

**Impact of the Training to Aid Patients with Stroke (TAP-S) Program on Caregiver
Knowledge, Burden, and Quality of Life: A Pilot Study**

**Dave Albert D. Patrimonio, M.D.¹, Sharon D. Ignacio, M.D.¹, Jennifer Marie J. Yang,
M.D.¹, John Albert D. Gonzales, M.D.¹**

Author Affiliations:

¹Department of Rehabilitation Medicine, Philippine General Hospital, University of the
Philippines Manila, Taft Avenue, Manila, Philippines

ABSTRACT

Introduction

Stroke is the second leading cause of death in the Philippines, and remains a significant cause of disability locally. Despite efforts to address gaps in health policies and programs in the current stroke system of care, providing adequate access to rehabilitation facilities for patients post-stroke remains a challenge for healthcare providers. Thus, it is important to understand the important role of families in management of stroke patients. There is a need to provide guidelines and specific training in caregiver-driven provision of care for patients. Providing proactive problem-solving interventions and caregiver education is an essential part in the comprehensive approach to address the emotional, psychological, and relational aspects of stroke recovery.

Objectives

This study aims to evaluate the effect of the Training to Aid Patients with Stroke (TAP-S) Program on caregiver knowledge, burden, and quality of life among informal caregivers of stroke patients across multiple assessment phases.

Methodology

A single-group pretest–posttest interventional study will be conducted among informal caregivers of stroke patients. Caregiver knowledge, burden, and quality of life will be assessed at baseline, immediately post-intervention, and two weeks post-discharge. Data will be summarized using descriptive statistics, and changes across assessment phases will be analyzed using repeated-measures statistical tests, with significance set at $p < 0.05$.

INTRODUCTION

Stroke remains one of the leading causes of disability worldwide, imposing a substantial physical, emotional, and financial burden on patients and their families. The journey of recovery often extends far beyond the acute phase of medical care, requiring ongoing rehabilitation to regain functional independence and improve quality of life. While healthcare professionals play a critical role in guiding rehabilitation, the active involvement of caregivers is indispensable. Caregivers, often family members or close acquaintances, serve as the primary support system, assisting with activities of daily living, medication management, and emotional support.

However, the transition to the caregiving role is seldom accompanied by formal training or adequate preparation. Many caregivers lack the necessary knowledge and skills to address the complex needs of stroke patients, leading to suboptimal rehabilitation outcomes and heightened caregiver burden (1). This gap underscores the importance of structured training programs tailored for caregivers, equipping them with the tools to effectively support stroke survivors throughout the recovery process.

Training caregivers has been shown to improve patient outcomes, enhance caregiver confidence, and reduce stress (2). By fostering a collaborative approach to rehabilitation, caregiver training not only empowers families but also eases the strain on healthcare systems. This paper explores the critical role of caregiver training in stroke rehabilitation, highlighting its impact on caregiver well-being and the overall rehabilitation trajectory.

REVIEW OF LITERATURE

The University of the Philippines - Philippine General Hospital (UP-PGH) Department of Rehabilitation Medicine (DRM) was founded in 1971 and has since catered to patients of all ages with diverse and varying diseases related to the field of Physiatry. It is currently the only rehabilitation center in the country equipped with facilities and services necessary to serve inpatients needing rehabilitative care (2).

Through its 15-bed capacity Rehabilitation Medicine Ward, the DRM provides a multitude of services to a wide variety of cases, with post-stroke patients being among the most common that are seen and managed on a daily basis. Patients are either transferred from other clinical services for intensive rehabilitation prior to discharge, or admitted on an outpatient basis if deemed appropriate. Patients would then undergo intensive therapy 5 days a week for 1-3 weeks, consisting of holistic rehabilitation management programs that involve both medical and allied medical services, including physical therapy, occupational therapy, speech and language pathology, psychology, and prosthetics and orthotics. Patients are then discharged and scheduled for regular follow up consults at the UP-PGH Outpatient Department.

To our knowledge there has not been any study in the UP-PGH setting regarding the outcomes of post-stroke patients admitted at the Rehabilitation Medicine Ward. Despite efforts of medical and paramedical personnel to maximize therapy for patients in order for them to attain the best possible functional outcomes during their admission, there still are limitations to the extent of the intensive rehab management being provided. In the setting of a Philippine public tertiary hospital, there are no established guidelines regarding the recommended duration of therapy for inpatients requiring intensive rehabilitation. A time and motion study done at the UP-PGH in 2024 showed a mean duration of 37 minutes and 32 seconds for a single physical therapy session for patients with neurological conditions, and only at least three minutes allotted for patient and caregiver instruction (14). Although these

instructions for mobility and functional exercises are constantly being emphasized throughout the session, caregivers are oftentimes left to their own devices in conducting these activities and thus may be unable to carry out the prescribed program.

Previous studies have demonstrated that interventional programs designed to empower caregivers in rendering long term patient assistance can lead to increased patient functional capacity and quality of life. For instance, in one study by Dharma et al. in 2018, patients who underwent a caregiver empowerment program based on the adaptation model (CEP-BAM) were found to have significantly increased functional capacity and quality of life compared to those given the standard intervention (3).

The CEP BAM in this study consisted of three phases of caregiver training in a span of 6 months to help the stroke patient adapt to their various disabilities once discharged from inpatient care – pre-education, intervention, and monitoring/evaluation. During the pre-education phase, a psychological approach was used to build relationships between the patient and their caregiver. In the intervention phase, several training programs were given to the caregivers consisting of education on stroke and its sequelae, training on adaptive coping strategies after stroke, training about body movement including ambulation, transfers, exercises, and ADLs, as well as education on maintaining an adequate self-psychological condition. Finally, in the monitoring/evaluation phase, caregivers were encouraged to guide the patient in performing the adaptation exercises regularly. These interventions were found to be effective in improving patient outcomes and quality of life after discharge.

In another study by Hong et al. in 2017 utilizing a similar caregiver education program for stroke rehabilitation, not only patients functional outcomes were significantly improved, but also caregiver satisfaction in comparison to those given the conventional rehabilitation treatment. In this study, participants enrolled in the intervention group received

therapy which included training education programs for formal caregivers in addition to the standard rehabilitation therapy (1.5 hours of physical, occupational, and speech therapy 5 days/week for 4 weeks). Caregivers in the intervention group were instructed to perform the strategies learned during the education programs for 10-20 minutes twice a day, and continued on for 4 weeks after completion of the intervention. Results then showed a significant increase in patient functional outcomes and caregiver satisfaction and a decrease in caregiver burden (5).

SIGNIFICANCE OF THE STUDY

Providing adequate access to rehabilitation services for stroke patients remains a challenge for healthcare providers. Stroke remains a fatal disease and is the second leading cause of death in the Philippines (6). For survivors, functional outcomes are not maximized due to gaps in the current stroke system of care. Locally, there are only 452 rehabilitation centers available to serve approximately 148 stroke cases per 100,000 people (7). Only 15.8% of hospitals in the country are equipped with rehabilitation centers. Furthermore, an audit study in 2015 reported that only 54.1% of hospitalized stroke patients were referred for rehabilitation, even in hospitals with the capacity to render rehab services (8).

Once stroke patients are discharged from the hospital, they often face numerous challenges that can impact their recovery and quality of life. Physical impairments such as weakness and paralysis, as well as cognitive and speech impairments make daily activities difficult. Emotional challenges such as depression, anxiety, and frustration are also common, as patients cope with changes in their independence and identity. Concerns regarding medication side effects, dependence, and long term impact also affect adherence to medications, potentially leading to poorer outcomes (12). Additionally, a lack of access to

rehabilitation services, financial constraints, and caregiver burden can further complicate recovery.

When families lack the necessary knowledge and skills to care for patients at home, the burden on them becomes greater. These families are often unaware of, or are not able to access, resources that could help them acquire the necessary knowledge and skills for patient care. In a study done by Kyeong Woo Lee et al. in 2015, approximately one-third of caregivers lacked adequate understanding of proper stroke patient care, and only 7.8% of participants received regular training, despite 65.4% expressing a willingness to undergo such education (4). Without adequate preparation, many caregivers feel overwhelmed while tending to their patients. Insufficient knowledge and skills among family caregivers may lead to reduced support for the patient, ultimately impacting the patient's quality of life (3).

The involvement of family caregivers as part of the patient's support system therefore plays a crucial role in enhancing the quality of life for individuals recovering from a stroke. These caregivers provide long-term intensive assistance to the patients, and thus should be empowered with the necessary knowledge and skills to effectively guide and care for the patient as they adjust to life after a stroke. There remains a critical need for systematic and regular training programs led by rehabilitation experts to enhance caregiver competence.

OPERATIONAL DEFINITION OF VARIABLES

VARIABLES	OPERATIONAL DEFINITION	CATEGORIES
Stroke type	Classification of a stroke based on its underlying etiology	Hemorrhagic Non-hemorrhagic (ischemic, transient ischemic attack)

Stroke classification	Classification of a stroke based on time from ictus	Subacute - 3 days to < 3 weeks Chronic - > 3 weeks (13)
Paresis	Partial loss of voluntary muscle movement or weakness, resulting from damage to the nervous system and confirmed through clinical evaluation	Right side Left side Bilateral No paresis
Education level of caregiver	Highest formal education achieved at time of study	College graduate High school graduate Elementary graduate None
Caregiver-patient relationship	How the caregiver is related to the patient	Husband/wife Child In-law Sibling
Patient age	Age (in years) at time of study	< 40 40-60 > 60
Caregiver age	Age (in years) at time of study	< 40 40-60 > 60

Caregiver self-efficacy	A caregiver's confidence in their ability to effectively manage the tasks and challenges associated with providing care for a dependent individual, including physical, emotional, and medical needs.	Measured using the Revised Scale for Caregiving Self-Efficacy
Patient quality of life	The overall well-being of a stroke survivor, encompassing physical, psychological, social, and functional domains as perceived by the patient in the context of their post-stroke recovery and daily living.	Measured using the Stroke Specific Quality of Life Scale (SS-QOL) 12-item scale (short version)

OBJECTIVES OF THE STUDY

The study aimed to determine the effect of the Training to Aid Patients With Stroke (TAP-S) Program on burden and quality of life of caregivers of subacute to chronic stroke patients admitted at the UP-PGH.

Specifically, the study aimed to:

1. To determine the effect of the TAP-S Program on caregiver knowledge regarding the basic principles of stroke management, rehabilitation, and home care, as measured at baseline (pre-intervention), immediately post-intervention, and two weeks post-discharge;

2. To assess caregiver burden at baseline, immediately post-intervention, and two weeks post-discharge; and
3. To evaluate caregiver quality of life at baseline, immediately post-intervention, and two weeks post-discharge following participation in the TAP-S program.

METHODOLOGY

STUDY DESIGN

The study will utilize a single-arm, repeated-measures interventional pilot design to evaluate the effect of the TAP-S Program on knowledge, burden, and quality of life among caregivers of subacute to chronic stroke patients admitted at the UP-PGH. Outcomes will be assessed at three time points: baseline (pre-test), immediately post-intervention (post test 1), and two weeks post-discharge (post test 2). Participant recruitment and data collection will be conducted over a three-month period in the inpatient wards, with follow-up assessments coordinated through the outpatient department. Data analysis will be performed after completion of data collection.

Participants will be recruited using a purposive sampling method. Participants will be selected through chart review or physician referrals based on inclusion and exclusion criteria and recruited either from the outpatient department as an elective admission for intensive rehabilitation, or from the acute care wards of other inpatient departments of the hospital. All eligible participants who consent to participate during the recruitment period will be included in the study.

STUDY POPULATION

The study will include adult patients in the subacute to chronic phase of stroke who had radiographically confirmed cerebrovascular disease, either hemorrhagic or non-hemorrhagic. Patients are considered to have a subacute stroke if the onset of illness, or ictus, was within the past 2 months, while chronic patients are those who had their ictus beyond 2 months from the study. Eligible patients will have a disability grade of 3, 4, or 5 on the Modified Rankin Scale and are under the continuous care of a primary caregiver. Patients will be excluded if they have: (1) a disorder of consciousness that precludes participation in the intervention, (2) unstable co-existing medical conditions, (3) expired during the course of the study, or (4) are discharged prior to completion of outcome assessments. Patients who are concurrently enrolled in any structured educational or caregiver training program other than the standard hospital course will also be excluded to avoid confounding effects.

Family caregivers are considered eligible for the study if: (1) they are primarily responsible for the patient's care, (2) have no prior experience caring for another chronically ill patient, and (3) are at least 18 years old. Exclusion criteria for caregivers include a change in the designated family caregiver, significant cognitive impairment or language barriers, and participation in an educational program other than the hospital's standard course during the study period.

Informed consent will be obtained from the participants prior to enrollment to the program (Appendix A). Participants retain the right to withdraw from the study at any time and for any reason. The investigator also reserves the right to withdraw a participant if continued involvement was deemed to pose a risk to the patient or caregiver, or if it could compromise the integrity of the study. All participant withdrawals will be documented, and only participants who complete all assessment phases will be included in the final analysis.

STUDY PROCEDURE

The content and structure of the TAP-S Program was discussed and formulated among medical specialists of the DRM and the Department of Neurology as well as senior paramedical staff of the DRM, and was developed through an extensive literature review using databases like Medline/PubMed. The TAP-S will be a one-week training course consisting of the learning modules outlined in Table 1.

Table 1. The Training to Aid Patients With Stroke (TAP-S) Program

Day	Topic	Member Involved
1	Introduction to stroke, stroke rehabilitation, and neuroplasticity	Neurologist Rehab doctor
2	Physical therapy principles and techniques for stroke patients	Physical Therapist
3	Home modifications and ADL adaptations for stroke patients	Occupational Therapist
4	Management of dysphagia and communication disorders resulting from stroke	Speech Therapist
5	Psychological well-being of caregivers and nursing care for stroke patients	Psychologist Rehab Nurse

The sociodemographic profile of each consenting participant will be obtained prior to the start of the program. The assessment tool will comprise of (1) a questionnaire assessing caregiver knowledge on basic principles of stroke rehabilitation and home care, (2) the Modified Caregiver Strain Index (MCSI), and (3) the World Health Organization Quality of Life Brief Version (WHOQOL-BREF). Physical copies of the questionnaires will be provided before implementation of the program (pre-test), on discharge (post-test 1), and two weeks post-discharge (post-test 2).

Caregiver Knowledge Questionnaire on Stroke Rehabilitation

The questionnaire evaluated caregivers' understanding of fundamental principles of stroke rehabilitation and home care. This was reviewed by medical specialists and senior paramedical staff from the Department of Rehabilitation Medicine, ensuring content relevance and expert agreement on item appropriateness. The 15-point questionnaire contained relevant items pertaining to the topics discussed during the course of the program. Total scores range from 0 to 15, with higher scores indicating greater caregiver knowledge and understanding of stroke management and home care.

Modified Caregiver Strain Index (MCSI) – Filipino version

The Modified Caregiver Strain Index (MCSI)–Filipino version is a 13-item screening tool that assesses strain related to caregiving, covering financial, physical, psychological, social, and personal domains. Each item is scored as 0 ("No"), 1 ("Sometimes"), or 2 ("Yes"), resulting in a total score ranging from 0 to 26. Higher scores indicate greater caregiver strain and burden. The Filipino translation has undergone validation to ensure cultural relevance and semantic equivalence, with acceptable reliability, making it a practical measure for evaluating caregiver burden in the local setting.

World Health Organization Quality of Life Brief (WHOQOL-BREF) Filipino Version

The WHOQOL-BREF Filipino version is a culturally adapted translation of the World Health Organization Quality of Life questionnaire, consisting of 26 items that measure

physical, psychological, social, and environmental domains of health-related quality of life. Items are rated on a 5-point Likert scale, with raw domain scores transformed according to WHO guidelines to a scale ranging from 0 to 100. Higher scores indicate better perceived quality of life. The Filipino version has been validated locally, particularly among older adults, demonstrating good reliability and construct validity, and has since been used in various patient and caregiver populations in the Philippines.

DATA ANALYSIS

Data will be analyzed using SPSS. Descriptive statistics will be used to summarize patient and caregiver characteristics. Categorical variables will be measured using frequency and percentages, while continuous variables, including measurements of knowledge, MCSI, and WHOQOL-BREF domain scores, will be studied using measures of central tendency (means) and dispersion (standard deviation).

To determine changes across the three assessment phases (pre-test, post-test 1, post-test 2), a repeated-measures multivariate analysis of variance (RM-MANOVA) will be conducted with assessment phase as the within-subjects factor and knowledge, MCSI, and WHOQOL-BREF domains (physical, psychological, social, and environment) as dependent variables. Pillai's Trace will be used to assess the overall multivariate effect.

If the multivariate test is significant, separate repeated-measures ANOVAs will be performed for each outcome. Mauchly's test of sphericity will be examined, and the Greenhouse–Geisser correction will be applied when the assumption is violated. Post hoc pairwise comparisons will be performed using the Bonferroni adjustments for statistically significant differences across assessment phases. Effect sizes will be reported using partial eta

squared (η^2), with statistical significance set at $p < 0.05$.

RESEARCH UTILIZATION

The outputs of this study will be disseminated through various channels, wherever applicable, including national and international fora, peer-reviewed journals, websites, and social media platforms.

Study findings will be available to the PGH administration, as well as to the Department of Rehabilitation Medicine, as these may be utilized as a springboard for planning programs and policies towards more disability-inclusive health services.

Study participants shall be given copies only of their own record if requested within the five-year time frame that the data collected are still being kept secure.

ETHICAL CONSIDERATIONS

This research will be done guided by the principles of GCP-ICH and the Declaration of Helsinki and will be conducted in accordance with Republic Act No. 10173, the Philippine Data Privacy Act of 2012. Informed consent specifying the purpose, duration, and procedure of the study shall be secured by the investigators from each study participant prior to data collection. The option to withdraw consent at any point in time will be emphasized. Informed consent forms will be provided both in English and in Filipino.

All information obtained in the course of this study will be treated with strict confidentiality. Participants will be assigned unique identification codes, and no directly identifying information (e.g., name, address, contact number) will be used in data analysis or

reporting. Data collection forms will be distributed in print. All research data will be secured to ensure the protection of participants' privacy.

This study is classified as minimal to low risk. However, potential risks to participants include breaches of privacy and confidentiality, especially concerning the handling of sensitive personal or health-related information. To mitigate these risks, all data will be anonymized and stored in password-protected computers and encrypted cloud storage accessible only to authorized members of the research team. Hard copies (e.g., consent forms, questionnaires) will be kept in a locked filing cabinet in a secure area within the institution. Only de-identified data will be used for analysis. Any dissemination of findings will ensure that individual participants cannot be identified. In the unlikely event of a data breach or unauthorized access, the matter will immediately be reported to the Philippine General Hospital (PGH) Data Privacy Officer and will follow institutional data breach protocols in accordance with the Data Privacy Act of 2012, including containment of the breach, assessment of its scope, and notification of affected individuals if necessary.

Upon completion of the study and after the required data retention period (five years), all data will be securely destroyed. Electronic files will be permanently deleted using secure digital wiping methods. Physical documents will be shredded using a cross-cut shredder. No personal data will be retained beyond this period to ensure full compliance with data privacy and ethical standards.

This study will not involve vulnerable study populations and will only recruit adult participants; thus, assent is not required.

No benefits or incentives, monetary or otherwise, will be given to the study participants. No foreseeable expenses will be incurred by the participants.

Although participants may not receive direct personal benefits from participating in this study, the findings are expected to contribute significantly to the advancement of knowledge in the field of stroke rehabilitation. This study aims to determine the effects of a caregiver-empowerment program, which may lead to improved clinical practices in stroke rehabilitation, better health outcomes, or enhanced patient care strategies.

On a broader scale, the results of this research may inform future programs, policies, or treatment protocols, thereby benefiting future patients, healthcare providers, and the medical community. The study may also contribute to the development of innovative approaches and evidence-based interventions in stroke rehabilitation.

No adverse impact on the community where the research will be implemented and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study, are expected.

DECLARATION OF CONFLICT OF INTEREST

There is no conflict of interest from the investigators in the conduct of this study.

DUTIES AND RESPONSIBILITIES OF RESEARCH PERSONNEL

The principal investigator will take full responsibility during the conduct of this study. The recruitment period will be conducted by the principal investigator and paramedical staff of the Department of Rehabilitation Medicine, with the assigned resident having been

oriented and trained with the study and its tools. The supervising investigators will guide the principal investigator in the development of a scientifically and ethically sound research protocol, assists in addressing ethical and scientific concerns raised by reviewing bodies, review interim and final reports for accuracy and consistency, supervise in the proper collection and recording of data including the duty to maintain the confidentiality of information and the privacy of human participants for all the phases of the research processes including the disposal or archival of data.

REFERENCES

1. Tziaka E, Tsiakiri A, Vlotinou P, Christidi F, Tsiptsios D, Aggelousis N, et al. A holistic approach to expressing the burden of caregivers for stroke survivors: A systematic review. *Healthcare (Basel)*. 2024;12(5):565.
doi:10.3390/healthcare12050565.
2. Department of Rehabilitation Medicine. University of the Philippines Manila College of Medicine. [Internet]. [cited 2023 Jun 6]. Available from:
<https://cm.upm.edu.ph/p/rehabilitation-medicine/>
3. Dharma KK, Damhudi D, Yarden N, Haeriyanto S. Increase in the functional capacity and quality of life among stroke patients by family caregiver empowerment program based on adaptation model. *Int J Nurs Sci*. 2018;5(4):357–64.
doi:10.1016/j.ijnss.2018.09.002.
4. Lee KW, Lim SH, Kim KH, Kim JH, Yoo JN. A survey of caregivers' knowledge about caring for stroke patients. *Ann Rehabil Med*. 2015 Oct;39(5):800-815.
doi:10.5535/arm.2015.39.5.800.

5. Hong SE, Kim CH, Kim EJ, Joa KL, Kim TH, Kim SK, et al. Effect of a caregiver's education program on stroke rehabilitation. *Ann Rehabil Med*. 2017;41(1):16–24. doi:10.5535/arm.2017.41.1.16.
6. Philippine Statistics Authority. Census-based population projections in collaboration with the Inter-Agency Working Group on Population Projections. [Internet]. 2010 [cited 2023 Jun 6]. Available from: https://psa.gov.ph/sites/default/files/attachments/hsd/pressrelease/Table4_9.pdf.
7. Collantes EV. The future of Stroke Society of the Philippines. [Internet]. 2020 [cited 2023 Jun 6]. Available from: <https://www.strokesocietyphilippines.org>.
8. Gonzalez-Suarez C, Grimmer K, Alipio I, Anota-Canencia EG, Santos-Carpio ML, Dizon JM, et al. Stroke rehabilitation in the Philippines: An audit study. *Disabil CBR Incl Dev*. 2015;26(3):44–67. doi:10.5463/dcid.v26i3.446.
9. Deyhoul N, Vasli P, Rohani C, Shakeri N, Hosseini M. The effect of family-centered empowerment program on the family caregiver burden and the activities of daily living of Iranian patients with stroke: a randomized controlled trial study. *Aging Clin Exp Res*. 2020;32(7):1343–52. doi:10.1007/s40520-019-01321-4.
10. Kerber KA, Brown DL, Skolarus LE, Morgenstern LB, Smith MA, Garcia NM, et al. Validation of the 12-item stroke-specific quality of life scale in a biethnic stroke population. *J Stroke Cerebrovasc Dis*. 2013;22(8):1270–2. doi:10.1016/j.jstrokecerebrovasdis.2012.08.011.
11. Steffen AM, McKibbin C, Zeiss AM, Gallagher-Thompson D, Bandura A. The revised scale for caregiving self-efficacy: reliability and validity studies. *J Gerontol B Psychol Sci Soc Sci*. 2002 Jan;57(1):P74–86. doi:10.1093/geronb/57.1.p74. PMID:

11773226.

12. Ogedegbe G, Tobin JN, Fernandez S, Cassells A, Diaz-Gloster M, Pickering TG, et al. The role of medication beliefs on adherence to prescribed antihypertensive medications among African Americans with hypertension: A mixed-methods study. *Patient Prefer Adherence*. 2013 Apr 9;7:87-94. doi:10.2147/PPA.S40149. PMID: 23637503; PMCID: PMC3631079.
13. Stroke Society of the Philippines. SSP Handbook of Stroke: Guidelines for Prevention, Treatment, and Rehabilitation. 6th ed. Quezon City: Stroke Society of the Philippines; 2014.
14. Duration of In-patient Physical Therapy at a Tertiary Hospital: Implications of a Time and Motion Study. *Acta Med Philipp* [Internet]. 2024 Nov. 15 [cited 2025 Mar. 5];58(20). Available from: <https://actamedicaphilippina.upm.edu.ph/index.php/acta/article/view/9535>

Informed Consent Form (English)

This informed consent form is for the eligible individuals of legal age who we are inviting to participate in this study.

Title of Study:

Impact of the Training to Aid Patients with Stroke (TAP-S) Program on Caregiver Self-Efficacy and Quality of Life of Stroke Patients: A Pilot Study

Name of Principal Investigator:

Dave Albert D. Patrimonio, M.D.

Name of Supervising Investigator:

Sharon D. Ignacio, M.D.

Jennifer Marie J. Yang, M.D.

John Albert D. Gonzales, M.D.

Name of Organization:

Department of Rehabilitation Medicine, Philippine General Hospital, University of the Philippines Manila

This informed consent form has two parts:

- **Information sheet** (to share information about the study with you)
- **Certificate of consent** (for signatures if you agree that you may participate)

You will be given a copy of the full Informed Consent Form. This ICF is valid until **DATE AS APPROVED BY** the Research Ethics Board (REB).

INFORMATION SHEET

Introduction and Objectives of the Study

Stroke is the second leading cause of death in the Philippines, and remains a significant cause of disability locally. Despite efforts to address gaps in health policies and programs in the current stroke system of care, providing adequate access to rehabilitation facilities for patients post-stroke remains a challenge for healthcare providers. Thus, it is important to understand the important role of families in management of stroke patients. There is a need to provide guidelines and specific training in caregiver-driven provision of care for patients. Providing proactive problem-solving interventions and caregiver education is an essential part in the comprehensive approach to address the emotional, psychological, and relational aspects of stroke recovery.

This study aims to assess the effects of the Training to Aid Patients With Stroke (TAP-S) Program, a pilot caregiver education program for post-stroke patients, caregiver knowledge

on stroke, caregiver self-efficacy, and patient quality of life for subacute to chronic stroke patients and their caregivers.

Type of Research Intervention

The study will employ a pre- and post-test control group design. Participants will be recruited using consecutive sampling and will be randomly allocated into either the intervention or control group. The measurement of patient quality of life, caregiver knowledge, and caregiver satisfaction will be performed three times (pre-test, on discharge, and one month post-discharge). Data analysis will employ descriptive statistics and correlation analysis. The total duration of participation in the study will be four months.

Choice of Study Site

The Philippine General Hospital (PGH) Department of Rehabilitation Medicine serves as an ideal setting for implementing an inpatient caregiver training program due to its status as a national tertiary referral center and a leading institution for rehabilitation care in the country. PGH caters to a high volume of stroke patients from diverse socio-economic backgrounds, offering a rich and relevant population for the study.

The department is equipped with specialized rehabilitation facilities and staffed by experienced physiatrists, therapists, and allied health professionals who are capable of delivering comprehensive stroke rehabilitation and caregiver education. This multidisciplinary expertise is crucial for the successful implementation and evaluation of a structured training program.

Moreover, PGH maintains strong academic and research capabilities as part of the University of the Philippines Manila, ensuring the availability of logistical support, ethical oversight, and data monitoring essential for high-quality research. The presence of both inpatient rehabilitation services and access to caregivers during hospital confinement provides a strategic opportunity to initiate training at a critical transition point in the patient's recovery.

Participant Selection

This study includes all eligible patients with subacute to chronic CVD infarcts and their caregivers. The estimated number of invited participants is **31**.

Voluntary Participation

Participation in this research is **VOLUNTARY**. You may withdraw **AT ANY TIME**, even

after agreeing to participate. You also have the right to object to or withhold consent for data processing if changes or amendments occur. Refusal or withdrawal **WILL NOT** affect your position or situation in the hospital.

Procedures

If you agree to join the research, please note the following procedure: PGH personnel who give their consent will be asked to complete a **physical questionnaire** supervised by a research assistant and/or nurse-in-charge. This will take approximately **30 to 60 minutes**. Your personal data will be collected, processed, and assigned a **control number** to ensure anonymity. Participants are expected to answer truthfully.

Risks, Benefits, and Compensation

By participating in this research, no foreseeable risks and costs are being anticipated as a result of your participation in this study, nor will you directly benefit from it. You will not receive any monetary compensation for participating.

Although you will not receive direct personal benefits from participating in this study, the findings are expected to contribute significantly to the advancement of knowledge in the field of stroke rehabilitation. On a broader scale, the results of this research may inform future programs, policies, or treatment protocols, thereby benefiting future patients, healthcare providers, and the medical community. The study may also contribute to the development of innovative approaches and evidence-based interventions in stroke rehabilitation.

Confidentiality

Any information that will point to your real identity will be omitted. You will be assigned a control number that will be used in the data collection tool. All data collected will be recorded and stored using the UP Google Account of the principal investigator, as well as in a separate flash drive dedicated to the study. Stored records will be kept for five years after the study completion, then these will be deleted and destroyed subsequently.

Data Use / Sharing the Results and Publication

The researchers emphasize that the data obtained from this research will be used for the development of more disability-inclusive health services in the PGH. Only those who are directly involved in the study will be able to use and process the gathered data. The study also complies with the **Data Privacy Act of 2012**. Lastly, the results of this research may be published for a larger audience so that other interested parties may learn from this research.

You will be informed of the results of the study. We will use the contact number that you provide in this form to contact you when the research results have been published.


Right to Refuse / Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in this research **AT ANY TIME**. You also have the right to object or withhold consent to processing in case of changes or any amendment to the information supplied.

Contact for Further Information

If you have any questions or concerns, you may contact the following:

Dr. Dave Albert D. Patrimonio (Principal Investigator)

 +63 949 173 1988

Dr. Patrimonio is currently undergoing **Residency Training in Rehabilitation Medicine** at the **Department of Rehabilitation Medicine, Philippine General Hospital**. He serves as the principal investigator and is undertaking this research as part of Residency Training requirements. Funds for this study will come from the **PGH Expanded Hospital Research Office (EHRO)**, the **Department of Rehabilitation Medicine**, and/or personal expenses as needed.

The UPMREB Ethics Review Panel 3 has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:

Dr. Doris R. Benavides

UPMREB Panel Chair

Address: Room 126, Ground Floor
National Institutes of Health, UP Manila
623 Pedro Gil St. Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph
Tel: +63 2 526-4346

SIGNED ASSENT STATEMENTS AND RESEARCHERS' CERTIFICATION

SIGNED ASSENT STATEMENT

I have read and confirmed that I understood and received a copy of the informed consent form of this study. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this research. I also understand that my participation in this research project is voluntary and that I am free to withdraw at any time.

DATE (MM/DD/YYYY):

CONSENT SIGNATURE OF THE PARTICIPANT:

PRINTED NAME OF THE PARTICIPANT:

CONTACT NUMBER OF THE PARTICIPANT:

I also agree to the archiving of my data gathered in this study and that these may be used for future research and development by the PGH administration and/or the Department of Rehabilitation Medicine.

DATE (MM/DD/YYYY):

CONSENT SIGNATURE OF THE PARTICIPANT:

RESEARCHER'S CERTIFICATION

We agree to conduct the study in accordance with the constraints imposed by this document. We confirm that the participant was given the opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of our ability. We confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICF has been provided to the participant.

DATE (MM/DD/YYYY):

CONSENT SIGNATURE OF THE RESEARCHER:

PRINTED NAME OF THE RESEARCHER:
