de la Victoria University Hospital (Malaga) and who, after medical discharge, are referred to the rehabilitation service of the Maritime Hospital of Torremolinos as outpatients by decision of the neurology and rehabilitation departments, but will not be inpatients in the Physical Medicine and Rehabilitation Unit for intensive rehabilitation.

Users who are referred to rehabilitation by obtaining a place as an inpatient, receive occupational therapy and physiotherapy daily for a period of maximum three months. However, patients who are referred to the rehabilitation service as an outpatient are taken home directly after discharge and are subsequently recalled for rehabilitation. The period that elapses from when they are discharged until they are called to begin their rehabilitation varies depending on the workload of the service, and can even be three months after discharge. Referral to external or intensive rehabilitation is made based on the rehabilitation potential, which takes into account certain criteria such as age, clinical situation and vascular injury existing at the time of discharge, social support, motivation and observed recovery. during admission. Patients assigned to the study program are included in an early occupational therapy intervention program and are compared with a control group that will receive usual care and rehabilitation.

Sample selection and size

The sample size “n” was calculated based on the main variable SAQOL-39 with the sample size determination formula for two independent groups, assuming a mean of 2.50, standard deviation of 0.75, significance level of 5%, a power of 80% and a critical difference of 0.54, obtaining a sample of 30 participants per group.

Therefore, two groups were formed: an intervention group of 30 patients who will receive the early Occupational Therapy program in addition to the rehabilitation that they would receive independently of this study, and a control group of 30 patients who will receive the conventional rehabilitation.

Eligible patients were assigned to EOTIPS or the control group according to a pre-established computer randomized designation in blocks of six.

Inclusion and exclusion criteria

All patients must have diagnostic confirmation of stroke with single or multiple vascular lesions that had occurred in the same time period, demonstrated by neuroimaging tests (CT or MRI), be over 18 years of age, go home on discharge and live within a maximum of 30 minutes away from the hospital center, with >2 or <26 points on the National Institute of Health scale (NIHSS), 30–100 points on the Barthel Index (BI) on the second day after the stroke (with BI 100, the patient

can be included if the Montreal Cognitive Assessment is <26) and having been referred to the rehabilitation service as an outpatient. Inclusion in the study occurs prior to hospital discharge, within a two- week interval after the stroke.

Exclusion criteria are: NIHSS > 26, BI < 30, and life expectancy < 1 year. Also excluded are people with a previous stroke, dementia or other types of diseases that cause dementia and other neurological, psychiatric or medical diseases (for example, severe epilepsy, traumatic brain injury, schizophrenia, COPD, severe or unstable heart disease, sleep apnea) concomitants that could alter cognitive function, presence of moderate or severe aphasia, people who do not understand Spanish or English, as well as patients who have been referred to the Physical Medicine and Rehabilitation Unit as inpatients to receive intensive rehabilitation or who are discharged to a care home.

The variables will take into account: age, sex, educational level, marital status, nationality, mother tongue, employment, vascular territory and lesion volume.

List of results and evaluations

Patient evaluations	
Quality of life	- SAQOL-39
Level of functional independence	- BI - mRS - SIS-16
Perceptual-cognitive skills	- MoCA
Sensory-motor skills	- Fugl Meyer - Berg - Time up & go
Communication skills	- CAL
Anxiety and/or depression levels	- Berg - Hamilton

Assessments to be used in the study (all translated into Spanish)

- *Stroke and Aphasia Quality of Life Scale - 39, SAQOL-39* (Lata-Caneda, Piñeiro- Temprano, García-Fraga, García- Armesto, Barrueco-Egido, Meijide-Failde, 2009). SAQOL-39 was derived from the Stroke-Specific Quality of Life Scale and four additional items specifically targeting patients with aphasia, covering four domains: physical, psychosocial, communication, and energy.

- *Montreal Cognitive Assessment*, *MoCA* (Lozano Gallego, Hernández Ferrándiz, Turró Garriga, Pericot Nierga, López- Pousa, Vilalta Franch, 2009). MoCA has been proposed as a screening tool that promises good sensitivity to deficits resulting from stroke and vascular cognitive impairment. MoCA includes sections on visuospatial/executive functions, naming, attention, language, abstraction,

memory, and orientation. It is scored out of 30 (extra point for <13 years of education) and the recommended “normal” limit is ≥26.

- *Modified Rankin Scale*, *mRS* (Van Swieten, Kodustaal, Visser, Schouten, Van Gijn, 1988). The mRS is used to describe disability in general. The scale ranges from 0 to 6, from perfect health with no symptoms to death.

- *Fugl-Meyer sensory motor assessment, FMA* (Ferrer González, Zarco Periñán, Ruiz de Vargas, Docobo Durantez, 2015). It evaluates the upper extremity (maximum score of 66 which corresponds to normal motor function) and lower extremity (maximum score of 34). Tenderness, passive range of motion, and pain during passive joint movements are also evaluated.

- *Timed up and go,TUG* (Hafsteinsdóttiret al, 2014). TUG assesses basic mobility, timing the time required for a person to stand up from a standardized chair, walk a distance of three meters, turn, return to the chair, and sit down again. A shorter time indicates better performance. It has been shown to be reliable and valid in this group of patients.

- *Berg Balance Scale, BBS* (Kudlac, Sabol, Kaiser, Kane, Phillips, 2019). BBS assesses functional balance. Performance on this test is scored from 0 (unable to perform) to 4 (normal performance) on 14 different tasks, including the ability to sit, stand, reach, bend, turn, and step. The maximum score on the BBS is 56. A higher score indicates better balance skills.

- *Barthel Index, BI* (Baztán, Pérez del Molino, Alarcón, San Cristobal, Izquierdo, Manzarbeitia, 1993). The Barthel Index measures the extent to which someone can function independently during basic activities of daily living (ADLs), i.e., feeding, bathing, grooming, dressing, bowel control, bladder control, grooming, chair transfers, ambulation and climbing stairs. Each performance element is rated on this scale with a given number of points assigned to each level. In this study, the modified version with 0–100 is used, where a lower score indicates dependence.

- *Stroke Impact Scale - 16, SIS-16* (Duncan, Lai, Bode, Perera, DeRosa, 2003). The usefulness of this scale is similar to that of the Barthel Index, although it is more sensitive than the latter for discriminating between patients with mild disabilities. It is designed especially for patients who have suffered a stroke, but it is also applicable to dementia. It is a reduced version of the Stroke Impact Scale version 3.0. The information can be obtained from the patient himself, or from the main caregiver (15) (16).

- *Communicative Activity Log, CAL* (Pulvermüller & Berthier, 2008). Scale that allows obtaining information on the communication capacity in the activities of daily life referring to comprehensive and expressive aspects of language. It is composed of 36 items (Likert-type scale, 0-6) that evaluate both the quality (items 1-18) and the quantity of patient communication (items 19-36). Performance is obtained through the sum of the scores on each item.

- *Beck Depression Inventory, BDI-2* (Steer, Brown, 1996). It is a self-administered questionnaire that consists of 21 multiple-choice questions. It is one of the most commonly used instruments to measure the severity of depression.

- *Hamilton Anxiety Scale* (Lobo et al, 2002). This scale evaluates the severity of anxiety globally in patients who meet criteria for anxiety or depression. In addition, this instrument is useful to monitor the response to treatment. It is composed of 14 items, 13 referring to anxious signs and symptoms and the last one assessing the patient's behavior during the interview.

The evaluations were carried out in both groups (control and intervention group) before discharge (after completion of the informed consent) and three months after the neurological event.

Timeline and data collection

Hospital discharge planning

The rehabilitation and neurology departments were responsible for referring patients to the occupational therapist and including them in the study. Before starting rehabilitation, the occupational therapist and her family explored the patient's needs and desires and decide individual goals for the intervention period.

Occupational Therapy intervention during the discharge process
The intervention has a person-centered approach that is based on who the user is: their context, their history, their family members, their individual strengths and weaknesses. Individualized objectives will be established, taking into account the patient's potential and limitations. Examples of goals could be: being able to wash independently, hanging clothes or riding the bus, or how to manage bills. OT intervention may involve training in different activities or thinking about different ways to adapt to difficult situations to achieve a goal. For example, for some patients the intervention may consist of carrying out

ADLs in which they have a limitation with the support of the occupational therapist with the aim of enhancing their sense of security during its performance. Data will be collected through note taking and analyzed with qualitative content analysis.

The designed OT intervention includes:

- Prior to discharge: Initial evaluation and a hospital session.
- Post-discharge: A two-hour home visit, telephone follow-up, a one-hour visit one month after discharge and final evaluation three months later.

This early OT intervention will be carried out independently of the usual care of the rehabilitation service of the Torremolinos Maritime Hospital.

Time planning

The project will begin in January 2021 and was estimated to last one year and three months (estimated completion in March 2022). Finally, the project was completed on November 2022.

Day 1: Hospital (1 hour) Initial interview and evaluation.
Day 2: Hospital (1 hour) Information about stroke. Postural care.
Day 3: Home (2 hours) Environment assessment, equipment and recommendations and establishment of individualized objectives.
Day 4 - day 29: PHONE FOLLOW-UP. Implementation of the rehabilitation by the patient and caregiver (individual objectives).
Day 30: Home (1 hours). Final assessment of individualized objectives at home.
After 3 months: Home (1 hour) Final evaluation.

Results analysis plan

The following analysis model was followed: to study the differences that may exist between one group and another, before and after the intervention, a repeated measures ANOVA was carried out; to check how some variables influence others, a multivariate analysis was carried out and, finally, to know the mean and normal distribution of the variables, descriptive statistics were performed. An intragroup analysis was included by performing paired T-test studies along with Wilcolxon for non-parametric measurements. The program used for data analysis was JAMOVI (version 2.3.26).

Difficulties and limitations of the study

Regarding the limitations of this study, it is worth highlighting the biases possibly derived from the adherence to treatment of the users and their caregivers, as well as the behavior and involvement of the family member in the process that will likely induce differences in the results. It is worth highlighting the importance of the word of the patient and the caregiver due to the telephone process of the intervention, since it can lead to differences in the instructions provided by the occupational therapist and, therefore, in the treatment and final result.

Furthermore, an important limitation is the heterogeneity of the sample, since we are generally talking about patients who have had a stroke of any location, extent and volume. The random distribution of patients may result in the two groups having significant differences in the severity of their injuries or their potential for recovery. Also due to the heterogeneity of each patient's rehabilitation process, it is understood that, of the total sample size, certain patients will subsequently receive a greater number of conventional rehabilitation sessions than others, and some patients will probably not even receive any sessions. This is why it seems

interesting to subsequently study the care received by each user three months after discharge, as well as their level of functionality and quality of life.

Ethical considerations

During data collection, the anonymity of users was guaranteed. Participants will be informed of the intervention and will be asked to sign an informed consent, with participation being voluntary and allowing the user to abandon whenever they wish.

The principles of the Declaration of Helsinki (17) were taken into account. Authorization will be requested from the hospital, as well as approval from the provincial research ethics committee to which the center is attached.

References

1. 2017-Guia-Prevencion-Ictus.pdf [Internet]. [citado 10 de noviembre de 2020]. Disponible en: https://www.portalfarma.com/Profesionales/campanaspf/categorias/Documents/2017-Guia- Prevencion-Ictus.pdf
2. Informe_ICTUS_Andalucia.pdf [Internet]. [citado 10 de noviembre de 2020]. Disponible en: https://www.sen.es/images/2020/atlas/Informes_comunidad/Informe_ICTUS_Andalucia.pdf
3. Abordaje del accidente cerebrovascular.pdf [Internet]. [citado 24 de marzo de 2020]. Disponible en: https://www.mscbs.gob.es/biblioPublic/publicaciones/docs/200204_1.pdf
4. Vloothuis JD, Mulder M, Veerbeek JM, Konijnenbelt M, Visser-Meily JM, Ket JC, et al. Caregiver-mediated exercises for improving outcomes after stroke. Cochrane Stroke Group, editor. Cochrane Database Syst Rev [Internet]. 21 de diciembre de 2016 [citado 27 de marzo de 2020]; Disponible en: http://doi.wiley.com/10.1002/14651858.CD011058.pub2
5. Cuadrado ÁA. Rehabilitación del ACV: evaluación, pronóstico y tratamiento. Galicia Clínica. 2009;70(3):25-40.
6. Mercado Padín, R. RR A. MARCO DE TRABAJO PARA LA PRÁCTICA DE TERAPIA OCUPACIONAL: Dominio y Proceso 2da Edición. 2010.
7. Ros YD, Bouhsain ME, Salcedo IV, Cantín RC. Plan of intervention from occupational therapy in a patient with right hemiplegia: treatment reoutfitter centre don functionality of upper extremity. :9.
8. on behalf of CONOCES Investigators Group, Mar J, Masjuan J, Oliva-Moreno J, Gonzalez-Rojas N, Becerra V, et al. Outcomes measured by mortality rates, quality of life and degree of autonomy in the first year in stroke units in Spain. Health Qual Life Outcomes. diciembre de 2015;13(1):36.
9. Alvarez-Sabín J, Quintana M, Masjuan J, Oliva-Moreno J, Mar J, Gonzalez-Rojas N, et al. Economic impact of patients admitted to stroke units in Spain. Eur J Health Econ HEPAC Health Econ Prev Care. mayo de 2017;18(4):449-58.
10. Brândal A, Eriksson M, Glader E-L, Wester P. Effect of early supported discharge after stroke on patient reported outcome based on the Swedish Riksstroke registry. BMC Neurol. 12 de marzo de 2019;19(1):40.
11. Langhorne P, Baylan S, Trialists ESD. Early supported discharge services for people with acute stroke. Cochrane Database Syst Rev [Internet]. 2017 [citado 10 de noviembre de 2020];(7). Disponible en: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000443.pub4/full
12. Fearon P, Langhorne P, Trialists ESD. Services for reducing duration of hospital care for acute stroke patients. Cochrane Database Syst Rev [Internet]. 2012 [citado 17 de

noviembre de 2020];(9). Disponible en: https://www.cochranelibrary.com/cdsr/doi/10.100 2/14651858.CD000443.pub3/full
13. García AMD. OCCUPATIONAL THERAPY'S TREATMENT IN CEREBROVASCULAR DAMAGES. Mª. :24.
14. Lieshout ECC van, van de Port IG, Dijkhuizen RM, Visser-Meily JMA. Does upper limb strength play a prominent role in health- related quality of life in stroke patients discharged from inpatient rehabilitation? Top Stroke Rehabil. 9 de marzo de 2020;1-9.
15. Carod-Artal FJ. Escalas específicas para la evaluación de la calidad de vida en el ictus. REV NEUROL. :11.
16. Reeves M, Lisabeth L, Williams L, Katzan I, Kapral M, Deutsch A, et al. Patient-Reported Outcome Measures (PROMs) for Acute Stroke: Rationale, Methods and Future Directions. Stroke. 2018;49(6):1549-56.
17. WMA - The World Medical Association- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects [Internet]. [citado 10 de noviembre de 2020]. Disponible en: https://www.wma.net/policies- post/wma-declaration-of-helsinki-ethical- principles-for-medical-research-involving-human-subjects/